

DECISIONS OF 77TH MEETING OF MEDICAL DEVICE BOARD HELD ON 30-01-2025

REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C & D) FOR LOCAL MANUFACTURE

Fresh Cases

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Apex Biotechnologies, Plot No. 8 Central Road Rawat, Rawalpindi (ELM-0086)	APL-401 Biochemistry Reagent for Electrolyte Analyzer Class: B Shelf Life: 2 years Fee:25000 Fee Slip No. 6314838967 Pack size: 1x3 pouch	Approved. The firm will submit the comparison data with the product approved by the reference countries as mentioned in rule 15 (2) for the six months.
2.	Apex Biotechnologies, Plot No. 8 Central Road Rawat, Rawalpindi (ELM-0086)	APL-500 Biochemistry Reagent for Electrolyte Analyzer Class: B Shelf Life: 2 years Fee:25000 Fee Slip No. 45981189 Pack size: 1x2 pouch	Approved. The firm will submit the comparison data with the product approved by the reference countries as mentioned in rule 15 (2) for the six months.
3.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) Date of Application: 12- 06-2024	Pro-cast Plaster of Paris (POP) Bandage Class A Shelf Life: 5 Years Fee: 5000 Fee Slip: 32915556125	Approved.
4.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's Cotton bandage BP (type II) Class A Shelf Life: 2 Years Fee: 5000 Fee Slip: 106233390 5cm x 3m,6.5cm x 3m 7.5cm x 3m,10cm x 3m 15cm x 3m,5cm x 4m 6.5cm x 4m,7.5cm x 4m 10cm x 4m,15cm x 4m 5cm x 5m,6.5cm x 5m 7.5cm x 5m,10cm x 5m 15cm x 5m,5cm x 6m 6.5cm x 6m,7.5cm x 6m	Approved.

		10cm x 6m,15cm x 6m	
5.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's Cotton Crepe Bandage BPC Class A Shelf Life: 2 Years Fee: 5000 Fee Slip: 27507061097 7.5cm x 3m,10cm x 3m 15cm x 3m,7.5cm x 4.5m,10cm x 4.5m, 15cm x 4.5m	Approved.
6.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's Absorbent Gauze Roll BPC (Sterile) Class B Shelf Life: 2 Years Fee: 10,000 Fee Slip: 809336861 1M X 2.5M,1M X 10M 1M X 20M,1M X 30M 1M X 40M	Approved subject to submission of differential fee.
7.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's Absorbent Gauze Roll BPC (Non-Sterile) Class A Shelf Life: 2 Years Fee: 5000 Fee Slip: 5828437330 1M X 2.5M,1M X 10M 1M X 20M,1M X 30M 1M X 40M	Approved.
8.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's cotton Stretched Bandage BP Class A Shelf Life: 2 Years Fee: 5000 Fee Slip: 0899550908 7.5cm x 3m,10cm x 3m 15cm x 3m,7.5cm x 4.5m,10cm x 4.5m, 15cm x 4.5m	Approved.
9.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan	Doctor's Cotton Bandage BP (type III) Class A Shelf Life: 2 Years Fee: 5000 Fee Slip: 028533445798 5cm x 3m,6.5cm x 3m 7.5cm x 3m,10cm x 3m 15cm x 3m,5cm x 4m 6.5cm x 4m,7.5cm x 4m 10cm x 4m,15cm x 4m 5cm x 5m,6.5cm x 5m 7.5cm x 5m,10cm x 5m 15cm x 5m,5cm x 6m 6.5cm x 6m,7.5cm x 6m 10cm x 6m,15cm x 6m	Approved.
10.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Head office: 111 Hali Road, Westridge 1, Rawalpindi	GLOW HbA1c Fluorescence Immunochromatographic Kit HbA1c Fluorescence Immunochromatographic Kit	Approved

	Manufacturing Facility: Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi [ELM-0028]	Class: B Shelf-life: 18 months Sizes: 40 pcs / pack Fee Challan No. 300995343 Rs. 25,000/-	
11.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Head office: 111 Hali Road, Westridge 1, Rawalpindi Manufacturing Facility: Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi [ELM-0028]	GLOW CRP Fluorescence Immunochromatography Kit CRP Fluorescence Immunochromatography Kit Class: B Shelf-life: 18 months Sizes: 40 pcs / pack Fee Challan No. 744630018 Rs. 25,000/-	Approved
12.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Head office: 111 Hali Road, Westridge 1, Rawalpindi Manufacturing Facility: Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi [ELM-0028]	GLOW PCT Fluorescence Immunochromatography Kit GLOW PCT Fluorescence Immunochromatography Kit Class: C Shelf-life: 18 months Sizes: 40 pcs / pack Fee Challan No. 2531576665 Rs. 25,000/-	Approved
13.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Head office: 111 Hali Road, Westridge 1, Rawalpindi Manufacturing Facility: Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi [ELM-0028]	GLOW β-HCG Fluorescence Immunochromatography Kit β-HCG Fluorescence Immunochromatography Kit Class: B Shelf-life: 18months Sizes: 40 pcs / pack Fee Challan No. 51610827 Rs. 25,000/-	Approved
14.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Head office: 111 Hali Road, Westridge 1, Rawalpindi Manufacturing Facility: Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi [ELM-0028]	GLOW SAA Fluorescence Immunochromatography Kit SAA Fluorescence Immunochromatography Kit Class: B Shelf-life: 18 months Sizes: 40 pcs / pack Fee Challan No. 73049017 Rs. 25,000/-	Approved
15.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [646-7L]	Surgimax Cotton Bandage (BP Type III) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 59461309347 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m,	Approved

		5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 3cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m.	
16.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [647-7L]	Surgimax Absorbent Cotton Wool (BPC) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 156140163665 Sizes: 25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram	Approved
17.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [648-7L]	Surgimax Elastic Stretch Crepe Bandage (BPC) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 88596453432 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m	Approved
18.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [649-7L]	Surgimax Cotton Bandage (USP Type IV) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 855618002394 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m,	Approved

		7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	
19.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [650-7L]	Surgimax Cotton Bandage (BP Type I) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 548074549636 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved
20.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [651-7L]	Surgimax Cotton Bandage (BP Type II) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 95832554818 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m,	Approved

		10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 3cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	
21.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [652-7L]	Surgimax Cotton Crepe Bandage (BPC) Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 787449384452 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m	Approved
22.	Surgiland Pvt Ltd. Behind AC Office G.T Road Kamoke (ELM-0087) [653-7L]	Surgimax Gauze Swab Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 832018548027 Sizes: 7.5cm x 7.5cm, 10cm x 10cm (single pack), 15cm x 15cm (8ply), 30cm x 30cm, 45cm x 45cm, 1 x 10m, 1 x 20m, 1 x 30m, 1 x 40m, 1 x 50m, 1 x 60m, 1 x 70m, 1 x 80m, 1 x 90m, 1 x 100m	Approved
23.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Cotton Crepe Bandage (BPC) Class A Shelf Life 5 years Fee: 6000 Fee Slip No. 001078395556 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm	Approved

		x 4.5m	
24.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Elastic Stretch Crepe Bandage (BPC) Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 90990681860 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5cm, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m	Approved
25.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Cotton Bandage (USP Type IV) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 83532611628 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 3cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved
26.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimax Cotton Bandage (BP Type III) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7090140394 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m,	Approved

		5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 3cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	
27.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Cotton Bandage (BP Type II) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7242751359 Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25cm x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 3cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved
28.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Absorbent Cotton Wool (BPC) Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 8238320163 Sizes:	Approved

		25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram	
29.	M/s J&A Med (Pvt.) Ltd., 2K-10M, Chak No. 196RB, Ghona Bhai Wala Road, Faisalabad. (ELM-0088)	Promax Surgimed Gauze Swab Class A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 139372428535 Sizes: 7.5cm x 7.5cm, 10cm x 10cm (single pack), 15cm x 15cm (8ply), 30cm x 30cm, 45cm x 45cm, 1 x 10m, 1 x 20m, 1 x 30m, 1 x 40m, 1 x 50m, 1 x 60m, 1 x 70m, 1 x 80m, 1 x 90m, 1 x 100m	Approved

Deferred Cases

S#	Firm Name	Product Details	Decision
30.	Jassh Pharma, 20KM, Ferozpur Road, Lahore (ELM-0037) [470-7L] August 2024	Carbosol Plus Hemodialysis Concentrate Class: C Shelf Life: 2 Years Fee: 20000 Fee Slip No. 0465176988 Application submitted on 30-08- 2024.	Approved. The firm will submit the comparison data with the product approved by the reference countries as mentioned in rule 15 (2) for the six months.
31.	Jassh Pharma, 20KM, Ferozpur Road, Lahore (ELM-0037) [471-7L] August 2024	Citrosol Haemodialysis Concentrate Hemodialysis Concentrate Class: C Shelf Life: 2 Years Fee: 20000 Fee Slip No. 741755240239 Application submitted on 30-08- 2024.	Approved. The firm will submit the comparison data with the product approved by the reference countries as mentioned in rule 15 (2) for the six months.

REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C & D) FOR IMPORT.

Sr. No.	Name & Address of the importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturer	Name of Medical Devices/ Shelf life /Class & codes / sizes (if any)	Decision
1.	LifeSpan Healthcare,	Legal Manufacturer:	Affix	Approved.

<p>Office #11, 7th Floor Gold Mine Plaza, 105- Ferozpur Road, Lahore, Pakistan.</p> <p>ELI-00736 4955-P</p>	<p>M/s Huaiyin Medical Instruments Co., Ltd. Address: No. 8 Mingyuan West Road, Qingjiangpu District, Huaian China</p> <p>FSC: China Validity: 24-Feb-2025</p> <p>FSC UK, MHRA issuance 03-07-2019 (issued for Egypt)</p>	<p>Silk Braided Sutures (Non- Absorbable) With and Without Needle</p> <p>Codes:</p> <p>SK46008F0, SK46008C0, SK75012B0, SK75012F0, SK74012B0, SK74012F0, SK75016F0, SK74016F0, SK73016F0, SK75016B0, SK73016B0, SK75017B0, SK73017B0, SK74020B0, SK74022B0, SK72022B0, SK71022B0, SK73022B0, SK73026B0, SK72026B0, SK71026B0, SK73026B1, SK72026B1, SK71026B1, SK70126B1, SK73028B0, SK73030B0, SK71030B0, SK72030B0, SK73028B0, SK72028B0, SK71028B0, SK70130B0, SK72036B,1 SK71036B1, SK70136B1, SK72040B0, SK71040B0, SK70240B0, SK70140B0, SK72045B0, SK71045B0, SK70145B0, SK70245B0, SK46010F4, SK45010F4, SK76012G2, SK75012G2, SK75016F2, SK74016F2, SK73016F2, SK75019F2, SK73019F2, SK74019F2, SK75019F4, SK74019F4, SK73019F4, SK74022B2, SK73022B2, SK72022B2, SK74026F2, SK73026F2, SK72026F2, SK73030B4, SK72030B4,SK71030B4, SK73030F4, SK72030F4, SK71030F4,SK72035B2, SK71035B2, SK70135B2, SK73036F2, SK72036F2, SK71036F2, SK70136F2, SK73036F4, SK72036F4, SK71036F4, SK71045F4, SK70145F4, SK70245F4, SK74026H2, SK73026H2, SK72026H2, SK44045A2, SK43045A2, SK42045A2, SK73055A2, SK72055A2, SK440X12, SK410X12, SK401X12, SK430X12, SK420X12, SK540X12, SK510X12, SK501X12, SK530X12, SK520X12, SK740X6, SK710X6, SK701X6</p>	
---	---	--	--

			Class-C	
			Shelf Life: 5 years	
2.	LifeSpan Healthcare, Office #11, 7th Floor Gold Mine Plaza, 105- Ferozpur Road, Lahore, Pakistan. ELI-00736 4956-P	<u>Legal Manufacturer:</u> Guangdong Baihe Medical Technologies Co., Ltd. No.89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China FSC Original: China Validity: 16-July-2024	Zencath Hemodialysis Catheter kit, Double lumen Codes: FH-1713, FH-1714, FH- 17915, FH-1715, FH-1716, FH-1813, FH-1814, FH- 181915, FH-1815, FH-1816, FH/FR2611, FR-2611W, FH/FR-2612, FR-2612W, FH/FR-2613, GR-2613W, FH/FR-2614, FR-2614, FH/FR-2615, FR-2615W, FH/FR-2911, FR-2911W, FH/FR-2912, FR-2912W, FH/FR-2913, FR-2913, FH/FR,-212911, FH/FR- 212911W, FR-291912, FR- 291912W,FH/FR-2914, FR- 2914W, FR-291915, FH/FR- 2915, FR-2915W, FR-291917, FR-291917W, FR-2926, FR- 2316, FR-2313, FR,-2313W, FR-2312, FR-2312W, FR+231912, FR-231912W, FR-231915, FR-231915W, FR-2314, FR-2314W, FR- 231917, FR-231917W, FR- 2315, FR-2315W, FR-2113, FR-2113W, FR-212912, FR- 212912W, FR-211912G, FH/FR-2114, FR-2114W, FH- FR-212913-5, FH-FR-211915, FH/FR-211915W, FH/FR- 211915G, FH/FR-2115, FR- 2115W, FR-2125 W, FH/FR- 2116, FR-2116W, FR-2115G, FR-211924, FR-211924W, FH/FR-2127, FR-2117W, FR- 2213, FR+2213W, FR- 221912G, FR-2216G, FH/FR- 2214, FR-2214W, FH/FR- 222913-5, FR-222913-5W, FR-221915G, FH/FR-2215, FR-2215W, FR-2225G, FG- 2215, FG-2215W, FH/FR- 2216, FR-2216W, FG-2216, FG-2216W, FR-221924, FR- 2217, FR-2414, FR-2217, FR- 2217W, FR-2414, FR-241915, FR-241915W, FR-2415, FR- 2415W, FR-252919,FR-2416, FR-2416W, FR-241924, FR- 241924W, FR-2417, FR-3214,	Approved.

			FR-3224, FR-321915, FR-3215, FR-3215W, FR-3216, FR-3216W, FR-321924, FR-321924W, FR-3217W, FR-3217	
			Class-D	
			Shelf Life: 3years	
3.	LifeSpan Healthcare, Office #11, 7th Floor Gold Mine Plaza, 105-Ferozpur Road, Lahore, Pakistan. ELI-00736 4958-P	<u>Legal Manufacturer:</u> M/s Huaiyin Medical Instruments Co., Ltd. Address: No. 8 Mingyuan West Road, Qingjiangpu District, Huaian China FSC: China Validity: 24-Feb-2025 FSC UK, MHRA issuance 03-07-2019 (issued for Egypt)	Affix PGLA (Polyglactin 910) Braided Sutures (Absorbable) With and Without Needle Codes: PGLA46008G8, PGLA37008G8, PGLA46008E8, PGLA45008E8, PGLA46010F0, PGLA46012B0, PGLA45012B0, PGLA55012B0, PGLA75016F0, PGLA74016F0, PGLA75016B0, PGLA56016B0, PGLA74016B0, PGLA74020B0, PGLA73020B0, PGLA72020B0, PGLA74022B0, PGLA73022B0, PGLA72022B0, PGLA71022B0, PGLA74026B0, PGLA73026B0, PGLA72026B0, PGLA71026B0, PGLA82026B1, PGLA81026B1, PGLA80126B1, PGLA73030B0 PGLA72030B0, PGLA71030B0, PGLA93030B0, PGLA92030B0, PGLA91030B0, PGLA70130B0, PGLA72036B0, PGLA71036B0, PGLA70136B0, PGLA82036B0, PGLA81036B0, PGLA80136B0, PGLA82036B1, PGLA81036B1, PGLA80136B1,	Approved

			PGLA71040B0 PGLA70240B0, PGLA70140B0, PGLA81040B0, PGLA80240B0, PGLA80140B0, PGLA71045B0, PGLA70145B0, PGLA81045B0, PGLA80145B0, PGLA70245B0, PGLA80245B0, PGLA46010F4, PGLA45010F4, PGLA46012F2, PGLA45012F2, PGLA45016F2, PGLA44016F2, PGLA43016F2, PGLA74019F2, PGLA73019F2, PGLA72019F2, PGLA74019F4, PGLA73019F4, PGLA72019F4, PGLA74022B2, PGLA73022B2, PGLA72022B2, PGLA44012F2, PGLA44026F2, PGLA43026F2, PGLA42026F2, PGLA74026F2, PGLA73026F2, PGLA72026F2, PGLA44026F4, PGLA43026F4, PGLA42026F4, PGLA74026F4, PGLA73026F4, PGLA72026F4, PGLA41026F4, PGLA71026F4, PGLA73030B4, PGLA71030B4, PGLA73030F4, PGLA72030F4, PGLA81030F4, PGLA72035B4, PGLA71035B4, PGLA70135B4, PGLA73036F2, PGLA72036F2, PGLA70136F2, PGLA72036F4, PGLA70136F4, PGLA71036F4, PGLA71045F4,PGLA71045F	
--	--	--	---	--

			<p>4,PGLA70245F4, PGLA72026B6, PGLA71026B6, PGLA72036B6, PGLA71036B6, PGLA70136B6, PGLA82036B6, PGLA81036B6, PGLA80136B6, PGLA72040B6, PGLA71040B6, PGLA70140B6, PGLA82040B6, PGLA81040B6, PGLA80140B6, PGLA74026H2, PGLA73026H2, PGLA72026H2, PGLA72026H0, PGLA71026H0, PGLA44045A2, PGLA43045A2, PGLA42045A2, PGLA73055A2, PGLA72055A2, PGLA1020, PGLA1010, PGLA1001, PGLA1220, PGLA1210, PGLA1201, PGLA1002, PGLA1202</p> <p>Class-D</p> <p>Shelf Life: 3 years</p>	
4.	<p>LifeSpan Healthcare, Office #11, 7th Floor Gold Mine Plaza, 105- Ferozpur Road, Lahore, Pakistan.</p> <p>ELI-00736 4959-P</p>	<p><u>Legal Manufacturer:</u> Guangdong Baihe Medical Technologies Co., Ltd. No.89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China</p> <p>FSC Original: China Validity: 16-July-2024</p>	<p>Zencath Central Venous Catheter kit</p> <p>Codes: Single Lumen: FV-1121, FV-1122, FV- 11299, FV-1123, FV-112912, FV-1124, FV-112915, FV- 1126, FV-1221, FV-1222, FV- 1223, FV-1224, FV-122915, FV-1225, FV-1226, FV-1228, FV-1321, FV-1322, FV-1323, FV-1324, FV-132915, FV- 1325, FV-1326, FV-1328, FV- 1421, FV-1422, FV-1423, FV- 1424, FV-142915, FV-1425, FV-1426, FV-1428, FV-1521, FV-1522, FV-1523, FV-1524, FV-152915, FV-1525, FV- 1526, FV-1528, FV-1624, FV- 162915, FV-1625, FV-1626, FV-1628</p> <p>Double Lumen: FV/FC-2421, FV/FC-2422, FV/FC-2423, FV/FC-2424,</p>	Approved

			<p>FV/FC-242915, FV/FC-2425, FV/FC-2426, FV/FC-2428, FV/FC-2521, FV/FC-2522, FV/FC-2523, FV/FC-2524, FV/FC-252915, FV/FC-2525, FV/FC-2526, FV/FC-2528, FV/FC-2724, FV/FC-272915, FV/FC-2725, FV/FC-2726, FV/FC-2728, FV-2824, FV-282915, FV-2825, FV-2826, FV-2828, FV-2921, FV-2922, FV-2923, FV-2924, FV-2925, FV-2926, FV-2927, FV-2928</p> <p>Triple Lumen: FV/FC-3421, FV/FC-3422, FV/FC-3423, FV/FC-3424, FV/FC-342915, FV/FC-3425, FV/FC-3426, FV/FC-3428, FV/FC-3521, FV/FC-3522, FV/FC-3523, FV/FC-3524, FV/FC-352915, FV/FC-3525, FV/FC-3526, FV/FC-3528, FV/FC-3724, FV/FC-372915, FV/FC-3725, FV/FC-3726, FV/FC-3728, FV/FC-3924, FV/FC-392915, FV/FC-3925, FV/FC-3926, FV/FC-3928</p> <p>Quad Lumen: FV-4921, FV-4922, FV-4923, FV-4924, FV-492915, FV-4925, FV-4926, FV-4928</p> <p>Class-D</p> <p>Shelf Life: 3 years</p>	
5.	<p>LifeSpan Healthcare, Office #11, 7th Floor Gold Mine Plaza, 105- Ferozpur Road, Lahore, Pakistan.</p> <p>ELI-00736 4960-P</p>	<p><u>Legal Manufacturer:</u> M/s Huaiyin Medical Instruments Co., Ltd. Address: No. 8 Mingyuan West Road, Qingjiangpu District, Huaian China</p> <p>FSC: China Validity: 24-Feb-2025 FSC UK, MHRA issuance 03-07-2019 (issued for Egypt)</p>	<p>Affix (Polyglycolic Acid Braided Sutures (Absorbable) With and Without Needle</p> <p>Codes: PGA3806.5G8. PGA4806.5G8. PGA4706.5G8. PGA3706.5G8, PGA47008G8, PGA46008G8, PGA46008E8, PGA45008E8, PGA46012B0, PGA45012B0, PGA55012B0, PGA54012B0, PGA74012B1, PGA73012B1, PGA46008C0, PGA47008E8, PGA36011G8, PGA35011G8, PGA45011G8, PGA46011G8, PGA56012F0, PGA55012F0, PGA54012F0, PGA55016F0, PGA54016F0, PGA56012F0, PGA75016B0, PGA74016B0, PGA74020B0,</p>	Approved

			PGA73020B0, PGA74022B0, PGA73022B0, PGA72022B0, PGA73026B0, PGA72026B0, PGA71026B0, PGA82026B1, PGA81026B1, PGA80126B1, PGA73030B0 PGA72030B0 PGA71030B0, PGA93030B0, PGA92030B0, PGA91030B0, PGA70130B0, PGA72036B0, PGA71036B0, PGA70136B0, PGA82036B0, PGA81036B0, PGA80136B0, PGA82036B1, PGA81036B1, PGA80136B1, PGA80236B1, PGA72040B0, PGA71040B0, PGA70240B0, PGA70140B0, PGA82040B0, PGA81040B0, PGA80240B0, PGA72045B0, PGA71045B0, PGA70145B0, PGA82045B0, PGA81045B0, PGA80145B0, PGA70245B0, PGA80245B0, PGA38008C4, PGA46010F4, PGA46010G4, PGA45010F4, PGA45010G4, PGA44010G4, PGA56010G4, PGA55010G4, PGA54010G4, PGA46012G4, PGA45012G4, PGA44012G4, PGA46012F2, PGA45012F2, PGA45016F2, PGA44016F2, PGA43016F2, PGA74019F2, PGA73019F2, PGA72019F2,PGA74019F4, PGA73019F4, PGA75017H6 PGA74017H6 PGA73017H6 PGA72026H2 PGA72019F4,, PGA44012F2, PGA56012G4, PGA55012G4, PGA54012G4, PGA44026F2, PGA43026F2, PGA42026F2, PGA74026F2, PGA73026F2, PGA72026F2, PGA44026F4, PGA43026F4, ,PGA42026F4, PGA74026F4, PGA73026F4 ,PGA72026F4, PGA41026F4, PGA71026F4, PGA73030B4 PGA71030B4 PGA73030F4 PGA81030F4, PGA72030F4, PGA72035B4, PGA71035B4, PGA70135B4, PGA73036F2, PGA72036F2, PGA71036F2, PGA73036F4. PGA72036F4, PGA70136F4, PGA71036F4, PGA71045F4, PGA70145F4, PGA74026H2, PGA73026H2, PGA72026H0, PGA71026H0, PGA62036H0, PGA60136H0, PGA74022B6, PGA73022B6, PGA72022B6, PGA74026B6, PGA73026B6,	
--	--	--	--	--

			PGA72026B6, PGA71026B6, PGA73030B6, PGA72030B6, PGA71030B6, PGA73036B6. PGA72036B6, PGA71036B6, PGA70136B6, PGA83036B6, PGA82036B6. PGA81036B6, PGA80136B6, PGA72040B6, PGA71040B6, PGA70140B6, PGA82040B6, PGA81040B6, PGA80140B6, PGA70240B6, PGA72045B6, PGA72030B9, PGA71030B9, PGA72036B9, PGA71036B9, PGA70136B9, PGA71045B6, PGA70145B6, PGA70245B6, PGA80240B6, PGA72036B10, PGA71036B10, PGA70136B10, PGA82036B10, PGA81036B10, PGA80136B10, PGA72040B9, PGA71040B9, PGA70240B9,PGA82040B10, PGA81040B10, PGA80240B10, PGA80140B10, PGA81045B9, PGA80245B9, PGA44045A2, PGA43045A2, PGA42045A2, PGA73055A2, PGA72055A2, PGA73060A2, PGA72060A2, PGA71060A2, PGA440X6, PGA410X6, PGA401X6 PGA430X6 PGA420X6 PGA440X12, PGA410X12, PGA401X12, PGA430X12, PGA420X12, PGA640X5, PGA610X5, PGA601X5, PGA920, PGA910, PGA901, PGA1020, PGA1010, PGA1001, PGA1220, PGA1210, PGA1201, PGA902, PGA1002, PGA1202 Class-D Shelf Life: 3 years	
6.	LifeSpan Healthcare, Office #11, 7th Floor Gold Mine Plaza, 105- Ferozpur Road, Lahore, Pakistan. ELI-00736 4961-P	<u>Legal Manufacturer:</u> M/s Huaiyin Medical Instruments Co., Ltd. Address: No. 8 Mingyuan West Road, Qingjiangpu District, Huaian China FSC: China Validity: 24-Feb-2025 FSC UK, MHRA issuance 03-07-2019 (issued for Egypt)	Affix Polypropylene Monofilament Sutures (Non-Absorbable) With and Without Needle Codes: PM31006.5G8, PM3906.5G8, PM3806.5G8, PM39008G8, PM38008G8, PM39008E8, PM38008E8, PM49011G8, PM48011G8, PM47011G8,	Approved

			PM48008G0, PM56010G0, PM58008G0, PM56012C0, PM76012C0, PM77012G0, PM76012G0, PM75012G0, PM75016G0, PM75020C0, PM73020C0, PM74016G0, PM75022B0, PM73022B0, PM74026B0, PM72026B0, PM83026C0, PM73030B0, PM71030B0, PM81036B1, PM82040B1, PM80140B1, PM81045B0, PM46008F4, PM46010F4, PM55012F4, PM45016F4, PM76016F2, PM75016F2, PM73016F2, PM73019F4, PM74019F2, PM72019F2, PM73022B2, PM74026F2, PM72026F2, PM73026F4, PM72026F4, PM71026F4, PM71036F2, PM70136F2, PM81040B4, PM81040F4, PM80140B4, PM81045F4, PM75016C6, PM75016G6, PM74016G6, PM72026C6, PM73030B6, PM71030B6, PM72036B6, PM70136B6, PM73045A2, PM71045A2, PM72055A2, PM71055A2	PM57010G0, PM47008G0, PM57008G0, PM55012C0, PM57012G0, PM56012G0, PM55012G0, PM76016G0, PM74016G0, PM74020C0, PM75016G0, PM75012C0, PM74022B0, PM72022B0, PM73026B0, PM84026C0, PM82026C, PM72030B0, PM82036B1, PM80136B1, PM81040B1, PM82045B0, PM80145B0, PM45010F4, PM56012F4, PM54012F4, PM44016F4, PM74016F2, PM75019F4, PM73019F2, PM74022B2, PM73026F2, PM74026F4, PM71026F2, PM72036F2, PM82040B4, PM82040F4, PM80140F4, PM80240B4, PM80145F4, PGA74016C6, PM73016G6, PM73026C6, PM74026C6, PM72030B6, PM70130B6, PM71036B6, PM74045A2, PM72045A2, PM73055A2, PM71055A2
			Class-C	

			Shelf Life: 5 years	
7.	Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan R&I Dated: 09/August/2024	Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de , http://www.melag.com LOA Validity: 23/07/2025 FSC Validity: 24/08/2028	Autoclave Cliniclave 45 M Class: C Shelf life: N/A Model: ME10048	Approved
8.	Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan R&I Dated: 09/August/2024	Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de , http://www.melag.com LOA Validity: 23/07/2025 FSC Validity: 24/08/2028	Autoclave Cliniclave 45 MD Class: C Shelf life: N/A Model: ME10049	Approved
9.	Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan R&I Dated: 09/August/2024	Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de , http://www.melag.com LOA Validity: 23/07/2025 FSC Validity: 24/08/2028	Autoclave Cliniclave 45 D Class: C Shelf life: N/A Model: ME10046	Approved
10.	Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan R&I Dated: 09/August/2024	Legal Manufacturer: Melag Medizintechnik: Geneststraße 6-10, 10829 Berlin, Germany, Tel: +49 30 757911-0, Fax: +49 30 757911-99, E-Mail: info@melag.de , http://www.melag.com LOA Validity: 23/07/2025 FSC Validity: 24/08/2028	Vacuklav 43 B+ (Premium-Plus-Class) Class: C Shelf life: N/A Model: ME10083	Approved
11.	Medical Equipment & Systems , 60/61 F.F.F Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan. ELI-00554	Legal Manufacturer: Fresenius Kabi AG, Else-Kroner-Str. 1 61352 Bad Homburg Germany. Manufacturing site: Fresenius Kabi (Nanchang) Co., Ltd. Qin Lan Road Nanchang Economic & Technological Development Zone 330013 Nanchang, Jiangxi Province, China.	Infusia SP7 Syringe Pumps Class-C Shelf Life: 5 Year Model: (INFSP7S-ED3)	Approved

		FSC: Germany. issuance 05-12-2023		
12.	Medical Equipment & Systems , 60/61 F.F.F Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan. ELI-00554	Legal Manufacturer: Fresenius Kabi AG, Else-Kroner-Str. 1 61352 Bad Homburg Germany. Manufacturing site: Fresenius Kabi (Nanchang) Co., Ltd. Qin Lan Road Nanchang Economic & Technological Development Zone 330013 Nanchang, Jiangxi Province, China. FSC: Germany. issuance 05-12-2023	Infusia SP7 Infusion Pumps Class-C Shelf Life: 5 Year Model: (INFVP7S-ED3)	Approved
13.	Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore. ELI-00045 5153-P 25,000/- 01-08-2024	Legal Manufacturer: Network Medical Products Ltd, Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, U.K. FSC: UK. Issuance 12-09-2019	Coronet (Standard Corneal Trephines) Class-B Shelf Life: 5 years Codes: 51-900-6.00, 51-900-6.25, 51-900-6.50, 51-900-6.75, 51-900-7.00, 51-900-7.25, 51-900-7.50, 51-900-7.75, 51-900-8.00, 51-900-8.25, 51-900-8.50, 51-900-8.75, 51-900-9.00, 51-900-9.25, 51-900-9.50, 51-900-9.75	Approved subject to sizes of the corneal trephines.
14.	Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore. ELI-00045 5154-P 25,000/- 01-08-2024	Legal Manufacturer: Network Medical Products Ltd, Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, U.K. FSC: UK. Issuance 12-09-2019	Coronet Dalk Clear-Vue Recipient (Vacuum Corneal Trephines) Class-B Shelf Life: 5 years Codes: 51-844-7.50, 51-844-8.00, 51-844-8.50, 51-844-9.00, 51-844-9.50	Approved subject to sizes of the corneal trephines.
15.	Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore.	Legal Manufacturer: Network Medical Products Ltd,	Coronet Standard with Cross Hair Corneal Trephines (Corneal Trephines)	Approved subject to sizes of the corneal trephines.

	ELI-00045 5155-P 25,000/- 01-08-2024	Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, U.K. FSC: UK. Issuance 12-09-2019	Class-B Shelf Life: 5 years Codes as per FSC:	
16.	Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore. ELI-00045 5156-P 25,000/- 01-08-2024	<u>Legal Manufacturer:</u> Network Medical Products Ltd, Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, U.K. FSC: UK. Issuance 12-09-2019	Coronet Long Handle Corneal Trephines (Corneal Trephines) Class-B Shelf Life: 5 years Codes as per FSC:	Approved subject to sizes of the corneal trephines.
17.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5174-P	<u>Legal Manufacturer:</u> Tianck Medical Co., Ltd, 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, dapeng new district, Shenzhen 518119, Guangdong P.R. China. FSC: China. Validity: 08-09-2024.	Balloon Inflation Device Class-B Shelf Life: 3 Year Codes: BID1, BID2	Approved
18.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5175-P	<u>Legal Manufacturer:</u> Tianck Medical Co., Ltd, 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, dapeng new district, Shenzhen 518119, Guangdong P.R. China. FSC: China. Validity: 08-09-2024.	Introducer Sets Class-B Shelf Life: 3 Year Codes: IS-0407, IS-0409, IS-0411, IS-0507, IS-0511, IS-0523, IS-0607, IS-0611, IS-0623, IS-0707, IS-0711, IS-0723, IS-0811, IS-0823, IS-0911, IS-0923, IS-1011	Approved
19.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5176-P	<u>Legal Manufacturer:</u> Tianck Medical Co., Ltd, 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, dapeng new district, Shenzhen 518119, Guangdong P.R. China. FSC: China. Validity: 08-09-2024.	Hemostasis valve sets Class-B Shelf Life: 3 Year Codes: HV	Approved
20.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi.	<u>Legal Manufacturer:</u> Tianck Medical Co., Ltd, 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong	Hydrophilic Guide Wire Class-B	Approved the PTFE type.

	ELI-00046 5177-P	Town, dapeng new district, Shenzhen 518119, Guangdong P.R. China. FSC: China. Validity: 14-07-2025.	Shelf Life: 3 Year Codes as per FSC	
21.	Assuza Incorporation, 17-Rabbani Road, Old Anarkali, Lahore. ELI-00546 5342-P	<u>Legal Manufacturer:</u> Guilin HBM Health Protection, Inc No. 1-2 Shuijing East Road, Economic and Technological Development Area, Guilin, Guangxi China. FSC: China. Validity: 22-09-2025.	Medispo (Latex Surgical Powdered Free Sterile Gloves) Class-B Shelf Life: 5 Year Sizes: 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5	Approved
22.	MEDIMAGE SEVICES. Suit #, 5/B, Peshawar Medical Centre, Shoba Bazaar, Peshawar. 6084-Kp	<u>Legal Manufacturer:</u> M/s LONGFIAN SCITECH CO, LTD Located address 2F &3F East section bulding 12, Power Valley Poineer Park #, 369, Huiyang street 071051 Baoding, hebei Province, China. FSC China validity 23-10-2024	Oxygen concentrator Class-C Shelf life: Models: JAY-5, JAY-10, JAY-5AW, JAY-5BW, JAY-1-D	Approved subject to Brand name of the device.
23.	FT Surgical, 916, Sagar Road, Sadar Bazar, Near Post Office, Lahore. ELI-01015 3979-P	<u>Legal Manufacturer:</u> Synergie Ingenierie Medicale S.A.R.L. (Synimed) Zone Artisanale de l'Angle - 19370 Chamberet - France. <u>Manufacturing site:</u> Laboratories SL S.A.- Curupayti 2611 (B1644GDC), San Fernando, Buenos 4503 (B1667JHA) Area de Promocion el Triangulo, Malvians Argentinas, Buenos Aires, Argentina. Original FSC: France. Date of Issuance: 02-04- 2024.	Synicem 1 Bone Cement Class-D Shelf Life: 3 Year Codes: 880018 (20g Powder and 10ml Liquid) 880021 (40g Powder and 20ml Liquid)	Approved
24.	FT Surgical, 916, Sagar Road, Sadar Bazar, Near Post Office, Lahore. ELI-01015 5378-P	<u>Legal Manufacturer:</u> Synergie Ingenierie Medicale S.A.R.L. (Synimed) Zone Artisanale de l'Angle - 19370 Chamberet - France. <u>Manufacturing site:</u> Laboratories SL S.A.- Curupayti 2611 (B1644GDC), San Fernando, Buenos 4503 (B1667JHA)	Synicem 1G Bone Cement with Gentamicin Class-D Shelf Life: 3 Year Codes: 880218 (20g Powder and 10ml Liquid)	Approved

		Area de Promocion el Triangulo, Malvians Argentinas, Buenos Aires, Argentina. Original FSC: France. Date of Issuance: 02-04-2024.	880223 (40g Powder and 20ml Liquid)	
25.	Total Technologies Pvt. Ltd, 696-J-2, M.A. Johar Town, Lahore, Pakistan. ELI-00129 5426-P	Legal Manufacturer: M/s Terumo Corporation, 44-1, 2-Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. Manufacturing facility: Ashitaka Factory of Terumo Corporation, 150, Maimaigicho, Fujinomiya City, Shizuoka Prefecture, 418-0015, Japan. FSC: Japan issuance 04-07-2023 (copy)	TERUFUSION (Infusion Pump Type SS3) Class-C Life time: 6 Year Codes as per FSC	Approved. Original documents are submitted previously.
26.	Total Technologies Pvt. Ltd, 696-J-2, M.A. Johar Town, Lahore, Pakistan. ELI-00129 5426-P	Legal Manufacturer: M/s Terumo Corporation, 44-1, 2-Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. Manufacturing facility: Ashitaka Factory of Terumo Corporation, 150, Maimaigicho, Fujinomiya City, Shizuoka Prefecture, 418-0015, Japan. FSC: Japan issuance 04-07-2023 (copy)	TERUFUSION Infusion Pump. LM3, 830 series Class-C Life time: 6 Year Codes as per FSC	Approved. Original documents are submitted previously.
27.	Cardiac Care, 848-C Shadman-1 Lahore, Pakistan. ELI-00070 5364-P	Legal Manufacturer: SmartCanula LLC. Chemindu Levant 145, 1005 Lausanne, Switzerland. Original FSC: Switzerland. Validity: 09-08-2027.	Venous SmartCanula (Venous SmartCanula) Class-D Shelf Life: 5 Year Codes: V 1/4 20F 530 ST V 1/4 20F 430 ST V 1/4 20F 340 ST V 1/4 20F 260 ST V 1/4 24F 730 ST V 1/4 24F 680 ST V 1/4 24F 630 ST V 1/4 24F 530 ST V 1/4 24F 430 ST V 1/4 24F 340 ST V 1/4 24F 260 ST	Approved subject to submission of separate fee for s type.
28.	Digital Imaging Systems, Habitat Apartments, Shadman	Legal Manufacturer: Abbott Medical, 3200 Lakeside Drive SANTA	HI-TORQUE VERSATURN TM (Hydrophilic Guide Wire)	Approved.

	II, Ghaus-ul-Azam Road, Lahore - 54000, Pakistan. ELI-00094 5425-P	CLARA, California USA. Manufacturing sites: i. Abbott Vascular 26531 YNEZ Rd. Temecula, CA USA 92591. ii. Abbott Vascular Road #2, km 58.0, Cruce Davilla BARCELONETA, PR USA 00617. Original FSC: USA. Validity: 07-12-2025.	Class-D Shelf Life: 2 Year Codes: 1013317, 1013317J, 1013319, 1013319J	
29.	Haji S. Ameer Din and Sons, 305-A Upper Mall Lahore 5400 Pakistan. ELI-00059 5394-P	Legal Manufacturer: Norlase ApS Brydehusvej 13 DK 2750 Ballerup Denmark. FSC: Denmark. Validity: 19-04-2025.	Norlase LION™ (Laser Indirect Ophthalmoscope Photo-coagulator) Class-C Service Life: 10 years Reference No: N006-9200 (DoC)	Approved.
30.	Total Technologies Pvt. Ltd 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 5495-P	Legal Manufacturer: Löwenstein Medical Innovation GmbH & Co. KG located at Weibkirchener Strabe.1 61449 Steinbech, Germany FSC: Germany Date of Issue: 14/06/2023	ELISA 500 (Intensive Care Ventilator) Class-C Shelf Life: 12 Years Art. No. AG-480500	Approved.
31.	Total Technologies Pvt. Ltd 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 5494-P	Legal Manufacturer: Löwenstein Medical Innovation GmbH & Co. KG located at Weibkirchener Strabe.1 61449 Steinbech, Germany FSC: Germany Date of Issue: 14/06/2023	ELISA 800 (Intensive Care Ventilator) Class-C Shelf Life: 12 Years Art. No. AG-370800	Approved.
32.	Total Technologies Pvt. Ltd 696 – J-2, M.A. Johar Town, Lahore, Pakistan License No.: ELI-00129 5493-P	Legal Manufacturer: Löwenstein Medical Innovation GmbH & Co. KG located at Weibkirchener Strabe.1 61449 Steinbech, Germany FSC: Germany Date of Issue: 14/06/2023	ELISA 800 VIT (Intensive Care Ventilator) Class-C Shelf Life: 12 Years Art. No. AG-370800-VIT	Approved.
33.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Bock, New Garden Town, Lahore.	Legal Manufacturer: Siare Engineering International Group S.P.A. Via Giulio Pastore, 18,	ARIA 104 (Lung ventilator for intensive care)	Approved subject to differential fee of 12,000/- .

	ELI-00135 5428-P	Localita Crespellano - 40053 Valsamoggia (BO) Italy. Original FSC: Italy. Issuance 14-09-2023	Class-C Shelf Life: 10 Year Model: ARIA 104	
34.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Bock, New Garden Town, Lahore. ELI-00135 5431-P	<u>Legal Manufacturer:</u> Siare Engineering International Group S.P.A. Via Giulio Pastore, 18, Localita Crespellano - 40053 Valsamoggia (BO) Italy. Original FSC: Italy. Issuance 14-09-2023	FALCON 202 (Lung ventilator) Class-C Shelf Life: 10 Year Model: FALCON 202	Approved subject to differential fee of 12,000/- .
35.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Bock, New Garden Town, Lahore. ELI-00135 5429-P	<u>Legal Manufacturer:</u> Siare Engineering International Group S.P.A. Via Giulio Pastore, 18, Localita Crespellano - 40053 Valsamoggia (BO) Italy. Original FSC: Italy. Issuance 14-09-2023	ARIA 150 (Lung ventilator) Class-C Shelf Life: 10 Year Model: ARIA 150	Approved subject to differential fee of 12,000/- .
36.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Bock, New Garden Town, Lahore. ELI-00135 5430-P	<u>Legal Manufacturer:</u> Siare Engineering International Group S.P.A. Via Giulio Pastore, 18, Localita Crespellano - 40053 Valsamoggia (BO) Italy. Original FSC: Italy. Issuance 14-09-2023	ARIA 150 C (Lung ventilator for intensive care) Class-C Shelf Life: 10 Year Model: ARIA 150 C	Approved subject to differential fee of 12,000/- .
37.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Bock, New Garden Town, Lahore. ELI-00135 5432-P	<u>Legal Manufacturer:</u> M/s Carestream Health, Inc. 150 Verona Street, Rochester, New York 14608, USA <u>Manufacturing Site:</u> Rayco (Shanghai) Medical Product Company Limited Building 7, No. 1510 Chuanqiao Road, China (Shanghai) Pilot Free Trade Zone 201206 Shanghai, People republic of China. FSC: China Valid till: 18-06-2025 510(k) Ref: No. K213568	DRX-Rise (Mobile X-Ray System) Class-C Service Life: 10 years Model: DRX – compass X	Approved subject to differential fee of 12,000/- .
38.	SH Vision, SXX-5S-57, Canal Park Main Market Bazar near	<u>Legal Manufacturer:</u> Mediphacos Industrias Medicas S/A, Av. Deputado	Mediflex (Hydrophobic Intraocular Lenses)	Approved with 4 years of shelf life.

	Ahmad Pharmacy Gulberg-II, Lahore. ELI-01220 5418-P	Cristovam Chiaradia, 777, Bunitis, Belo Horizonte - Minas Gerais - Brazil. Original FSC: Brazil. Validity: 22.05-2026	Class-C Shelf Life: 5 Year Model: Easy Flex Pre-loaded	
39.	SH Vision, SXX-5S-57, Canal Park Main Market Bazar near Ahmad Pharmacy Gulberg-II, Lahore. ELI-01220 5417-P	<u>Legal Manufacturer:</u> Mediphacos Industrias Medicas S/A, Av. Deputado Cristovam Chiaradia, 777, Bunitis, Belo Horizonte - Minas Gerais - Brazil. Original FSC: Brazil. Validity: 22.05-2026	BIOS (Foldable Hydrophilic Intraocular Lenses) Class-C Shelf Life: 5 Years Model: Bios-D3	Approved
40.	Humayun Dental Supplies, 43m Mozang Road, Lahore ELI: 00063 4941-P	<u>Legal Manufacturer:</u> Medigma Biomedical GmbH SiemenstraBe, 10, 78564 Wehingen, Germany FSC: Germany Date of Issue: 19/03/2021	Mars™ (Dental Implant) Class-C Shelf Life: 5 years Codes & Sizes: As per FSC	Approved
41.	Humayun Dental Supplies, 43m Mozang Road, Lahore ELI: 00063 4942-P	<u>Legal Manufacturer:</u> Medigma Biomedical GmbH SiemenstraBe, 10, 78564 Wehingen, Germany FSC: Germany Date of Issue: 19/03/2021	Fix™ (One Piece Dental Implant) Class-C Shelf Life: 5 years Codes & Sizes: As per FSC	Approved
42.	Humayun Dental Supplies, 43m Mozang Road, Lahore ELI: 00063 4943-P	<u>Legal Manufacturer:</u> Medigma Biomedical GmbH SiemenstraBe, 10, 78564 Wehingen, Germany FSC: Germany Date of Issue: 19/03/2021	Fix Tite™ -S (Spiral Dental Implant) Class-C Shelf Life: 5 years Codes & Sizes: As per FSC	Approved
43.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5516-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent GM Cover Screw Class-C Shelf Life: 5 Year Codes: 117.021, 117.022	Approved
44.	Stupra International,	<u>Legal Manufacturer</u>	Neodent	Approved

	289-A, Muslim Town Lahore. ELI-00953 5517-P	Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	(GM Healing Abutment) Class-C Shelf Life: 5 Years Codes: 106.208, 106.209, 106.210, 106.211, 106.213, 106.214, 106.215, 106.216, 106.217	
45.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5518-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent (GM Mini Conical Abutment) Class-C Shelf Life: 5 Years Codes: 115.243, 115.244, 115.245, 115.246, 115.247, 115.248	Approved
46.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5519-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent (GM Micro Abutment) Class-C Shelf Life: 5 Years Codes: 115.255, 115.256, 115.257, 115.258, 115.259, 115.260	Approved
47.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5520-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023	Neodent (GM Helix Acqua Implant) Class-C Shelf Life: 2 Years Codes: 140.957, 140.990, 140.943, 140.944, 140.945, 140.946, 140.947, 140.988, 140.982, 140.983, 140.984, 140.985, 140.986, 140.987, 140.948,	Approved

		FSC: Switzerland. Validity: 31-01-2027.	140.949, 140.950, 140.951, 140.952, 140.989, 140.953, 140.954, 140.955, 140.956	
48.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5521-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent (GM Helix Implant) Class-C Shelf Life: 5 Years Codes: 109.943, 109.944, 109.945, 109.946, 109.947, 109.982, 109.983, 109.984, 109.985, 109.986, 109.948, 109.949, 109.950, 109.951, 109.952, 109.953, 109.954, 109.955, 109.956, 109.1009, 109.1010, 109.1011, 109.1012	Approved
49.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5522-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent GM Exact Click Universal Abutment 17/30 Class-C Shelf Life: 5 Years Codes as per FSC 114.542, 114.543, 114.544, 114.545, 114.546, 114.547, 114.548, 114.549, 114.550, 114.551, 114.552, 114.553, 114.554, 114.555, 114.556, 114.557, 114.558, 114.559, 114.560, 114.561, 114.562, 115.563, 114.564, 114.565	Approved
50.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5523-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent GM Exact Titanium Base with Removable screw Class-C Shelf Life: 5 Years Codes: 135.260, 135.261, 135.262, 135.263, 135.272, 135.273, 135.274, 135.275, 135.266, 135.267, 135.268, 135.269, 135.278, 135.279, 135.280, 135.281, 135.282, 135.252	Approved
51.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5524-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u>	Neodent GM Exact Abutment Class-C Shelf Life: 5 Years	Approved

		JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Codes: 115.237, 115.238, 115.239, 115.240, 115.241	
52.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5525-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent GM Exact Click Universal Abutment Class-C Shelf Life: 5 Years Codes: 114.566, 114.567, 114.568, 114.569, 114.570, 114.571, 114.572, 114.573, 114.574, 114.575, 114.576, 114.577, 114.578, 114.579, 114.580, 114.581, 114.582, 114.583, 114.584, 114.585, 114.586, 114.587, 114.588, 114.589	Approved
53.	Stupra International, 289-A, Muslim Town Lahore. ELI-00953 5526-P	<u>Legal Manufacturer</u> Institute Straumann AG Peter Merian-Weg 12 4002 Basel, Switzerland. <u>Manufacturing site:</u> JJGC Industria e Comercio de Materialis Dentarios S. A Av. Juscelino Kubitschek de Oliveira, 3291-CIC Curitiba Parana BR Postal code 81270-4000 FSC Brazil 12-12-2023 FSC: Switzerland. Validity: 31-01-2027.	Neodent GM Exact Mini Conical Abutment Class-C Shelf Life: 5 Years Codes: 115.249, 115.251, 115.252, 115.253, 115.254	Approved
54.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315 5648-P	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 23-09-2024	MultiFiltrate PRO-Kit HDF 400 (Therapy set for acute dialysis treatments) Class-C Shelf life: 3 years Article no. MultiFiltrate PRO-Kit HDF 400 (F00008138) Ultraflux AV 400S (5007341)	Approved subject to submission of differential fee as per New S.R.O 1324 (I)/2024 dated 30- 08-2024.

			MultiFiltrate PRO HDF (F00002438)	
55.	Fresenius Medical Care Pakistan (Pvt) Ltd, Office Address 27-C, 1st Floor, TAMC Building, M.M. Alam Gulberg-III, Lahore. ELI-00315 5543-P	<u>Legal manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC Germany issuance 23-09-2024	MultiFiltrate Kit MPS P1 Dry (Therapy set for acute dialysis treatments) Class-C Shelf life: 3 years Article no. MultiFiltrate Kit MPS P1 Dry (F00003316) Plasma flux P1 dry (5008021) MultiFiltrate MIDI Set (F00003060) Filtrate Bag 10 L (5029011)	Appoved subject to submission of differential fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.
56.	Total Technologies (Pvt) Ltd, 696, J-2 Johar Town, District Lahore, Pakistan. ELI-00129 5560-P	<u>Legal Manufacturer</u> Shenzhen Prunus Medical Co., Ltd 6th Floor, 8th Floor and 9th Floor, No. 71-3, Xintian Road, Xintian Community, Fuhai Street, Bao'an District, 518103 Shenzhen, Guangdong, China. Original FSC: China. Validity: 06-01-2025.	Prunus (Anesthesia Machine) Class-C Service Life: 10 years Model: Boaray 600D	Approved.
57.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5396-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Angiographic syringe, DSA) Class-D Shelf life: 3 years Codes: AS12NL, CT-190-A1, CT-200A1, CT-200-A1/D, DSA-150-A1, DSA-200-A1, MRI-65/115-A1/D	Approved in class-B subject to submission of fee for Ct and MRI syringes.
58.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5397-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Angiography catheter) Class-D Shelf life: 3 years Codes as per FSC	Deferred for clarification of class of Medical device and submission of declaration of conformity.
59.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi.	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak.	Cardiohealth (Angiographic Closure Pad) Class-D	Approved in Class-B

	ELI-00046 5398-P	No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Shelf life: 3 years Codes: ACP-FP, ACP-RP, ACP-SRP	
60.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5399-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Balloon Inflation Device) Class-D Shelf life: 3 years Codes: IFD-20, IFD-20S, IFD-30, IFD-30S	Approved in Class-B
61.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5400-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Connecting tube) Class-D Shelf life: 3 years Codes: CT12P030, CT12P060, CT12P100, CT12P120, CT12P120, CT12P150, CT12P180, CT12P200	Approved in Class-B
62.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5401-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Guidewires) Class-D Shelf life: 3 years Codes: GW14H190F, GW-14S190F, GW32P150J, GW32P260J, GW35H150A, GW35H180A, GW35H260A, GW35P150J, GW35P150S, GW35P180J, GW38P150J	Approved in Class-B
63.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5402-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Guiding Catheter) Class-D Shelf life: 3 years Codes as per FSC	Approved in Class-B
64.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi.	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey.	Cardiohealth (Hemostasis Valve set) Class-D	Approved in Class-B

	ELI-00046 5403-P	FSC: Spain Issuance 13-06-2024.	Shelf life: 3 years Codes: HVS-PC25, HVS-PC50, HVS-PP25, HVS-PP50, HVS-SC	
65.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5404-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Introducer set) Class-D Shelf life: 3 years Codes: ISF10F11, ISF4F09, ISF5F11, ISF6F11, ISF7F11, ISF8F11, ISF9F11, ISR4F07, ISR5F07, ISR5F11, ISR6F07, ISR6F11	Approved in Class-B
66.	Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi. ELI-00046 5405-P	<u>Legal Manufacturer:</u> Cardiohealth, Asik Veysel Mahallesi. 5821/1 Sokak. No:6, Karabaglar Izmir, Turkey. FSC: Spain Issuance 13-06-2024.	Cardiohealth (Manifold) Class-D Shelf life: 3 years Models: MKIT M2ROFF M3ROFF	Approved in Class-B
67.	Future D Pakistan, House No. 482, G3, Johar Town, Lahore. ELI-00568 5629-P 62,000/- fee	<u>Legal Manufacturer:</u> VATECH Co. Ltd., 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea. FSC: Korea. Date of Issuance: 02-05-2024.	Green X12 (Dental Computed Tomography X-ray System) Class-C Service life: 10 years Model: (PHT-75CHS)	Approved subject to submission of valid CE marked document.
68.	Future D Pakistan, House No. 482, G3, Johar Town, Lahore. ELI-00568 5630-P 62,000/- fee	<u>Legal Manufacturer:</u> VATECH Co. Ltd., 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea. FSC: Korea. Date of Issuance: 02-05-2024.	Green X18 (Computed Tomography X-ray System) Class-C Service life: 10 years Model: (PHT-75CHS)	Approved subject to submission of valid CE marked document.
69.	Future D Pakistan, House No. 482, G3, Johar Town, Lahore. ELI-00568 5631-P 62,000/- fee	<u>Legal Manufacturer:</u> VATECH Co. Ltd., 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea. FSC: Korea. Date of Issuance: 02-05-2024.	Green X (Computed Tomography X-ray System) Class-C Service life: 10 years Model:	Approved subject to submission of valid CE marked document.

			(PHT-75CHS)	
70.	Future D Pakistan, House No. 482, G3, Johar Town, Lahore. ELI-00568 5632-P 62,000/- fee	Legal Manufacturer: VATECH Co. Ltd., 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea. FSC: Korea. Date of Issuance: 02-05- 2024.	Vatech A9 (Computed Tomography X-ray System) Class-C Service life: 10 years Model: PHT-30CSS	Approved subject to submission of valid CE marked document.
71.	Future D Pakistan, House No. 482, G3, Johar Town, Lahore. ELI-00568 5633-P 62,000/- fee	Legal Manufacturer: VATECH Co. Ltd., 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea. FSC: Korea. Date of Issuance: 02-05- 2024.	PaX-i (Digital X-ray Imaging System) Class-C Service life: 10 years Model: PCH-2500	Approved subject to submission of valid CE marked document.
72.	Siemens Healthcare Private Limited 4 th Floor, State Life Building, 15-A, Davis Road, Lahore. ELI-00146 5607-P 62,000/- fee	Legal Manufacturer: Siemens Healthcare GmbH, Henkestr.127, 91052, Erlangen, Germany Telephone: +49 (9131) 84 0 Official Website: https://www.siemens- healthineers.cn/ <u>FSC Germany issuance</u> <u>15-12-2023</u> <u>510(k) No. K231577</u>	MOBILETT IMPACT (Mobile Basic Diagnostic X- ray System, Digital) Class-C Service life: 10 years Identifier No. (11647500)	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of revised fee.
73.	Siemens Healthcare Private Limited 4 th Floor, State Life Building, 15-A, Davis Road, Lahore. ELI-00146 5601-P 62,000/- fee	Legal Manufacturer: Siemens Healthcare GmbH, Henkestr.127, 91052, Erlangen, Germany Telephone: +49 (9131) 84 0 Official Website: https://www.siemens- healthineers.cn/ <u>FSC Germany issuance</u> <u>15-12-2023</u> <u>510(k) No. K231577</u>	MOBILETT ELARA MAX (Mobile Basic Diagnostic X- ray System, Digital) Class-C Service life: 10 years Identifier No. (11107444)	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of revised fee.
74.	Siemens Healthcare Private Limited 4 th Floor, State Life Building, 15-A, Davis Road, Lahore. ELI-00146 5603-P 50,000/- fee	Legal Manufacturer: Siemens Healthcare GmbH, Henkestr.127, 91052, Erlangen, Germany Manufacturing facility: Siemens Shanghai Medical Equipment Ltd. 278 Zhou Zhu Road, Shanghai 201318, P.R. China	LUMINOS Impulse (X-ray system, diagnostic, fluoroscopic, general-purpose stationary, analogue) Class-C Service life: 10 years	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of revised fee.

		Telephone: +86 (021)38891815 Fax: N/A Official Website: https://www.siemens-healthineers.cn/ <u>FSC Germany issuance</u> 04-11-2024	Product Identification (11506518)	
75.	AA Traders, P-871-B, Basement, Chen One Road, Peoples Colony # 1, District Faisalabad, Pakistan. ELI-00836 5649-P 62,000/- fee	<u>Legal Manufacturer:</u> Zhejiang Runqiang Medical Instruments Co. Ltd 599 Ruifeng Street, Xiuzhou District, 314031 Jiaying City, Zhejiang Province, Peoples Republic of China. 314031 Original FSC: China. Validity: 26-03-2025.	HEARTCARE (Disposable Anesthesia Needle (Spinal Needle/Epidural Needle/RF Needle) Class-D Shelf Life: 5 Year Codes: AN-E, AN-S, AN-N, AN-E/SII	Approved subject to submission of fee for Epidural and RF needle and Design examination certificate.
76.	Medico International, B-235, Block B, Satellite Town, Rawalpindi Pakistan. ELI-01038 5502-P 62,000/-	<u>Legal Manufacturer:</u> Sejoy Biomedical Co, Ltd. Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone 311100 Hangzhou City, Zhejiang, China. Original FSC: China. Validity: 09-05-2026.	MEDICO (Blood Glucose Monitoring system (BG-201) and Test Strips (BS-102) Class-C Shelf Life: 24 Month Model: Meter (BG-201) Strips (102)	Approved subject to submission of fee as per new revised notification for fee.
77.	Medifar Impex International (Pvt) Ltd, Suit No. 403-404, 4th Floor, Mohammadia Plaza College Road, Rawalpindi. ELI-00536 5597-P 62,000/-	<u>Legal Manufacturer:</u> Zhejiang Shuyou Surgical Instruments Co., Ltd 3689, East Yangguang Avenue, DIPU Street, Anji, Huzhou City, Zhejiang Province, China. Original FSC: China. Validity: 10-09-2025.	Shu You (Disposable Electro Surgical Pencil) Class-C Shelf life: 3 years Codes as per FSC	Approved subject to submission of revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
78.	Medifar Impex International (Pvt) Ltd, Suit No. 403-404, 4th Floor, Mohammadia Plaza College Road, Rawalpindi. ELI-00536 5598-P 62,000/-	<u>Legal Manufacturer:</u> Zhejiang Shuyou Surgical Instruments Co., Ltd 3689, East Yangguang Avenue, DIPU Street, Anji, Huzhou City, Zhejiang Province, China. Original FSC: China. Validity: 13-12-2025.	Shu You (Disposable Electro Surgical Pads) Class-C Shelf life: 5 years Codes as per FSC	Approved subject to submission of revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
79.	Highsea Pharmaceutica, 2nd Floor, 39-Commercial Area,	<u>Legal Manufacturer:</u> SIDAPHARM P.C 21, Stageiriti & 24, Em.Fili str.,	SIDA-LENS Hydrophobic Intraocular Lens	Board approved the product SEDA LENS SDHB6130i as the

	Cavalry Ground, Lahore - Pakistan. ELI-01251 5466-P 62,000/-	Thessaloniki GR-54352, Greece Original FSC: Greece. Date of Issuance: 25-09-2024.	Class-C Shelf life: 5 years Model: SDHB SDHBY SDHB6130i SDHB130S	importer has only authorization for this variant SEDA LENS SDHB6130i .
80.	Akram Brothers and Co, 89-D Jail road, Lahore Cty, Punjab Province, Pakistan. ELI-00324 5510-P 62,000/-	Legal Manufacturer: Kollsut International Inc. 1763 NE 162nd Street, North Miami Beach, FL33162 USA. Original FSC: USA. Validity: 11-06-2025.	Kollgut Chrom (Sterilized Absorbable Catgut Chromic Suture) Class-D Shelf life: 5 years Codes: As per DoC	Approved subject to submission of FQA and DE certificates and fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.
81.	Vertex Medical Pvt Ltd, 401-402, Block-F, Johar Town, Lahore-Lahore-Pakistan ELI-00150 5645-P 62,000/-	Legal Manufacturer: Dragerwerk AG & Co. KGaA, Moislinger Allee 53-55 23542 Lubeck, Germany. FSC: Germany Date of Issuance: N/A	Drager SCIO FOUR Class-C Shelf life: N/A Models: SCIO Four Oxi plus (6871801) SCIO Four plus (6871802) SCIO Four Oxi (6871803) SCIO Four (6871804)	Approved subject to submission of fee for each model.
82.	3M SURGICALS, Plot-5, ST-172, Sarwar Road Rawalpindi. ELI-00122 5594-P 62,000/-	Legal Manufacturer: Biovic Sdn. Bhd. 12A Jalan PJU 3/40, Sunway Damansara Technology Park, 47810 Petaling Jaya, Selangor, Malaysia. Original FSC: Malaysia. Validity: 05-11-2026.	AVATAR ® PTFE Vascular Graft Class-C Shelf Life: 5 years Codes as per FSC	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of products applied as family.
83.	Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 6118-kpk	Legal Manufacturer: Boston Scientific Corporation 300, Boston scientific Way, Marlborough, MA 01752 USA. Manufacturing Site Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela, Costa Rica FSC US FDA validity 23-05-2025	EkoSonic Endovascular Device (Ultrasound thrombolysis System Catheter; Pulmonary/ Peripheral Class-D Shelf life: 36 Months Codes as per FSC 500-55106, 500-55112, 500-	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of products applied as family. Updated LOA and clarification of Brand name.

			55118, 500-55124, 500-55130, 500-55140, 500-55150, 500-56106, 500-56112, 500-56118, 500-56124	
84.	Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 6119-kpk	<u>Legal Manufacturer:</u> Boston Scientific Corporation 300, Boston scientific Way, Marlborough, MA 01752 USA. <u>Manufacturing Site</u> Boston Scientific Corporation 4100 Hamline Avenue North St. Paul Minnesota-55112 USA. FSC US FDA validity 23-05-2025	EKOS Control System 4.0 (Ultrasound thrombolysis system control unit) Class-C Shelf life: N/A Codes: EKOS Control Unit 4.0 Console (600-40500) EKOS Control Unit 4.0 Console (H7493959340010) EKOS Control Unit 4.0 Console, Remanufactured (H749395934001R0) EKOS Connector Interface Cable (700-10410) EKOS Connector Interface Cable (H7493966540060)	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of products applied as family. Updated LOA
85.	M/s Mian Enterprises Office No.UG-400, Deans Trade Center, Peshawar Cantt 25000 Pakistan ELI-00507 13540 (R&I)	<u>Legal Manufacturer:</u> M/s Kowa Company Ltd., Japan. 4-14, 3-Chome, Nihonbashi- Honcho, Chuo-ku, Tokyo 103-8433, Japan <u>Manufacturing Site:</u> 3-1, 1-chome, Shin- Miyakoda, Hamana-ku, Hamamatsu, Shizuoka, 431- 2103, Japan	Avansee Preload 1P Toric (Hydrophobic Intraocular Lens) Class-C Shelf Life: 5 Years Codes: YP-Tx (x: 2, 3, 4, 5, 6, 7, 8, or 9)	Approved
86.	M/s Mian Enterprises Office No.UG-400, Deans Trade Center, Peshawar Cantt 25000 Pakistan ELI-00507 13541 (R&I)	<u>Legal Manufacturer:</u> M/s Kowa Company Ltd., Japan. 4-14, 3-Chome, Nihonbashi- Honcho, Chuo-ku, Tokyo 103-8433, Japan <u>Manufacturing Site:</u> 3-1, 1-chome, Shin- Miyakoda, Hamana-ku, Hamamatsu, Shizuoka, 431- 2103, Japan	Avansee Preload 1P Toric Clear (Hydrophobic Intraocular Lens) Class-C Shelf Life: 5 Years Codes: CP-Tx (x: 2, 3, 4, 5, 6, 7, 8, or 9)	Approved

87.	<p>Gulfam Brothers, Office No. 702, 7th Floor, Land Mark Plaza Jail Road Lahore.</p> <p>H. No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore.</p> <p>ELI-00028 5539-P</p>	<p>Legal Manufacturer KONFORT OZEL SAGLIK HIZMETLERI TIBBI MALZEMELER SAN. VE TIC. LTD. STI. Organize Sanayi Bölgesi 9. Cad No. 32, ESKISEHIR, TURKEY.</p> <p>FSC: Turkey. Date of Issuance: 22-10-2021.</p>	<p>CONFORT Vacuum Assisted Wound Closure Set Abdomen (Hydrophobic)</p> <p>Class-C</p> <p>Shelf life: 3 years</p> <p>Codes: FD90004</p>	<p>Approved subject to submission of valid FSC, ISO 13485 and CE certificate.</p>
88.	<p>M/s Ferozs Laboratories Limited (ELI-00120)</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752</p> <p>Manufacturing Site: Biocompatibles UK Limited Chapman House, Farnham Business Park Weydon Lane, Farnham Surrey GU9 8QL UK</p> <p>Date of R&I 29-12-2022</p> <p>LOA Validity: 31-12-2024 FSC MHRA validity 26-05-2025</p>	<p>TheraSphere Administration Accessory Kit</p> <p>Class D</p> <p>Service Life: 10 years</p> <p>Codes/Sizes: OTT-SPE-FP-617</p>	<p>Approved subject to submission of Updated LOA</p>
89.	<p>M/s Ferozs Laboratories Limited (ELI-00120)</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752</p> <p>Manufacturing Site: B. Braun Medical Inc., 901 Marcon Boulevard, Allentown, Pennsylvania, 18109-9341, United States</p> <p>Date of R&I 29-12-2022</p> <p>LOA Validity: 31-12-2024 FSC MHRA validity 26-05-2025</p>	<p>TheraSphere Administration Set</p> <p>Class D</p> <p>Shelf Life: 03 years</p> <p>Codes/Sizes: OTT-SPE-FP-001</p>	<p>Approved subject to submission of Updated LOA</p>
90.	<p>M/s Ferozs Laboratories Limited (ELI-00120)</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752</p> <p>Manufacturing Site: CEA Medical Manufacturing, Inc.,</p>	<p>TheraSphere Administration Set</p> <p>Class D</p> <p>Shelf Life: 01 years</p>	<p>Approved subject to submission of Updated LOA</p>

		1735 Merchants Court, Colorado Springs, Colorado, 80916, United States Date of R&I 29-12-2022 LOA Validity: 31-12-2024 FSC MHRA validity 26-05-2025	Codes/Sizes: OTT-SPE-FP-226	
91.	M/s Ferozsos Laboratories Limited (ELI-00120)	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: BOSTON SCIENTIFIC CORPORATION 780 BROOKSIDE DRIVE SPENCER, IN USA 47460 Date of R&I 02-01-2020 LOA Validity: 31-12-2024 FSC US FDA validity 25-06-2020	Percuflex Plastic Biliary Stent Class C Shelf Life: 03 years Codes/Sizes: M00533610 M00533620 M00533630 M00533640 M00533650 M00533660 M00533670 M00533680 M00533690 M00533700	Approved subject to submission of Updated LOA and FSC.
92.	M/s Ferozsos Laboratories Limited (ELI-00120)	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: BOSTON SCIENTIFIC CORPORATION 780 BROOKSIDE DRIVE SPENCER, IN USA 47460 Date of R&I 02-01-2020 LOA Validity: 31-12-2024 FSC US FDA validity 25-06-2020	Biliary Introducer Class C Shelf Life: 03 years Codes/Sizes: M00533910 M00533920	Approved subject to submission of Updated LOA and Brand name.
93.	M/s Ferozsos Laboratories Limited (ELI-00120)	Legal Manufacturer: Northgate Technologies Inc. 1591 Scottsdale Court Elgin, IL USA 60123 Manufacturing Site: Northgate Technologies Inc. 1591 Scottsdale Court Elgin, IL USA 60123 Date of R&I 02-01-2020 LOA	AUTOLITH TOUCH BIPOLAR ELECTROHYDRAULIC LITHOTRIPTER AND ACCESSORIES Class C Shelf Life: 03 years Codes/Sizes:	Approved subject to submission of Updated LOA

		Validity: 31-12-2024 FSC US FDA validity 26-04-2024	M005466800 M00546750 M00546760 M00546620	
94.	M/s Ferozsons Laboratories Limited (ELI-00120)	<u>Legal Manufacturer:</u> Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 <u>Manufacturing Site:</u> BOSTON SCIENTIFIC CORPORATION 302 Parkway, Global Park La Aurora, Heredia COSTA RICA Date of R&I 17-10-2022 <u>LOA</u> Validity: 31-12-2024 FSC US FDA validity 08-06-2023	IntellaMap Orion High Resolution Mapping Catheter and accessories Class D Shelf Life: 01 years Codes/Sizes: M004RC64S0	Approved subject to submission of Updated LOA
95.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal Karachi. (ELI-00294) 3938-C 62,000/-	<u>Legal Manufacturer:</u> Shenzhen Creative Industry Co., Ltd. Floor 5, BLD 9, BaiWangxin High-tech Industrial Park, Songbai road, Xili Street, Nanshan district, Shenzhen China. FSC China validity 14-01-2025 FSC Germany issuance 17-06-2023	Vital Signs Monitor Vital Signs Monitor Class-C Service life: 10 years Model: PC900	Approved subject to submission of brand name.
96.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal Karachi. (ELI-00294) 3939-C 62,000/-	<u>Legal Manufacturer:</u> Shenzhen Creative Industry Co., Ltd. Floor 5, BLD 9, BaiWangxin High-tech Industrial Park, Songbai road, Xili Street, Nanshan district, Shenzhen China. FSC China validity 14-01-2025 FSC Germany issuance 17-06-2023	Vital Signs Monitor Vital Signs Monitor Class-C Service life: 10 years Model: UP7000	Approved subject to submission of brand name.
97.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal Karachi. (ELI-00294) 3996-C 62,000/-	<u>Legal Manufacturer:</u> Shenzhen Creative Industry Co., Ltd. Floor 5, BLD 9, BaiWangxin High-tech Industrial Park, Songbai road, Xili Street, Nanshan district, Shenzhen China. FSC China validity 14-01-2025 FSC Germany issuance 17-	Vital Signs Monitor Vital Signs Monitor Class-C Service life: 10 years Model: K-10, K12, K15	Approved subject to submission of brand name and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.

		06-2023 510 (k) K192343		
98.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3995-C 62,000/-	Legal Manufacturer: Bio Med Devices Inc. 61 Soundview Road, Guilford, CT 06437, USA FSC US FDA validity07-02- 2026	TV-100 ICU/Transport Ventilator Transport Ventilator Class-C Service life: 10years Model: TV-100	Approved
99.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3994-C 62,000/-	Legal Manufacturer: Bio Med Devices Inc. 61 Soundview Road, Guilford, CT 06437, USA FSC US FDA validity07-02- 2026	BMD Air Oxygen Blender Class-C Service life: 10years Model: 2003FFE1	Deferred for the clarification of Brand name.
100.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3800-C 62,000/-	Legal Manufacturer: TENDE Elektronik Yazılım Mühendislik İletişim Makina Sanayi ve Ticaret Limited Şirketi Ahi Evran OSB Mahallesi, Akhun Caddesi No: 5/1 06935 Sincan / ANKARA / TÜRKİYE FSC Turkey validity 07-01- 2027 FSC Belgium issuance 15-10-2024	TENDE Infant Radiant Warmer Class-C Shelf life: N/A Model: VAV-IW	Approved
101.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3797-C 62,000/-	Legal Manufacturer: TENDE Elektronik Yazılım Mühendislik İletişim Makina Sanayi ve Ticaret Limited Şirketi Ahi Evran OSB Mahallesi, Akhun Caddesi No: 5/1 06935 Sincan / ANKARA / TÜRKİYE FSC Turkey validity 07-01- 2027 FSC Belgium issuance 15-10-2024	TENDE (Intensive Care Transport Baby Incubator) Class-C Shelf life: N/A Model: VAV-TR	Approved
102.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3998-C	Legal Manufacturer: TENDE Elektronik Yazılım Mühendislik İletişim Makina Sanayi ve Ticaret Limited Şirketi Ahi Evran OSB Mahallesi, Akhun Caddesi No: 5/1	TENDE LED Phototherapy Device Class-C Shelf life: N/A	Approved subject to submission of revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.

	62,000/-	06935 Sincan / ANKARA / TÜRKİYE FSC Turkey validity 07-01-2027 FSC Belgium issuance 15-10-2024	Models: Babyblue 360 (Tunnel type) Careblue LPT-240-2 Babyblue LPT-240	
103.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3999-C 62,000/-	Legal Manufacturer: TENDE Elektronik Yazılım Mühendislik İletişim Makina Sanayi ve Ticaret Limited Şirketi Ahi Evran OSB Mahallesi, Akhun Caddesi No: 5/1 06935 Sincan / ANKARA / TÜRKİYE FSC Turkey validity 07-01- 2027 FSC Belgium issuance 15-10-2024	TENDE (Intensive Care Baby Incubator) Class-C Shelf life: N/A Model: VAV	Approved
104.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal Karachi. (ELI-00294) 3940-C 62,000/-	Legal Manufacturer: Great Group Medical Co., Ltd No. 168, Xingong 2nd Rd., Tianzhong Township, Changhua County 520, Taiwan. FSC Taiwan issuance 31-05-2024	GGM Respiratory Humidifier Class-C Shelf life: 3 years Model: VH-2600A	Approved
105.	Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi. (ELI-00249) 3319-C September 2024 50,000/-	Legal Manufacturer: Simeks Tibbi Urunler San ve Tic Ltd Sti, Istanbul Endustri ve Ticaret Serbest Bolgesi, Aydinli Sb Mah, 10. Sol, No:5, 34953 Tuzla, Istanbul, Turkey. FSC Turkey issuance 05-05- 2024 FSC MHRA 27-05-2025	Simvalve Flex PTV (Valvuloplasty) Balloon Catheter Class-D Shelf life: 3 years Codes as per FSC	Approved subject to submission of valid FQA and DEC. Fee as per New S.R.O 1324 (I)/2024 dated 30- 08-2024 for the products applied as family.
106.	Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi. (ELI-00249) 3318-C September 2024 50,000/-	Legal Manufacturer: Simeks Tibbi Urunler San ve Tic Ltd Sti, Istanbul Endustri ve Ticaret Serbest Bolgesi, Aydinli Sb Mah, 10. Sol, No:5, 34953 Tuzla, Istanbul, Turkey. FSC Turkey issuance 05-05- 2024 FSC MHRA 27-05-2025	Simvalve Force PTV (Valvuloplasty) Balloon Catheter Class-D Shelf life: 3 years Codes as per FSC	Approved subject to submission of valid FQA and DEC. Fee as per New S.R.O 1324 (I)/2024 dated 30- 08-2024 for the products applied as family.
107.	Aesthetic Life 4th Floor, Plot No. 16-C Ittehad Commercial Are, Khyben-e-Nishat , DHA Phase Vi, Karachi.	Legal Manufacturer: Candela Corporation, 251 Locke Drive, Marlborough, MA 01752, USA. Contract Manufacturer:	Candela GentleYag Pro-U (Laser Machine) Class-C	Approved.

	(ELI-01029) 3004-C 50,000/- 22-08-2024	NPA de Mexico S, de R.L. de C.V, Sor Juana Ines de la Cruz # 20150 Interior 5 Cd. Industrial TIJUANA, Baja California MEXICO 22444 FSC US FDA validity 30-04-2026	Shelf life: N/A Model: 9914-00-9020	
108.	Aesthetic Life 4th Floor, Plot No. 16-C Ittehad Commercial Are, Khyben-e-Nishat , DHA Phase Vi, Karachi. (ELI-01029) 3005-C 50,000/- 22-08-2024	Legal Manufacturer: Candela Corporation, 251 Locke Drive, Marlborough, MA 01752, USA. Contract Manufacturer: Jabil Circuit (Shanghai), Ltd 500 Tian Lin Road Shanghai, China 200233 FSC US FDA validity 30-04-2026	Candela GentleMax Pro Plus (Laser Machine) Class-C Shelf life: N/A Model: 9914-CH-9036	Approved
109.	Aesthetic Life 4th Floor, Plot No. 16-C Ittehad Commercial Are, Khyben-e-Nishat, DHA Phase Vi, Karachi. (ELI-01029) 2639-C 50,000/- 16-05-2024	Legal Manufacturer: Euromi Biosciences Zoning Industriel des Plenesses11 Rue Des Nouvelles Technologies 4821 Andrimont, Belgium. FSC Belgium issuance 09-04-2024	CEREFORM Classic Round Shape Smooth Silicone Gel Filled Breast Implants Class-D Shelf life: 5 years Codes: Burcher provided for codes including Low profiles, Medium profiles, Intermediate profiles, High profiles and very high profiles. Volume Range from 100 to 900cc.	Approved subject to submission of revised fee and form for Aptima and Ellipse. Also submit fee for each as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of products applied in family.
110.	FY Diagnostics & Surgicals Anum Blessing, Suite No. 203, 209 Near Duty Free Shop. Bl -7/8, K.C.H.S.U. Shahrah-e-Faisal Karachi. (ELI-00323) 3577-C 62,000/-	Legal Manufacturer: Taidoc Technology Corporation B1-7F, No. 127, Wugong 2nd Rd, Wugu District, New Taipei City 24888, Taiwan. FSC Taiwan validity 01-02-2027	U-RIGHT Blood Glucose Test Strips Class-C Shelf life: 27 Months Model: TD-4251	Approved
111.	FY Diagnostics & Surgicals Anum Blessing, Suite No. 203, 209 Near Duty Free Shop. Bl -7/8, K.C.H.S.U. Shahrah-e-Faisal Karachi. (ELI-00323) 3660-C 62,000/-	Legal Manufacturer: Taidoc Technology Corporation B1-7F, No. 127, Wugong 2nd Rd, Wugu District, New Taipei City 24888, Taiwan. FSC Taiwan validity 01-02-2027	U-RIGHT Blood Glucose Monitoring system Class-C Shelf life: Not mentioned Model: TD-4251	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for the application applied as System.
112.	FY Diagnostics &	Legal Manufacturer:	HDV Ab ELISA	Approved subject to

	Surgicals Anum Blessing, Suite No. 203, 209 Near Duty Free Shop. B1 -7/8, K.C.H.S.U. Shahrah-e-Faisal Karachi. (ELI-00323) 3659-C 62,000/-	Dia.Pro Diagnostics Bioprobes S.r.l. Via Giosue Carducci 27 - 20099 Sesto San Giovanni, Milan Italy. FSC Italy issuance 05-04-2024	HDV Ab ELISA Class-D Shelf life: 15 Months Code: KAPDDAB	submission of Brand name.
113.	K.S. Agencies Office No 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) 3654-C 62,000/-	<u>Legal Manufacturer:</u> Hangzhou Fushan Medical Appliances Co., Ltd No. 1288. South Jin'xi Street. Linglong Industrial Park. Lin'an City, Zhejiang P.R. China. FSC China validity 01-03-2026	Enduro Peg Kit (Percutaneous Endoscopic Gastrostomy kit) Class-C Shelf life: 3 years Sizes: 12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR	Approved
114.	K.S. Agencies Office No 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) 3654-C 62,000/-	<u>Legal Manufacturer:</u> Hangzhou Fushan Medical Appliances Co., Ltd No. 1288. South Jin'xi Street. Linglong Industrial Park. Lin'an City, Zhejiang P.R. China. FSC China validity 01-03-2026	Enduro Gastrostomy Tube (Peg Replacement tube, Endoscopic Gastrostomy Tube) Class-C Shelf life: 3 years Sizes: 12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR	Approved
115.	Basic Pharmaceuticals (Pvt) Ltd, 14-A, Babar Block New Garden Town, Lahore ELI – 00408 1839-P	<u>Legal manufacturer:</u> Fresenius Kabi AG, 61346 Bad Homburg Germany <u>Physical manufacturing site:</u> Fenwal International, Inc. Address: Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. De S.C. Haina, Dominican Republic FSC Original: Germany Date of Issuance: 20-07-2023	C5L Platelet Set (C5L Platelet Apheresis Set) Article no: 9400201 Class B Shelf life 36 months	Approved
116.	Basic Pharmaceuticals (Pvt) Ltd, 14-A, Babar Block New Garden Town, Lahore ELI – 00408 1838-P	<u>Legal manufacturer:</u> Fresenius Kabi AG, 61346 Bad Homburg Germany <u>Physical manufacturing site:</u> Fenwal International, Inc. Address: Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. De S.C. Haina, Dominican	PLI Set PL1 Plasma Exchange Set Product No:9400401 Class B Shelf life 36 months	Approved

		Republic FSC Original: Germany Date of Issuance: 20-07-2023		
117.	Basic Pharmaceuticals (Pvt) Ltd, 14-A, Babar Block New Garden Town, Lahore ELI – 00408 1837-P	Legal manufacturer: Fresenius Kabi AG, 61346 Bad Homburg Germany Physical manufacturing site: Fenwal International, Inc. Address: Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. De S.C. Haina, Dominican Republic FSC Original: Germany Date of Issuance: 20-07-2023	PIYA Set (P1YA White Blood Cell Set) Product No: 9400431 Class B Shelf life 36 months	Approved
118.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 28 Jan 2021 Fee Challan No.: 2070374, 0509253033, 7819373648 PKR: 62,000/-	Legal Manufacturer: M/s CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.	Onsite Malaria Pf/Pv Ab Combo Rapid Test Kit Class: C Shelf life: 24 month Codes/Size: R0111C	Approved
119.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 28 Jan 2021 Fee Challan No.: 64173003710 PKR: 62,000/-	Legal Manufacturer: M/s CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.	Onsite Malaria Pf/Pan Ag Rapid Test Kit Class: C Shelf life: 24 month Codes/Size: R0113C	Approved.
120.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 28 Jan 2021 Fee Challan No.:	Legal Manufacturer: M/s CTK BIOTECH, INC. Address: 13855 STOWE Dr. Poway, California USA.	Onsite Syphilis Ab Combo Rapid Test Kit Class: C Shelf life: 24 month Codes/Size: R0031C	Approved

	2070375, 996316158, 198647572 PKR: 62,000/-			
121.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 20 May 2020 Fee Challan No.: 2026100, 9359608849, 1055906506 PKR: 28,000/-	Legal Manufacturer: M/s CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.	Onsite HEV IgM Rapid Test Kit Class: C Shelf life: 24 month Codes/Size: R0095C	Approved
122.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 11 Jan 2021 Fee Challan No.: 2077402, 68440962939, 973464162 PKR: 60,000/-	Legal Manufacturer: Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein CK-MB Fast Test Kit Class: C Shelf life: 24 month	Approved subject to submission of size/code.
123.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 13 July 2021 Fee Challan No: 41969681554, 2897133095, 86996305088 PKR: 62,000/-	Legal Manufacturer: Guilin Royalyze Medical Instrument Co., Ltd, Business, 13 Lushan Road, Lushan Industrial Park, Zicheng Economic Development Zone, Guilin 541199, China.	INST-ANSWER Multi Monitoring Meter Class: C Shelf life: 5 Years Codes/Size: LBM-01	Approved
124.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030,	Legal Manufacturer: Guilin Royalyze Medical Instrument Co., Ltd, Business, 13 Lushan Road,	INST-ANSWER Blood Glucose Test Strips Class: C	Approved

	Pakistan. (ELI-00442) R&I Dated: 06 Aug 2021 Fee Challan No: 5985508449 PKR: 62,000/-	Lushan Industrial Park, Zicheng Economic Development Zone, Guilin 541199, China.	Shelf life: 24 month Codes/Size:BG-01	
125.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 06 Aug 2021 Fee Challan No: 24998430341 PKR: 62,000/-	Legal Manufacturer: Guilin Royalze Medical Instrument Co., Ltd, Business, 13 Lushan Road, Lushan Industrial Park, Zicheng Economic Development Zone, Guilin 541199, China.	INST-ANSWER Total Cholesterol Test Strips Class: C Shelf life: 24 month Codes/Size: TC-01	Approved
126.	M/s Mian Scientific Corporation (PVT) Ltd 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442) R&I Dated: 01 Feb 2024 Fee Challan No: 991694777704 33395733 PKR: 62,000/-	Legal Manufacturer: Guangzhou Wondfo Biotech Co, Ltd No.8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou P.R China.	Tisenc High Sensitive Cardiac Troponin-I Test Kit Class: C Shelf life: 24 month Codes/Size: 12tests/kit, 24tests/kit, 36tests/kit, 48tests/kit, 60tests/kit	Deferred for the clarification that what is the link between Guangzhou Wondfo Biotech and Tisenc, China.
127.	M/S SH Vision SXX-5S-57, Canal Park Main Market Bazar near Ahmad Pharmacy Gulberg- II, Lahore Pakistan. ELI-01220	Legal Manufacturer: Henan Universe Intraocularlens Research & Manufacture Company Ltd No. 8 Guohuai Ave., Zhengzhou, Henan 450001, China. FSC China validity: 27-06-2025	PCF60/L Foldable intraocular lenses Class C Shelf Life: 3 Years Model: PCF60/L	Approved
128.	M/S SH Vision SXX-5S-57, Canal Park Main Market Bazar near Ahmad Pharmacy Gulberg- II, Lahore Pakistan. ELI-01220	Legal Manufacturer: Henan Universe Intraocularlens Research & Manufacture Company Ltd No. 8 Guohuai Ave., Zhengzhou, Henan 450001, China.	PCF60/AL Foldable intraocular lenses Class C Shelf Life: 3 Years Model:	Approved

		FSC China validity: 27-06-2025	PCF60/AL	
129.	M/S SH Vision SXX-5S-57, Canal Park Main Market Bazar near Ahmad Pharmacy Gulberg- II, Lahore Pakistan. ELI-01220	<u>Legal Manufacturer:</u> Henan Universe Intraocularlens Research & Manufacture Company Ltd No. 8 Guohuai Ave., Zhengzhou, Henan 450001, China. FSC China validity: 27-06-2025	Ophthalmic Hydroxypropyl Methylcellulose (Viscoelastic Solution) Class C Shelf Life: 3 Years	Approved
130.	Treu-Dynamic International (Pvt) Ltd (ELI-00175)	OSTEOPORE International PTE Ltd. Located at 2-Tukang Innovation Grove, NO.09-06 Med TechHub, Singapore 618305. Email: sales@osteopore.com <u>FSC Singapore issuance 2020</u>	Osteopore PCL Scaffold Bone Filler (Neuro Bone Implants System) Class-D Shelf life: 5 years Codes: Osteomesh PC 11 (10,10,1) Osteomesh PC 11 (15,15,1) Osteomesh PC 11 (20,10,0.75) Osteomesh PC 11 (25,17,1) Osteomesh PC 11 (25,25,0.75) Osteomesh PC 11 (25,25,1) Osteomesh PC 11 (25,25,1.25) Osteomesh PC 11 (25,25,1.5) Osteomesh PC 11 (25,25,2) Osteomesh PC 11 (30,10,0.75) Osteomesh PC 11 (30,30,0.75) Osteomesh PC 11 (30,30,1) Osteomesh PC 11 (40,40,0.75) Osteomesh PC 11 (40,40,1) Osteomesh PC 11 (40,40,1.25) Osteomesh PC 11 (40,40,1.5) Osteomesh PC 11 (40,40,2) Osteomesh PC 11 (50,50,0.75) Osteomesh PC 11 (50,50,1) Osteomesh PC 11 (50,50,1.25) Osteomesh PC 11 (50,50,1.5) Osteomesh PC 11 (50,50,2) Osteomesh PC 11 (50,50,3) Osteomesh PC 11 (50,50,4) Osteomesh PC 11 (50,50,5) Osteomesh PC 11 (60,15,5) Osteomesh PC 11 (60,20,5) Osteomesh PC 11 (60,25,5) Osteomesh PC 11 (60,30,5) Osteomesh PC 11 (60,35,5) Osteomesh PC 11 (80,20,2) Osteomesh PC 11 (80,60,1) Osteomesh PC 11 (100,15,5) Osteomesh PC 11 (100,20,5)	The board approved the Osteomesh bone filler subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of fee for System.

			Osteomesh PC 11 (100,25,5) Osteomesh PC 11 (100,30,5) Osteomesh PC 11 (100,35,5) Osteomesh PC 11 (100,100,1) Osteomesh PC 11 (100,100,1.25) Osteomesh PC 11 (100,100,1.5) Osteomesh PC 11 (100,100,2) Osteomesh PC 11 (100,100,3) Osteomesh PC 11 (100,100,4) Osteomesh PC 11 (100,100,5) Osteomesh PC 12 (10,10,0.75) Osteomesh PC 12 (15,15,1) Osteomesh PC 12 (20,10,0.75) Osteomesh PC 12 (25,17,1) Osteomesh PC 12 (25,25,0.75) Osteomesh PC 12 (25,25,1) Osteomesh PC 12 (25,25,1.25) Osteomesh PC 12 (25,25,1.5) Osteomesh PC 12 (25,25,2) Osteomesh PC 12 (30,10,0.75) Osteomesh PC 12 (30,30,0.75) Osteomesh PC 12 (30,30,1) Osteomesh PC 12 (39,39,1) Osteomesh PC 12 (39,10,1.25) Osteomesh PC 12 (40,40,0.75) Osteomesh PC 12 (40,40,1) Osteomesh PC 12 (40,40,1.25) Osteomesh PC 12 (40,40,1.5) Osteomesh PC 12 (40,40,2) Osteomesh PC 12 (50,50,0.75) Osteomesh PC 12 (50,50,1) Osteomesh PC 12 (50,50,1.25) Osteomesh PC 12 (50,50,1.5) Osteomesh PC 12 (50,50,2) Osteomesh PC 12 (50,50,3) Osteomesh PC 12 (50,50,4) Osteomesh PC 12 (50,50,5) Osteomesh PC 12 (60,15,5) Osteomesh PC 12 (60,20,5) Osteomesh PC 12 (60,25,5) Osteomesh PC 12 (60,30,5) Osteomesh PC 12 (60,35,5) Osteomesh PC 12 (80,20,2) Osteomesh PC 12 (80,60,1) Osteomesh PC 12 (100,15,5) Osteomesh PC 12 (100,20,5) Osteomesh PC 12 (100,25,5) Osteomesh PC 12 (100,30,5) Osteomesh PC 12 (100,35,5) Osteomesh PC 12 (100,100,1) Osteomesh PC 12 (100,100,1.25) Osteomesh PC 12 (100,100,1.5) Osteomesh PC 12 (100,100,2) Osteomesh PC 12 (100,100,3)	
--	--	--	---	--

			Osteomesh PC 12 (100,100,4) Osteomesh PC 12 (100,100,5) Osteomesh PC 17 (100,2,4) Osteomesh PC 17 (100,3.5,4) Osteomesh PC 17 (100,5,5) Osteomesh PC 17 (100,6,5) Osteomesh PC 17 (100,7,5) Osteomesh PC 17 (100,10,5) Osteomesh PC 18 (60,2,4) Osteomesh PC 18 (60,3.5,4) Osteomesh PC 18 (60,5,5) Osteomesh PC 18 (60,6,5) Osteomesh PC 18 (60,7,5) Osteomesh PC 18 (60,10,5) Osteomesh PC 19 (100,6,5) Osteomesh PC 19 (100,7,5) Osteomesh PC 19 (100,10,10) Osteomesh PC 20 (15,15,15) Osteomesh PC 20 (20,20,1.5) Osteomesh PC 20 (20,20,2) Osteomesh PC 20 (25,25,1) Osteomesh PC 20 (30,30,1) Osteomesh PC 20 (40,40,1.5) Osteomesh PC 20 (40,40,2) Osteomesh PC 20 (60,60,1.5) Osteomesh PC 20 (60,60,2) Osteoplug PC 21 (4,4,9) Osteoplug PC 21 (4,4,11) Osteoplug PC 21 (4,4,13) Osteoplug PC 21 (4,4,15) Osteoplug PC 21 (4.5,4,9) Osteoplug PC 21 (4.5,4,11) Osteoplug PC 21 (4.5,4,13) Osteoplug PC 21 (4.5,4,15) Osteoplug PC 21 (5,4,9) Osteoplug PC 21 (5,4,11) Osteoplug PC 21 (5,4,13) Osteoplug PC 21 (5,4,15) Osteoplug PC 21 (5.5,4,9) Osteoplug PC 21 (5.5,4,11) Osteoplug PC 21 (5.5,4,13) Osteoplug PC 21 (5.5,4,15) Osteoplug PC 21 (6,4,5,9) Osteoplug PC 21 (6,4,5,11) Osteoplug PC 21 (6,4,5,13) Osteoplug PC 21 (6,4,5,15) Osteoplug PC 21 (6.5,5,9) Osteoplug PC 21 (6.5,5,11) Osteoplug PC 21 (6.5,5,13) Osteoplug PC 21 (6.5,5,15) Osteoplug PC 21 (7,5,9) Osteoplug PC 21 (7,5,11) Osteoplug PC 21 (7,5,13) Osteoplug PC 21 (7,5,15) Osteoplug PC 21 (7.5,5,5,9) Osteoplug PC 21 (7.5,5,5,11) Osteoplug PC 21 (7.5,5,5,13) Osteoplug PC 21 (7.5,5,5,15)	
--	--	--	---	--

			<p>Osteoplug PC 21 (8,6,9) Osteoplug PC 21 (8,6,11) Osteoplug PC 21 (8,6,13) Osteoplug PC 21 (8,6,15) Osteoplug PC 21 (8.5,6.5,9) Osteoplug PC 21 (8.5,6.5,11) Osteoplug PC 21 (8.5,6.5,13) Osteoplug PC 21 (8.5,6.5,15) Osteoplug PC 21 (9,7,9) Osteoplug PC 21 (9,7,11) Osteoplug PC 21 (9,7,13) Osteoplug PC 21 (9,7,15) Osteoplug PC 22 (8,8,4) Osteoplug PC 22 (9,9,4) Osteoplug PC 22 (10,10,4) Osteoplug PC 22 (11,11,4) Osteoplug PC 22 (12,12,4) Osteoplug PC 22 (13,13,4) Osteoplug PC 22 (14,14,4) Osteoplug PC 22 (15,15,4) Osteoplug PC 22 (8,8,5) Osteoplug PC 22 (9,9,5) Osteoplug PC 22 (10,10,5) Osteoplug PC 22 (11,11,5) Osteoplug PC 22 (12,12,5) Osteoplug PC 22 (13,13,5) Osteoplug PC 22 (14,14,5) Osteoplug PC 22 (15,15,5) Osteoplug PC 23 (8,8,4) Osteoplug PC 23 (9,9,4) Osteoplug PC 23 (10,10,4) Osteoplug PC 23 (11,11,4) Osteoplug PC 23 (12,12,4) Osteoplug PC 23 (13,13,4) Osteoplug PC 23 (14,14,4) Osteoplug PC 23 (15,15,4) Osteoplug-C PC 24 (10,10,4) Osteoplug-C PC 24 (11,11,4) Osteoplug-C PC 24 (12,12,4) Osteoplug-C PC 24 (13,13,4) Osteoplug-C PC 24 (14,14,4) Osteoplug-C PC 24 (15,15,4) Osteoplug-C PC 24 (10,10,5) Osteoplug-C PC 24 (11,11,5) Osteoplug-C PC 24 (12,12,5) Osteoplug-C PC 24 (13,13,5) Osteoplug-C PC 24 (14,14,5) Osteoplug-C PC 24 (15,15,5) Osteomesh PC 25 (10,10,10) Osteomesh PC 25 (10,10,15) Osteomesh PC 25 (15,15,15) Osteoplug PC 26 (8,7,4) Osteomesh PC 30 (30,25,0.75,0) Osteomesh PC 30 (30,25,1,0) Osteomesh PC 30 (30,1.25,0) Osteomesh PC 30 (30,1.5,0) Osteomesh PC 30 (30,2,0)</p>	
--	--	--	---	--

			<p>Osteoplug-C PC32 (5,5,5) Osteoplug-C PC32 (6,6,6) Osteoplug-C PC32 (7,7,7) Osteoplug-C PC32 (9,9,9) Osteomesh PC 33 (15,10,4) Osteomesh PC 33 (15,15,4) Osteomesh PC 34 (35,49,1) Osteomesh PC 34 (35,49,1.25) Osteomesh PC 34 (35,49,1.5) Osteomesh PC 34 (35,49,2) Osteomesh PC 35 (44,24,3,9.5) Osteomesh PC 36, PC 50, PC 51, PC 52, PC 53, PC 54, PC 55, PC 60.</p>	
131.	<p>Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore.</p> <p>ELI-00045 5152-P</p>	<p><u>Legal Manufacturer:</u> M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China.</p> <p>FSC China validity 06-07-2025</p> <p>FSC: Germany. Issuance 27-10-2021</p>	<p>Simedice Hydrophobic Aspheric Foldable IOL's</p> <p>Class-C</p> <p>Shelf Life: 5 years</p> <p>Models: SM60AS SM60AS1 SM60AS2 SM60AS3</p>	<p>Deferred for the provision of following:</p> <p>Original documents are missing, copies provided.</p> <p>There is confusion between the Legal manufacturer and manufacturing site. Clarify the connection between Henan <i>Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China</i> and <i>Simedice Biotechnologies Inc., 251 Little Falls, Drive, Wilmington, Delaware 19808, USA.</i></p> <p>No brief description of the device is provided.</p> <p>DoC is missing.</p>
132.	<p>Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore.</p> <p>ELI-00045 5163-P</p>	<p><u>Legal Manufacturer:</u> Simedice Biotechnologies Inc., 251 Little Falls, Drive, Wilmington, Delaware 19808, USA.</p> <p>FSC: Germany issuance 27-10-2021</p>	<p>Simedice (Hydrophobic Aspheric Preloaded Foldable IOL's)</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Models: AS-P22, AS1-P22, AS2-P22, AS3-P22</p>	<p>Deferred for the provision of following:</p> <p>Original documents are missing, copies provided.</p> <p>There is confusion between the Legal manufacturer and manufacturing site. Clarify the connection between Henan <i>Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai</i></p>

				<p><i>Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China and Simedice Biotechnologies Inc., 251 Little Falls, Drive, Wilmington, Delaware 19808, USA.</i></p> <p>No brief description of the device is provided.</p> <p>DoC is missing.</p>
133.	<p>Assuza Incorporation, 17-Rabbani Road, Old Anarkali, Lahore.</p> <p>ELI-00546 5146-P</p>	<p><u>Legal Manufacturer:</u> Guangdong Ecan Medical Co., Ltd. Building No, 222, Xindu Road, Cheng Jiao Street, Cong Hua District, 510920, Guangzhou City, Guangdong Province, People's Republics of China.</p> <p>FSC: China. Validity: 05-08-2025.</p>	<p>ECAN Disposable Latex Foley Urethral Catheters</p> <p>Class-B</p> <p>Shelf Life 5 Years</p> <p>Model 2-way Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr 18Fr, 20Fr, 22Fr, 24Fr</p>	<p>Deferred for the provision of following:</p> <p>The device is already registered for Bio care, Karachi.</p>
134.	<p>Kiswa Cares, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi.</p> <p>ELI-00211 5411-P</p>	<p><u>Legal Manufacturer:</u> Avizor S.A. Avenida de la Innovacion, 2 - 28919, Leganes - Spain.</p> <p>Original FSC: Spain. Issuance: 16-04-2024.</p>	<p>Avizor Lacrifresh Aloe (Wetting and Lubrifying Solution for all types of Contact Lenses)</p> <p>Class-C</p> <p>Shelf Life: 3 Years (3 months after opening)</p>	<p>Disposed off as the case was addressed in 76th MDB meeting.</p>
135.	<p>Kiswa Cares, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi.</p> <p>ELI-00211 5412-P</p>	<p><u>Legal Manufacturer:</u> Avizor S.A. Avenida de la Innovacion, 2 - 28919, Leganes - Spain.</p> <p>Original FSC: Spain. Issuance: 16-04-2024.</p>	<p>Avizor Lacrifresh OCU-DRY 0,2% Multidosis Preservative Free Wetting and Lubrifying Solution for all types of Contact Lenses</p> <p>Class-C</p> <p>Shelf Life: 3 Years (3 months after opening)</p>	<p>Disposed off as the case was addressed in 76th MDB meeting.</p>
136.	<p>Kiswa Cares, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi.</p> <p>ELI-00211 5413-P</p>	<p><u>Legal Manufacturer:</u> Avizor S.A. Avenida de la Innovacion, 2 - 28919, Leganes - Spain.</p> <p>Original FSC: Spain. Issuance: 16-04-2024.</p>	<p>Avizor Lacrifresh Moisture Preservative Free (Wetting and Lubrifying Solution for all types of Contact Lenses)</p> <p>Class-C</p>	<p>Disposed off as the case was addressed in 76th MDB meeting.</p>

			Shelf Life: 3 Years (3 months after opening)	
137.	Kiswa Cares, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi. ELI-00211 5414-P	<u>Legal Manufacturer:</u> Avizor S.A. Avenida de la Innovacion, 2 - 28919, Leganes - Spain. Original FSC: Spain. Issuance: 16-04-2024.	Avizor Lacrifresh OCU-DRY 0,3% Multidosis Preservative Free (Wetting and Lubrifying Solution for all types of Contact Lenses) Class-C Shelf Life: 3 Years (3 months after opening)	Disposed off as the case was addressed in 76 th MDB meeting.
138.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5406-P	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® Malaria Pv/Pf Chip-based Real Time Duplex PCR Test for Plasmodium vivax and Plasmodium falciparum. Class-C Shelf Life-2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
139.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5407-P	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® Salmonella Chip-based Real Time PCR Test for Salmonella spp. Class-C Shelf Life-2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
140.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5408-P	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® Rabies Chip-based Real Time PCR Test for Rabies Virus. Class-C Shelf Life-2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
141.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate,	Truenat® Dengue/Chikungunya Chip-based Real Time Duplex PCR Test for Dengue and	The board referred the case to Authority since the import is from India.

	Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5409-P	Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Chikungunya. Class-C Shelf Life-2 Years Codes as per FSC	
142.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5482-P	Legal Manufacturer: Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® COVID-19 Chip-based Real Time Duplex PCR Test for COVID-19. Class-C Shelf Life-2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
143.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5483-P	Legal Manufacturer: Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® Influenza A/B Chip-based Real Time Duplex PCR Test for Influenza A and Influenza B Virus. Class-C Shelf Life-2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
144.	Lab Diagnostic Systems (SMC) Pvt. Ltd, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. Warehouse: Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan. ELI-00496 5484-P	Legal Manufacturer: Molbio Diagnostics Private Limited, Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa - 403722, India. FSC: India. Issuance date: 06-05-2022.	Truenat® HPV-HR Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16, 31 and 18, 45. Class-C Shelf Life: 2 Years Codes as per FSC	The board referred the case to Authority since the import is from India.
145.	Moazzam Traders, Shop No. 4, Jalil Plaza, Gujranwala. ELI-00775 5490-P	Legal Manufacturer: Hangzhou Rollmed Co., Ltd, Room 913, Yuanmao Mansion. No. 5 wen'er west Rd Hangzhou, Zhejiang Province, P.R of China. FSC: missing	Doctor Check Disposable Infusion Set Class-C Shelf Life: 3 Years Models/ sizes: Not provided	Deferred for the provision of following: Credentials. Stability studies for the claimed shelf life. The provided agreement is copy w/o notarization and

				<p>mentioned the brand Rollmed whereas the firm applied Doctor Check.</p> <p>FSC is missing.</p> <p>The submitted ISO 13485 and CE certificates are w/o notarization.</p> <p>The firm applied on CE certificate but the provided CE certificate is missing the subject device or annex of products.</p> <p>The firm applied in Class-C whereas the subject device falls in Class-B (IIa).</p> <p>Description of device is not provided.</p>
146.	<p>Shafia Enterprises, 2nd Floor, Nigra Center Patiala Ground Link Mcleod Road Lahore.</p> <p>ELI-00766 5638-P Fee-62,000/-</p>	<p><u>Legal Manufacturer:</u> Laboratorios SL SA Curupayti 2611 B1644GDC, San Fernando 1644-Buenos Aires Argentina.</p> <p>FSC: France. Date of Issuance: 04-08-2023.</p>	<p>Subiton Quirurgico RO 40g Subiton Quirurgico RO 20g Subiton Quirurgico Gun 60g (Bone Cement)</p> <p>Class-D</p> <p>Shelf Life: 36 Month</p> <p>Codes: 880000 (RO 40g) 880020 (RO 20g) 880300 (Gun 60g)</p>	<p>Deferred for the provision of following: Form 7A unsigned and unstamped.</p> <p>Firm applied the product as cluster.</p> <p>Scanned documents are provided.</p> <p>DoC is not provided.</p>
147.	<p>Shafia Enterprises, 2nd Floor, Nigra Center Patiala Ground Link Mcleod Road Lahore.</p> <p>ELI-00766 5637-P Fee-62,000/-</p>	<p><u>Legal Manufacturer:</u> Laboratorios SL SA Curupayti 2611 B1644GDC, San Fernando 1644-Buenos Aires Argentina.</p> <p>FSC: France. Date of Issuance: 04-08-2023.</p>	<p>Subiton Quirurgico G 40g Subiton Quirurgico G 20g Subiton Quirurgico GUN G 60g (Bone Cement with Gentamycin)</p> <p>Class-D</p> <p>Shelf Life: 36 Month</p> <p>Codes: 880200 (G 40g) 880220 (G 20g) 880400 (Gun G 60g)</p>	<p>Deferred for the provision of following: Form 7A unsigned and unstamped.</p> <p>Firm applied the product as cluster.</p> <p>Scanned documents are provided.</p> <p>DoC is not provided.</p>
148.	<p>Physiomed Pvt Ltd, 268/3, Kamal Road, Saddar, Rawalpindi.</p> <p>ELI-00199 5639-P 31,000/- fee</p>	<p><u>Legal Manufacturer:</u> Abbot Medical, Costa Rica, Ltda., Edificio #44 Calle 0, Ave.2 Zona Francea El Coyal, Alajuela, Costa Rica, Country: Costa Rica.</p>	<p>Ensite Precision Surface Electrode Kit (Implantable device)</p> <p>Class-D</p> <p>Shelf Life: 18 Month</p>	<p>Deferred for the provision of following:</p> <p>The firm applied in Class-D whereas in DoC the device falls in Class-I. clarification is required</p>

		FSC: USA. Validity: 07-06-2025.	Model: EN0020-P	LOA and ISO 13485 are expired. CE certificate is missing.
149.	Physiomed Pvt Ltd, 268/3, Kamal Road, Saddar, Rawalpindi. ELI-00199 5641-P 31,000/- fee	<u>Legal Manufacturer:</u> Abbot Medical, Costa Rica, Ltda., Edificio #44 Calle 0, Ave.2 Zona Francea El Coyal, Alajuela, Costa Rica, Country: Costa Rica. FSC: USA. Validity: 07-06-2025.	Ensile X EP System Surface Electrode Kit (Implantable device) Class-D Shelf Life: 18 Month Model: ENSITE-SEK-5-01	Deferred for the provision of following: The firm applied in Class-D whereas in DoC the device falls in Class-I. clarification is required LOA and ISO 13485 are expired. CE certificate is missing.
150.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5550-P 62,000/-	<u>Legal Manufacturer</u> Hologic, Inc. 250 Campus Drive, Marlborough, MA 01752, USA. FSC: USA. Validity: 01-02-2025.	Fluent (Fluid Management System) Class-C Service life: 3 years Model: FLT-100 Accessories included in system are Fluent Fluid Management System Pack of six procedure kits (FLT-112, FLT-112S) Fluent fluid management waste bag (FLT-005) Fluent Fluid management tissue trap (FLT-010) 500g weight Fluent Power cord Fluent Basket	Approved The firm will submit clarification reghading Fluent Power cord and Fluent Basket
151.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5552-P 62,000/-	<u>Legal Manufacturer</u> Hologic, Inc. 250 Campus Drive, Marlborough, MA 01752, USA. FSC: USA. Validity: 01-02-2025.	NovaSure Impedance (Controlled Endometrial Ablation System) Class-C Service life: 24 Months Model: NS 2000 NS 2013 NS V5-001, NSV5-003, RFC 2010	Approved. The firm applied in system, so revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.

152.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5656-P 62,000/-	<u>Legal Manufacturer:</u> Abbott Medical St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA FSC: USA. Validity: 11-12-2025.	Merlin™ 2.0 Patient Care System Programmer (Programmer for cardiac implantable devices and their external components) Class-D Shelf Life: N/A Model: Merlin TM 2.0 Patient Care System Programmer Hardware MER3700 Merlin TM 2.0 Patient Care System Programmer Software MER3600 Programmer Telemetry Wand 3630W	Approved. The firm applied in system, so revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.
153.	Intek Corporation (Pvt) Ltd, Office # 501 Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000. ELI-00794 5627-P 50,000/-	<u>Legal Manufacturer:</u> Occlutech Tibbi Urunler San.ve Tic.Ltd.Sti. AHL Serbest Bolgesi, E-5 Blok 34149, Istanbul Turkey. Original FSC: Turkey. Date of Issuance: 01-04-2024 valid for 3 years.	Occlutech PDA Occluder (Patent Ductus Arteriosus Closure Device) Class-D Shelf Life: 5 Year Codes as per FSC	Approved subject to the deregistration of already issued registration certificate. Board acceded to the request of the M/s Intek Corporation, #517, Kohistan Towers, Mehfooz Road, Opposite AFIC Saddar Rawalpindi for deregistration of the product and cancel the product registration and approved the product in the name of M/s Intek Corporation (Pvt) Ltd, Office # 501, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi as the legal manufacturer abroad has changed the authorization of the product from M/s Intek Corporation, Rawalpindi to Intek Corporation (Pvt) Ltd, Rawalpindi.
154.	Intek Corporation (Pvt) Ltd, Office # 501 Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000. ELI-00794 5628-P 62,000/-	<u>Legal Manufacturer:</u> OrbusNeich Medical B.V., Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands. <u>Manufacturing sites:</u> OrbusNeich Medical B.V., Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands.	Teleport (Micro Catheter) Class-D Shelf life: 2 years Codes/ size variants: Netherland FSC 220 -13-2000	Board acceded to the request of the M/s Intek Corporation, #517, Kohistan Towers, Mehfooz Road, Opposite AFIC Saddar Rawalpindi for deregistration of the product and cancel the product registration and approved the product in the

		<p style="text-align: center;">and</p> <p>OrbusNeich Medical Co., Ltd (Shenzhen), No. 1 Jinkui Road, Futian Free Trade Zone, Shenzhen 518038, China.</p> <p>Original FSC: Netherlands. Validity: 31-12-2027. FSC China validity 04-07-2025</p>	<p>220 -15-2000 221 -13-2000 221 -15-2000</p>	<p>name of M/s Intek Corporation (Pvt) Ltd, Office # 501, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi as the legal manufacturer abroad has changed the authorization of the product from M/s Intek Corporation, Rawalpindi to Intek Corporation (Pvt) Ltd, Rawalpindi.</p>
155.	<p>KISWA CARES, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi, Pakistan.</p> <p>ELI-00211 5643-P 62,000/-</p>	<p>Legal Manufacturer: T. Strong Inc. 56, Seobu-ro 346beon-gi, Jinyeong-eup, Gimhae-si, Gyeongsangnam-do Republic of Korea.</p> <p>Original FSC: Korea Date of Issuance: 21-10-2024.</p>	<p>UFIT Dental implant system Abutment, Fixture, kit Class-C</p> <p>Shelf life: not mentioned</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following: Multiple products applied in single application.</p> <p>The trade/brand name in DoC is ABBA System, clarification is required.</p> <p>Multiple codes applied. Submit the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of fee for Family.</p>
156.	<p>KISWA CARES, Office No. 7, Gulf Plaza, Chandni Chowk Rawalpindi, Pakistan.</p> <p>ELI-00211 5644-P 62,000/-</p>	<p>Legal Manufacturer: MD Tech S r l Via F.lli Bandiera NCC 80026 Casoria Italy.</p> <p>FSC: missing</p>	<p>I-STREAM I-STREAM-C I-STREAM-GL I-STREAM-Z I-STREAM-P I-STREAM-X I-STREAM-TORIC I-STREAM-DIFFREX I-STREAM-DIFFREX TRIFOCAL PLUS</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Codes: not provided</p>	<p>Approved subject to the submission of fee required as Multiple products applied in single application. Give your priority in this case and apply separately for others subject to provision of codes/models.</p>
157.	<p>Future D Pakistan, House No. 482, G3, Johar Town, Lahore.</p> <p>ELI-00568 5279-P 62,000/-</p>	<p>Legal Manufacturer: NOVODENT SA, Y-PARC Technopole, Avenue des Sciences 11, CH-1400 Yverdon-les-Bains, Switzerland.</p> <p>FSC: Switzerland. Validity: 21-08-2027.</p>	<p>i-LiNQ Dental Implant System</p> <p>Class-C</p> <p>Shelf Life: 5 Year</p> <p>Codes as per FSC</p>	<p>Approved subject to the submission of fee required as Multiple products applied in single application including fixture, abutments, screw, capping, drill etc. Separate all and submit fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for family.</p>
158.	<p>Cardio Life, House No. 534, Ground Floor Lane</p>	<p>Legal Manufacturer:</p>	<p>GEMED (Central Venous Catheter)</p>	<p>Deferred for the provision of following:</p>

	1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi. ELI-00984 5276-P 62,000/-	Gemed Saglik Urunleri Sanayi Ve Tic. Ltd. Sti, Hurriyet Mah. Adnan Kahveci Cad. No: 27/B 34876 Yakacik Kartal Istanbul / Turkiye. FSC: Turkey. Date of issuance: 12-10-2023 valid for 3 years	Class-D Shelf life: 5 years Codes as per FSC	FQA and DEC are missing. Single, double and triple lumen, all applied in single application. Fee is not as per revised fee notification.
159.	Opti Med, 2nd Floor Hassan Plaza 6A Jail Road, Lahore, 54000-Pakistan ELI: 00501 5549-P 62,000/-	Legal Manufacturer: 1stQ GmbH Konrad-Zuse-Ring 23, 68163 Mannheim, Germany FSC Germany Date of Issue: 02-09-2024	1stQ Intraocular Lens (Hydrophilic Intraocular Lens) Class-C Shelf Life: 5 years Code: Preloaded Basis Z Hydrophilic yellow (B1XB Y0)	Deferred for the provision of following: The applied name is hydrophilic whereas in FSC it is mentioned as hydrophobic, clarification is required.
160.	Shahco Medical (Pvt) Ltd, 729C, Opposite Unique School, Faisal Town, Lahore. ELI-00230 5647-P 62,000/-	Legal Manufacturer: Winner Guilin Latex Co., Ltd, No. 6, Wushan Road, Guilin, China, 541001 FSC: China. Validity: 14-05-2025.	Classic Latex Male Condom Class-C Shelf life: 5 years Models: Smooth W47mm, W49mm, W52mm, W53mm, W55mm, W57mm Non-Smooth W47mm, W49mm, W52mm, W53mm, W55mm, W57mm Smooth with Physically delayed function W52 Non-Smooth with Physically delayed function W52	Deferred for the provision of following: Original documents. CE or Ref country FSC is not provided.
161.	Amir Enterprises, 1st Floor Plaza No. 55, Opp. Security Checkpoint Gate No. 1, Gulshan Abad, Adyala Road, Rawalpindi. ELI-00410 5606-P 62,000/-	Legal Manufacturer: Ophthalmic Experts Ltd, 50 Ripple Road, Barking, Ess, IG11 7PG, United Kingdom. FSC: MHRA Date of Issuance: 07-01-2019.	ISIGHT Intraocular Lens PMMA Polymethylmethacrylate Class-C Shelf life: 5 years Model: PCC13065 CRO	Deferred for the provision of following: Original documents. The applied brand is not mentioned in LOA and FSC. The brand name in FSC is Xpert.
162.	Amir Enterprises, 1st Floor Plaza No. 55, Opp. Security Checkpoint Gate No. 1, Gulshan Abad, Adyala Road, Rawalpindi.	Legal Manufacturer: Ophthalmic Experts Ltd, 50 Ripple Road, Barking, Ess, IG11 7PG, United Kingdom. FSC: MHRA	TRUFOCUS Hydrophilic Acrylic Clear Foldable Intraocular Lens Class-C	Deferred for the provision of following: Original documents. The applied brand is not

	ELI-00410 5604-P 62,000/-	Date of Issuance: 07-01-2019.	Shelf life: 5 years Model: HCL1130606CRA	mentioned in LOA and FSC. The brand name in FSC is I-Xpert, BIOL.
163.	Amir Enterprises, 1st Floor Plaza No. 55, Opp. Security Checkpoint Gate No. 1, Gulshan Abad, Adyala Road, Rawalpindi. ELI-00410 5605-P 62,000/-	Legal Manufacturer: Ophthalmic Experts Ltd, 50 Ripple Road, Barking, Ess, IG11 7PG, United Kingdom. FSC: MHRA Date of Issuance: 07-01-2019.	Occuvue Hydrophobic preloaded Intraocular Lens Class-C Shelf life: 5 years Model: FLL112560 NYA	Deferred for the provision of following: Original documents. The applied brand is not mentioned in LOA and FSC. The brand name in FSC is Mestro, BIOL.
164.	M. Yousaf & Co, 79-M Block, Gulberg-III, Lahore. ELI-00302 5473-P 62,000/-	Legal Manufacturer: Grena Biomed Ltd, Chelsea House, Chelsea Street, Nottingham, Nottinghamshire, NG7 7HP, United Kingdom. Original FSC: UK. Validity: 27-05-2025.	4Seal Hemostatic Powder Class-C Shelf life: 36 Months Codes: 1203-HP001 (1g) 1203-HP003 (3g) 1203-HP005 (5g)	Deferred for the provision of following: Form-7A is unsigned and no information is provided in relevant section. LOA expired on 14 th Jan, 2025. ISO 13485 is also expired.
165.	M. Yousaf & Co, 79-M Block, Gulberg-III, Lahore. ELI-00302 5474-P 62,000/-	Legal Manufacturer: Grena Biomed Ltd, Chelsea House, Chelsea Street, Nottingham, Nottinghamshire, NG7 7HP, United Kingdom. Original FSC: UK. Validity: 27-05-2025.	NE'X Glue Surgical Adhesive Class-C Shelf life: 36 Months Codes: 0206-NX10 (10ml) 0206-NX2 (2ml) 0206-NX5 (5ml)	Deferred for the provision of following: Form-7A is unsigned and no information is provided in relevant section. LOA expired on 14 th Jan, 2025. ISO 13485 is also expired.
166.	Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3, Rawalpindi. ELI-00984 5465-P 62,000/-	Legal Manufacturer: Delta Med S.P.A, Via Guido Rossa 20, 46019 Viadana (MN) - Italy. Original FSC: Italy. Date of Issuance: 12-08-2024.	Delta Med Arterial Cannula Class-D Shelf Life: 5 Year Codes: 393083103122 (3Fr x 8cm) 394103103222 (4Fr x 10cm)	Deferred for the provision of following: Firm applied in Class-D but no DEC is provided. DoC is missing. Shelf life studies and manufacturing details are missing. Essential principle checklist is missing. Firm applied in family. Revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
167.	Cor-Med, 2nd Floor,	Legal Manufacturer:	EasyEndo FLEX	Deferred for the

	38/62, Bank Road, Saddar, Rawalpindi. ELI-00226 5478-P 62,000/-	Ezisurg Medical Co., Ltd, No. 399, Miaoqiao Rd., Pudong New District, 201315 Shanghai, P.R. China. FSC: China. Validity: 03-02-2025.	Loading Unit Class-C Shelf Life: 3 Year Codes as per FSC	provision of following: Form-7A unsigned. Subject device is missing in FSC. Original Documents are missing. Shelf life studies and manufacturing details are missing. Essential principle checklist is missing.
168.	Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore. ELI-00133 5410-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin, People's Republic of China. FSC: China. Issuance: 13-05-2024 valid for 2 years.	TPRI Disposable Extra Corporeal Circuit Tube - Cardioplegia Delivery System Class-D Shelf Life: 3 Year Codes as per FSC	Deferred for the provision of following: Firm applied in Class-D but no DEC is provided. In DoC it is mentioned as IIA Class product. Applied on CE basis and in extension notification the mentioned Class is IIA. 35 codes/sizes applied, revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for family.
169.	Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore. ELI-00133 5130-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin, People's Republic of China. FSC: China. Issuance: 13-05-2024 valid for 2 years.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Adult) Class-D Shelf Life: 3 Year Codes as per FSC	Deferred for the provision of following: Firm applied in Class-D but no DEC is provided. In DoC it is mentioned as IIA Class product. Applied on CE basis and in extension notification the mentioned Class is IIA. Pediatric, infant and baby type are also applied, revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for family.
170.	Treu-Dynamic International (Pvt) Ltd, Office No. C-206, 2nd Floor, City Towers, Main Boulevard, Gulberg, Lahore.	<u>Legal Manufacturer:</u> Matrix Surgical Holdings, LLC dba Matrix Surgical USA 98 Bledsoe Road Newnan, Georgia 30265 USA.	OMNIPORE® Surgical Implants Class-C Shelf Life 5 years	Deferred for the provision of following: The firm applied in family more than 20 different implants are applied in single application.

	ELI-00175 5260-P 50,000/-	FSC: USA. Validity: 14-02-2025.	Codes as per FSC	The firm is required to give priority in this case and submit separate application for each type depending upon the location where implant is to be applied and revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024.
171.	UniCore Surgicals, Office No. 301 Plaza # 28, 3rd Floor, Block C, Bahria Orchard Phase 2, Main Boulevard, Lahore. ELI-01223 5362-P 25,000/-	Legal Manufacturer: SC MEDIKAL URUNLER SANAYI VE TICARET LTD. STI. Pancar Mah, Gol Sokak No. 52/A, Torbali, Izmir, Turkey. FSC: Ankara Turkey. Date of Issuance: 09-03-2022 valid for 3 years.	Evoss Dental Implants (Body, metric screw, suprastructure) Dental Implants Device Class-C Shelf Life: 3 Year Codes as per FSC	Deferred for the provision of following: The firm applied multiple implants in single application. Some accessories mentioned falls in Class-A and B. The firm is required to apply separately for implants depending upon the location. Fee submitted for Class-B. Revised the fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024
172.	A One Traders, Makkah Tower, 3rd Floor Room, No. 303, Namak Mandi Peshawar, ELI: 00480 4640-Kp	Legal Manufacturing: M/s Anhui Kangning Industrial (Group) Co., Ltd, South of Latitude Three Way, West of Longitude Four-way Economicdevelopment Zone Tianchang City, Anhui,China FSC: China Date of Issue: 25/08/2023 valid for 2 years	Safe+ CATGUT (chromic Absorbable suture) Class-D Shelf life: 5 years Codes & Sizes: As per FSC	Deferred for the provision of following: CE or Ref country certificate is not provided for the subject device.
173.	Zaidi Traders, House No. 263, F Block Satellite Town Rawalpindi. ELI-00328 5016-P	Legal Manufacturer: Medico (Huaian) Co. Ltd, No. 9, South Guangzhou Road, Huaian, 223000 Jiangsu, China. FSC: China. Validity: 11-07-2025.	NICRYL-NMC Vicryl Polygactin Absorbable Surgical Suture with needle) Class-B Shelf Life: 5 Year Codes: Given in technical documents	Deferred for the provision of following: The FSC copy provided mentioned the general term of surgical suture, no types and category is mentioned. The subject device falls in Class-D whereas the firm applied in Class-B. The generic of device is not clear. No legal documents are provided, only copies of

				<p>LOA and Chinese's FSC is provided.</p> <p>ISO 13485, FQA and DEC are missing.</p> <p>FSC of Reference country is not provided.</p> <p>Stability studies and manufacturing details are missing.</p> <p>Essential Principle checklist is missing.</p> <p>DoC is not provided.</p>
174.	<p>Zaidi Traders, House No. 263, F Block Satellite Town Rawalpindi.</p> <p>ELI-00328 5017-P</p>	<p><u>Legal Manufacturer:</u> Medico (Huaian) Co. Ltd, No. 9, South Guangzhou Road, Huaian, 223000 Jiangsu, China.</p> <p>FSC: China. Validity: 11-07-2025.</p>	<p>NORSIL-NMC (Black Braided Silk Non-Absorbable Surgical suture with Needle)</p> <p>Class-B</p> <p>Shelf Life: 5 Year</p> <p>Codes: Given in technical documents</p>	<p>Deferred for the provision of following:</p> <p>The FSC copy provided mentioned the general term of surgical suture, no types and category is mentioned.</p> <p>The subject device falls in Class-D whereas the firm applied in Class-B.</p> <p>The generic of device is not clear.</p> <p>No legal documents are provided, only copies of LOA and Chinese's FSC is provided.</p> <p>ISO 13485, FQA and DEC are missing.</p> <p>FSC of Reference country is not provided.</p> <p>Stability studies and manufacturing details are missing.</p> <p>Essential Principle checklist is missing.</p> <p>DoC is not provided.</p>
175.	<p>Zaidi Traders, House No. 263, F Block Satellite Town Rawalpindi.</p> <p>ELI-00328 5018-P</p>	<p><u>Legal Manufacturer:</u> Medico (Huaian) Co. Ltd, No. 9, South Guangzhou Road, Huaian, 223000 Jiangsu, China.</p> <p>FSC: China.</p>	<p>NORGUT-NMC (Polyglycolic Monofilament Surgical Suture with Needle)</p> <p>Class-B</p> <p>Shelf Life: 5 Year</p>	<p>Deferred for the provision of following:</p> <p>The FSC copy provided mentioned the general term of surgical suture, no types and category is mentioned.</p>

		Validity: 11-07-2025.	Codes: Given in technical documents	<p>The subject device falls in Class-D whereas the firm applied in Class-B.</p> <p>The generic of device is not clear.</p> <p>No legal documents are provided, only copies of LOA and Chinese's FSC is provided.</p> <p>ISO 13485, FQA and DEC are missing.</p> <p>FSC of Reference country is not provided.</p> <p>Stability studies and manufacturing details are missing.</p> <p>Essential Principle checklist is missing.</p> <p>DoC is not provided.</p>
176.	Zaidi Traders, House No. 263, F Block Satellite Town Rawalpindi. ELI-00328 5030-P	<u>Legal Manufacturer:</u> Medico (Huaian) Co. Ltd, No. 9, South Guangzhou Road, Huaian, 223000 Jiangsu, China. FSC: China. Validity: 11-07-2025.	NORLENE-NMC (Polypropylene Non-Absorbable Surgical Sterile Suture with Needle) Class-B Shelf Life: 5 Year Codes: Given in technical documents	Deferred for the provision of following: The FSC copy provided mentioned the general term of surgical suture, no types and category is mentioned. The subject device falls in Class-D whereas the firm applied in Class-B. The generic of device is not clear. No legal documents are provided, only copies of LOA and Chinese's FSC is provided. ISO 13485, FQA and DEC are missing. FSC of Reference country is not provided. Stability studies and manufacturing details are missing.

				Essential Principle checklist is missing. DoC is not provided.
177.	Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi. (ELI-00249) 3649-C 50,000/-	<u>Legal Manufacturer:</u> Shanghai Heartcare Medical Technology Corporation Ltd., 01st & 03rd Floor, Building # 38, #356, Zhengbo Road, LIN-CANG Special Area, China. FSC China validity 14-11-2023	HEARTCARE CAPTOR Thrombectomy Device Class-D Shelf life: 5 years Codes: HC*TDE-4020 HC*TDE-4040 HC*TDE-6020 HC*TDE-6030	Deferred for the provision of following: The firm applied in Class-D but DEC is not provided. LOA, FSC, ISO 13485 all are expired. DoC is missing. FSC of any reference country/CE documents are not provided. CAPTOR Thrombectomy Device is mentioned in FSC of China. Fee submission is not as per revised
178.	Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi. (ELI-00249) 3734-C 50,000/-	<u>Legal Manufacturer:</u> Shanghai Heartcare Medical Technology Corporation Ltd., 01st & 03rd Floor, Building # 38, #356, Zhengbo Road, LIN-CANG Special Area, China. FSC China validity 14-11-2023	FullBlock Balloon Guiding Catheter Class-D Shelf life: 2 years Codes: SM*BGC-S80 SM*BGC-S95 SM*BGC-S+80 SM*BGC-S+95	Deferred for the provision of following: The firm applied in Class-D but DEC is not provided. LOA, FSC, ISO 13485 all are expired. DoC is missing. FSC of any reference country/CE documents are not provided. FullBlock Brand mentioned in LOA and FSC. Fee submission is not as per revised
179.	Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi. (ELI-00249) 3094-C 50,000/-	<u>Legal Manufacturer:</u> Shanghai Heartcare Medical Technology Corporation Ltd., 01st & 03rd Floor, Building # 38, #356, Zhengbo Road, LIN-CANG Special Area, China. FSC China validity 14-11-2023	Extraflex Distal Access Catheter Class-D Shelf life: 2 years Codes as per FSC	Deferred for the provision of following: The firm applied in Class-D but DEC is not provided. LOA, FSC, ISO 13485 all are expired. DoC is missing.

				FSC of any reference country/CE documents are not provided. Extraflex Brand mentioned in LOA and FSC. Fee submission is not as per revised
180.	J.F International, 4th Floor, 10-C, 6th Sunset Commercial Lane, Phase 2 Ext, DHA, Karachi. (ELI-00246) 3848-C 75,000/-	<u>Legal Manufacturer:</u> Longfian Scitech Co., Ltd. 2F 3F, East Section, Building 121, Power Valley, pioneer Park, No. 369 Huiyang Street, 071051, Boading, Hebei Province China. FSC China validity 04-07-2026	Longfian Medical Oxygen Concentrator Class-C Shelf life: 5 years Models: JAY-5B W JAY-10 JAY-10D	Deferred for clarification since the same device Longfian Medical Oxygen Concentrator having model, no JAY-5 is registered for Nasir Brothers in 17 th meeting of MDB with the same Brand name from the same manufacturer.
181.	Safemed Technologies Office address: Apt;3 2 nd Floor, Retoon Palaza, Sector G-15/4, Islamabad. Warehouse address: Apt;3 2 nd Floor, Retoon Palaza, Sector G-15/4, Islamabad. ELI 00296	<u>Legal Manufacturer:</u> Epic International (Thailand) Co. Ltd. 500/73 Moo2, Tasit, Pluakdaeng Rayong Thailand 21140 Date of R&I 10-05-2024 Last reply submitted: <u>FSC:</u> Country of Origin Issued on: 28-09-2022 <u>FSC:</u> FSC of Reference Country TGA, Australia DV-2022-MC-18887-1 <u>LOA</u> Validity: 31-12-2026 <u>EC Certificate</u> Validity: 18-05-2028 <u>ISO 13485</u> Validity: 12-01-2026	SmarteZ Pump Elastomeric Pump (Soft Shell & Hard Shell) Class C Shelf Life: 35 months Codes/Sizes: <ul style="list-style-type: none">• SMARTeZ Pump – Long infusion Time• SMARTeZ Pump – Short infusion Time• SMARTeZ Pump – Chemotherapy• SMARTeZ Pump – Chemo CS	Approved subject to submission of fee for SMARTeZ Pump – Chemotherapy SMARTeZ Pump – Chemo CS
182.	M/s.Innovate Medical Technologies Pvt Ltd.	<u>Legal Manufacturer:</u> M/s Coloplast A/S Hølstedam	Biatain Alginate Ag (Alginate Dressing with Silver)	Approved

	Plot # C-4, Block #7, Gulshan e Iqbal Karachi ELI- 00352	1, 3050 Humble Baek Denmark Tel: + 4549111111 Website: www.coloplast.com LOA Validity: 19/02/2027 FSC: Denmark Validity: Valid Until 7-August-2025 ISO-13485 Validity: Valid Until 08-09-2027 CE Certificate: Valid Until 26-August-2026	sodium hydrogen zirconium phosphate) Class C Shelf Life: 3 Years Codes / Sizes <table border="1"> <tr><td>(10x10cm)</td></tr> <tr><td>(15x15cm)</td></tr> <tr><td>(20x30cm)</td></tr> </table>	(10x10cm)	(15x15cm)	(20x30cm)	
(10x10cm)							
(15x15cm)							
(20x30cm)							
183.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286)	Legal Manufacturer: KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Atakent Mah. 221 Sk. No.: 3A Rota Office, A Blok Kat:14 D:82-83, 34200 Kucukcemece, Turkey Manufacturing Site: KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey FSC Turkey issuance 27-03- 2024 valid for 3 years.	Onesept PA Wancare Wancare Onesept PA Paracetic Acid 2350 PPM+Activator Class: C Shelf Life: 2 Years Codes as per FSC Fee 62000/-	Approved subject to submission of valid CE marked document and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.			
184.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286)	Legal Manufacturer: KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Atakent Mah. 221 Sk. No.: 3A Rota Office, A Blok Kat:14 D:82-83, 34200 Kucukcemece, Turkey Manufacturing Site: KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey FSC Turkey issuance 27-03- 2024 valid for 3 years.	One Spray Wancare Alcohol-Based Fast Acting Spray Disinfectant for Medical Equipment Class: B Shelf Life: 2 Years Codes as per FSC Fee 31000/-	Approved subject to submission of valid CE marked document and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.			

185.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286)	<u>Legal Manufacturer:</u> KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Atakent Mah. 221 Sk. No.: 3A Rota Office, A Blok Kat:14 D:82-83, 34200 Kucukcemece, Turkey <u>Manufacturing Site:</u> KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey FSC Turkey issuance 27-03-2024 valid for 3 years.	OneSurface Wipes Wancare Alcohol-Free Fast Acting Disinfectant Wipes for Medical Devices Class: B Shelf Life: 2 Years Fee 31000/- Codes as per FSC	Approved subject to submission of valid CE marked document and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
186.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286)	<u>Legal Manufacturer:</u> KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Atakent Mah. 221 Sk. No.: 3A Rota Office, A Blok Kat:14 D:82-83, 34200 Kucukcemece, Turkey <u>Manufacturing Site:</u> KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI., Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey FSC Turkey issuance 27-03-2024 valid for 3 years.	OneSpray Wipes Wancare Wancare OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices Class: B Shelf Life: 2 Years Codes as per FSC Fee 31000/-	Approved subject to submission of valid CE marked document and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
187.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti., Battalgazi Mah. Sark Cad. Aytop, I Blok No: 14 Sultanbeyli-Istanbul – Turkey. FSC 06-03-2024 valid for 3 years.	Biorad Rayd Guanide Medical Instruments And Endoscopes Disinfectant Class: C Shelf Life: 3 Years Codes as per FSC Fee 62000/-	Approved subject to submission of valid CE marked document and revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
188.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort Care Colling Gel Patch Class: A Shelf Life: 5 Years Codes as per FSC Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life.

				EPSP checklist. DoC is missing. FSC/CE marked document
189.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Jiangsu Shuangsheng Medical Appliance Co., Ltd No. 12, Dandong industrial Zone, Lingkou Town, Danyang city, Jiangsu Province, China FSC China valid till 17-04- 2023	Comfort Care Anti Decubitus Mattress Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
190.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Jiangsu Shuangsheng Medical Appliance Co., Ltd No. 12, Dandong industrial Zone, Lingkou Town, Danyang city, Jiangsu Province, China FSC China valid till 17-04- 2023	Comfort Care Oxygen Concentrator Class: B Shelf Life: 5 Years Fee 25000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
191.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Jiangsu Shuangsheng Medical Appliance Co., Ltd No. 12, Dandong industrial Zone, Lingkou Town, Danyang city, Jiangsu Province, China FSC China valid till 17-04- 2023	Comfort Care Nebulizer Class: B Shelf Life: 5 Years Fee 25000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
192.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-	<u>Legal Manufacturer:</u> Jiangsu Shuangsheng Medical Appliance Co., Ltd No. 12, Dandong industrial	Comfor Care Portable Phlegm Suction Unit Class: B	Deferred for the provision of following:

	Iqbal, Karachi (ELI-00286) 19-12-2022	Zone, Lingkou Town, Danyang city, Jiangsu Province, China FSC China valid till 17-04- 2023	Shelf Life: 5 Years Fee 25000/-	Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
193.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort care surgical Tape Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
194.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort care wound dressing Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
195.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e- Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort Care First Aid Bandage Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist.

				DoC is missing. FSC/CE marked document
196.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort Care Zinc Oxide Plaster Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
197.	Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) 19-12-2022	<u>Legal Manufacturer:</u> Zhejiang Bangali Medical Products Co., Ltd No. 118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province China	Comfort Care Corn Plaster Class: A Shelf Life: 5 Years Fee 5000/-	Deferred for the provision of following: Credentials, LOA, FSC, ISO 13485, FQA all documents are expired and copies. Stability studies for the claimed shelf life. EPSP checklist. DoC is missing. FSC/CE marked document
198.	Cardiac Care 848-C Shadman-1 Lahore, Pakistan. ELI-00070 62,000/-	<u>Legal Manufacturer:</u> Tisgenx, Inc. 15615 Alton Parkway, Suite 450, Irvine, CA 92618 (949) 670-0403, USA https://tisgenx.com/ <u>FSC US FDA validity</u> <u>24-03-2026</u>	Invengenx® Bovine Pericardial Tissue Patch Class-D Shelf life: 3 years Codes as per FSC	Approved subject to submission of revised fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of fee for Family.
199.	Cor-Med, 2TM Floor, 38/62, Bank Road, Saddar, Rawalpindi. ELI-00226 5395-P 25-10-2025 31,000/-	<u>Legal Manufacturer:</u> DeRoyal Industries, Inc 200 DeBusk Lane Powell, Tennessee 37849, USA. <u>Manufacturing site:</u> DeRoyal industries, Inc, 1703 Highway 33S New Tazewell, TN, USA.	DeRoyal Safeliner Suction Canister Class-C Shelf Life: 5 Year Codes: 71-6510 (1000cc) 71-6515 (1500cc)	Approved in Class-B

		Original FSC: USA. Validity: 04-08-2026.	71-6530 (3000cc)	
200.	Safeway Systems Pakistan, <u>New Address:</u> 1st Floor Ayub Plaza, Misrial Road, near Bhata Chowk, Rawalpindi. <u>Old Address:</u> Office No. 04, 2nd Floor Amna Shopping Plaza Chur Chowk Rawalpindi. ELI-00308 5622-P 62,000/-	<u>Legal Manufacturer:</u> Shunmei Medical Co., Ltd R301 and R401, Building B, Shenchanggang Investment Co., Ltd., No. 8, Jinlong First Road, Baolong Community, Baolong Street, Longgang District, Shenzhen, 518116 Guangdong, P.R. China. Original FSC: China. Validity: 27-02-2025.	Shun Monitor Central Venous Catheter Kit, Single Class-D <u>Shelf Life:</u> 3 years Codes as per FSC	Approved subject to submission of form-7A and fee for each type as per New S.R.O 1324 (I)/2024 dated 30-08-2024 of fee.
201.	M/s The Vision Venture Company Flat No.01, 2 nd Floor, Abbas Tower, Near Taqwa Masjid, Khyber Super Market, Peshawar Cantt. Peshawar ELI-01281 62,000/-	<u>Legal Manufacturer:</u> M/s META BIOMED CO., LTD. Republic of Korea. 270, Osogsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea. FSC Korea issuance 11-01-2024	Metapex Plus (Calcium Hydroxide Temporary Filling Material) Class-D Shelf Life: 2 Years Codes as per FSC Metapex Plus 4.4 Metapex Plus 2.2 Metapex Plus 0.8	Approved in Class-B
202.	S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan. ELI-00849 5454-P 50,000/-	<u>Legal Manufacturer:</u> <u>Manufacturer:</u> Jiangsu Webest Medical Products Co., Ltd, Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China. <u>Exporter:</u> Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China. FSC: China. Date of Issuance: 05-07- 2024. Valid for 2 years	Secure I.V Cannula Class-B Shelf Life: 5 Year Sizes as per FSC	Deferred for the provision of following: Three types of cannula applied, Pen type, with wing and with injection port. Separate each type. No linkup letter is provided between Jiangsu Webest Medical Products Co., Ltd, No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China and Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China.

				FSC of any reference country or CE marked document is not provided.
203.	S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan. ELI-00849 5456-P 50,000/-	<u>Legal Manufacturer:</u> <u>Manufacturer:</u> Jiangsu Webest Medical Products Co., Ltd, Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China. <u>Exporter:</u> Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China. FSC: China. Date of Issuance: 05-07-2024. Valid for 2 years	Secure Latex Surgical Gloves Class-B Shelf life: 5 years Sizes as per FSC.	Deferred for the provision of following: Powdered and Powdered free both are applied. Separate each type. No linkup letter is provided between Jiangsu Webest Medical Products Co., Ltd, No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China and Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China. FSC of any reference country or CE marked document is not provided.
204.	SM Impex. Address of Importer Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah-e-Liaquat, Karachi, Pakistan. ELI-00473	Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. (Manufacturing site) M/s Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey. FSC: Turkey Validity: Valid 01.03.2027 FSC MHRA: 27/02/2025 LOA Validity: 21.05.2027 ISO-13485 Validity: 04.07.2026 CE Validity: 26. 09. 2024 (extension letter attached)	Geotek Tumor Marking Needle Class D Shelf Life: 5 Years Codes / Sizes Model: GTM1810, GTM1815, GTM1820, GTM1825, GTM1910, GTM1915, GTM1920, GTM1925, GTP1410, GTP1412, GTP1415, GTP1610, GTP1615, GTP1810, GTP1812, GTP1815, GTP1820, GTP1825, GTP1910, GTP1915, GTP1920, GTP1925	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for Family.
205.	SM Impex. Address of Importer Office No. B-309 3rd Floor, New Chali Trade	Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. (Manufacturing site)	Geotek Ureteral Stent Sets Class C	Approved subject to submission of fee as per New S.R.O 1324 (I)/2024 dated 30-08-2024 for

	Centre, Shahrah-e-Liaquat, Karachi, Pakistan. ELI-00473	M/s Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey. FSC: Turkey Validity: Valid 01.03.2027 FSC MHRA: 27/02/2025 LOA Validity: 21.05.2027 ISO-13485 Validity: 04.07.2026 CE Validity: 26. 09. 2024 (extension letter attached)	Shelf Life: 5 Years Codes / Sizes Model: VDJP37-BEO, VDJP37-OEC, VDJP47-BEO, VDJP47-OEC, VDJP06-BEO, VDJP06-OEC, GDJ316-BEO, GDJ416-BEO, VDJ47-BEO, VDJ47-OEC, VDJ48-BEO, VDJ48-OEC, VDJ06-BEO, VDJ06-OEC, GUC370-OE, GUC370-CE, GUC470-OE, GUC470-CE, GUC570-OE, GUC570-CE, GUC670-OE, GUC670-CE,	Family.
206.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, Romania. FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid up to 26-05-2024 ISO 13485 validity date: 11-04-2025 CE Certificate (FQA) validity date 01-11-2023 LOA valid upto 31-12-2026	Biosilk Suture Silk Suture Multifilament Natural Coated Non-absorbable. Class: C Shelf life: 5-years Codes as per FSC: BX 5xxxx W-loop BL-black B-blue Fee vide slip No. 0735547274 : 62000/-	Approved. The firm shall submit valid Free Sale Certificate.
207.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, Romania. FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024 ISO 13485 validity date: 11-04-2025	Bioster Suture Polyester Suture Multifilament Synthetic Coated Non-absorbable Class: C Shelf life: 5-years Codes as per FSC: BX 4xxxx, BX 4xxxxW W-white Fee vide slip No.30530288 : 62000/-	Approved. The firm shall submit valid Free Sale Certificate.

		CE Certificate (FQA) validity date 01-11-2023 LOA valid up to 31-12-2026		
208.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u> FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024 ISO 13485 validity date: 11-04-2025 CE Certificate (FQA) validity date 01-11-2023 LOA valid up to 31-12-2026	BIONIL MONOx SUTURE Polyamide (Tip 6.6) Suture Monofilament Synthetic Non-absorbable Shelf Life 5 Year Class: C Codes as per FSC: BX 7xxxx, BX W7xxxx, BX 7xxxxBL, BX 7xxxxB, W-loop BL-black B-blue Fee vide slip No.30094284: 62000/-	Approved. The firm shall submit valid Free Sale Certificate.
209.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u> FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024 ISO 13485 validity date: 11-04-2025 CE Certificate (FQA) validity date 01-11-2023 LOA valid up to 31-12-2026	Bionil Multix Suture Polyamide (Tip 6.6) Suture Multifilament Synthetic Coated Non-absorbable Shelf Life 5 Year Class: C Codes as per FSC: BX 6xxxx, BX W6xxxx, BX 6xxxxBL, BX 6xxxxB, W-loop BL-black B-blue Fee vide slip No.653323542715: 62000/-	Approved. The firm shall submit valid Free Sale Certificate.
210.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u> FSC:	Dacril Suture Polyglycolic Acid Multifilament Coated Absorbable Shelf Life 3 Year Class: D Codes as per FSC:	Approved. The firm shall submit valid Free Sale Certificate.

		<p>Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024</p> <p>ISO 13485 validity date: 11-04-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023. Design Examination CE Certificate validity date 01-11-2023</p> <p>LOA valid up to 31-12-2026</p>	<p>BX 1xxxx, BX W1xxxx, BX 1xxxxU W-loop U-undyed Fee vide slip No.6680705104: 62000/-</p>	
211.	<p>OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u></p> <p>FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024</p> <p>ISO 13485 validity date: 11-04-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023. Design Examination CE Certificate validity date 01-11-2023</p> <p>LOA valid up to 31-12-2026</p>	<p>DACRIL RAPID SUTURE Polyglycolic Acid Multifilament coated Fast Absorbable</p> <p>Shelf Life 3 Year Class: D</p> <p>Codes as per FSC: BX 8xxxx, Fee vide slip No.5572786136: 62000/-</p>	Approved. The firm shall submit valid Free Sale Certificate.
212.	<p>OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u></p> <p>FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024</p>	<p>DACRIL 910 SUTURE Polyglycolic Acid Multifilament coated Fast Absorbable</p> <p>Shelf Life 3 Year Class: D</p> <p>Codes as per FSC: BX-PG 1xxxx, BX-PG W1xxxx, BX-PG 1xxxxU W-loop U-undyed Fee vide slip No. 830554693:</p>	Approved. The firm shall submit valid Free Sale Certificate.

		<p>ISO 13485 validity date: 11-04-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023.</p> <p>Design Examination CE Certificate validity date 01-11-2023</p> <p>LOA valid up to 31-12-2026</p>	62000/-	
213.	<p>OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, Romania.</p> <p>FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024</p> <p>ISO 13485 validity date: 11-04-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023.</p> <p>Design Examination CE Certificate validity date 01-11-2023</p> <p>LOA valid up to 31-12-2026</p>	<p>MONOx SUTURE Poly (Glycolide-co-Caprolactone) (75/25) Monofilament Absorbable</p> <p>Shelf Life 3 Year Class: D</p> <p>Codes as per FSC: BX 9xxxx, BX W9xxxx, BX 9xxxxU, W-loop U-undyed</p> <p>Fee vide slip No.231953424617: 62000/-</p>	Approved. The firm shall submit valid Free Sale Certificate.
214.	<p>OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, Romania.</p> <p>FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024</p> <p>ISO 13485 validity date: 11-04-2025</p>	<p>PDO-x SUTURE Polydioxanone Monofilament Absorbable</p> <p>Shelf Life 3 Year Class: D</p> <p>Codes as per FSC: BX 2xxxx, BX W2xxxx, W-loop</p> <p>Fee vide slip No.09561397: 62000/-</p>	Approved. The firm shall submit valid Free Sale Certificate.

		CE Certificate (FQA) validity date 01-11-2023. Design Examination CE Certificate validity date 01-11-2023 LOA valid up to 31-12-2026		
215.	OptimX Pharma, 2nd Floor, 7-A, Queens Road, Lahore. ELI-00945	<u>Legal Manufacturer & Manufacturing Site:</u> Biosintex S.R.L. 4 Vladiceasca Street, 077168 Snagov, <u>Romania.</u> FSC: Free Sale Certificate (FSC) issued by Mo Health, National Agency for Medicines & Medical Devices of Romania valid upto 26-05-2024 ISO 13485 validity date: 11-04-2025 CE Certificate (FQA) validity date 01-11-2023. Design Examination CE Certificate validity date 01-11-2023 LOA valid up to 31-12-2026	BIOPRO SUTURE Polypropylene Monofilament Non-absorbable Shelf Life 3 Year Class: D Codes as per FSC: BX 3xxxx, BX W3xxxx, W-loop BX 3xxxxW, W-white BX-CV3 abxxxxc, BX-CV3 cardio Suture. BL-black B-blue a-T or R needle e point b-E or H needle curvature Fee vide slip No.14312499: 62000/-	Approved. The firm shall submit valid Free Sale Certificate.
216.	M/s Raffay Associates, Office NO, 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi ELI: 00021	<u>Legal Manufacturer & Manufacturing Site:</u> Taewoong Medical Co., Ltd 14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, <u>South Korea.</u> <u>FSC Korea issued on 23/01/2019</u> <u>FSC UK MHRA issued on 09/07/2018</u> FSC: Free Sale Certificate (FSC) No.20230017079 issued by Mo Food and Drug Safety, Korea issued on 08-02-2023. Statement (wherein Free Sale of the product is indicated) issued by Mo Health, Welfare and Sport, the Netherlands valid upto 25-03-2024.	Niti-S Biliary Covered Stent (Bumpy) Biliary Covered Stent Shelf Life 3 Year Class: C Codes as per FSC: Niti-S Biliary Covered Stent (BK0604CW2, BK0606CW2, BK0608CW2, BK0804CW2, BK0806CW2, BK0808CW2, BK1006CW2, BK1008CW2) Fee vide slip No. 331676845: 62000/-	Approved. The firm shall submit valid Free Sale Certificate of the reference country or valid CE Certificate (FQA)

		<p>ISO 13485 validity date: 25-03-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023.</p> <p>Design Examination CE Certificate validity date 25-03-2024</p> <p>LOA issued on 15-01-2019</p>		
217.	M/s Raffay Associates, Office NO, 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi ELI: 00021	<p><u>Legal Manufacturer & Manufacturing Site:</u> Taewoong Medical Co., Ltd 14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, <u>South Korea.</u></p> <p><u>FSC Korea issued on 23/01/2019</u> <u>FSC UK MHRA issued on 09/07/2018</u></p> <p>FSC: Free Sale Certificate (FSC) No.20230017078 issued by Mo Food and Drug Safety, Korea issued on 08-02-2023.</p> <p>Statement (wherein Free Sale of the product is indicated) issued by Mo Health, Welfare and Sport, the Netherlands valid upto 25-03-2024.</p> <p>ISO 13485 validity date: 25-03-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023.</p> <p>Design Examination CE Certificate validity date 25-03-2024</p> <p>LOA issued on 15-01-2019</p>	<p>Niti-S Biliary Covered Stent (Giobor) Biliary Covered Stent</p> <p>Shelf Life 3 Year Class: C</p> <p>Codes as per FSC: (BS0806FP, BS0808FP, BS0810FP, BS1006FP, BS1008FP, BS1010FP)</p> <p>Fee vide slip No. 70226596: 62000/-</p>	Approved. The firm shall submit valid Free Sale Certificate of the reference country or valid CE Certificate (FQA)
218.	M/s Raffay Associates, Office NO, 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi ELI: 00021	<p><u>Legal Manufacturer & Manufacturing Site:</u> Taewoong Medical Co., Ltd 14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, <u>South Korea.</u></p> <p><u>FSC Korea issued on 23/01/2019</u></p>	<p>Niti-S (Esophageal Covered Stent [Full covered Type])</p> <p>Shelf Life 3 Year Class: C</p> <p>Codes as per FSC: ES2218F, ES2218F2,</p>	Approved. The firm shall submit valid Free Sale Certificate of the reference country or valid CE Certificate (FQA)

		<p><u>FSC UK MHRA issued on 09/07/2018</u></p> <p>FSC: Free Sale Certificate (FSC) No.20230017075 issued by Mo Food and Drug Safety, Korea issued on 08-02-2023.</p> <p>Statement (wherein Free Sale of the product is indicated) issued by Mo Health, Welfare and Sport, the Netherlands valid upto 25-03-2024.</p> <p>ISO 13485 validity date: 25-03-2025</p> <p>CE Certificate (FQA) validity date 01-11-2023.</p> <p>Design Examination CE Certificate validity date 25-03-2024</p> <p>LOA issued on 15-01-2019</p>	<p>ES2223F, ES2223F2, ES2418F, ES2418F2, ES2418F, ES2418F2, ES2818F, ES2818F2, ES2823F, ES2823F2</p> <p>Fee vide slip No. 5912131493: 62000/-</p>	
219.	<p>Ideal Healthcare Products, 47-A, Pak Block Allama Iqbal Town, 54000 Lahore Pakistan.</p> <p>ELI-00827</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> LABORATOIRES ANIOS, Address: 1 rue de l'Espoir, 59260 Lezennes, France.</p> <p>FSC: Free Sale Certificate (FSC) issued by CCI Paris France issued on 09-01-2023.</p> <p>ISO 13485 validity date: 31-03-2027</p> <p>LOA valid upto 23-09-2026</p>	<p>ANIOSYME X3 Detergent disinfectant for manual use or automatic machines for invasive devices</p> <p>Shelf Life 2 Year Class: C</p> <p>Codes/Pack size: 5L & 1L</p> <p>Fee vide slip No. 65959216218: 62000/-</p>	<p>Approved subject to submission of the complete quantitative composition of the product.</p>
220.	<p>Ideal Healthcare Products, 47-A, Pak Block Allama Iqbal Town, 54000 Lahore Pakistan.</p> <p>ELI-00827</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> LABORATOIRES ANIOS, Address: 1 rue de l'Espoir, 59260 Lezennes, France.</p> <p>FSC: Free Sale Certificate (FSC) issued by CCI Paris France issued on 09-01-2023.</p>	<p>Micro 10+ Detergent / Disinfectant for manual use and / or automatic machines for invasive devices</p> <p>Shelf Life 2 Year Class: C</p> <p>Codes/Pack size: 5L Can & 1L Bottle</p>	<p>Approved</p>

		ISO 13485 validity date: 31-03-2027 LOA valid upto 23-09-2026	Fee vide slip No. 3629876257: 62000/-	
221.	Ideal Healthcare Products, 47-A, Pak Block Allama Iqbal Town, 54000 Lahore Pakistan. ELI-00827	<u>Legal Manufacturer & Manufacturing Site:</u> LABORATOIRES ANIOS, Address: 1 rue de l'Espoir, 59260 Lezennes, France. FSC: Free Sale Certificate (FSC) issued by CCI Paris France issued on 09-01-2023. ISO 13485 validity date: 31-03-2027 LOA valid upto 23-09-2026	STERANIOS 2% Disinfectant for manual use and / or automatic machines for invasive devices Shelf Life 2 Year Class: C Codes/Pack size: 5L Can & 1L Bottle Fee vide slip No 7831343331.: 62000/-	Approved subject to submission of the complete quantitative composition of the product.
222.	S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan. ELI-00849	<u>Legal Manufacturer & Manufacturing Site:</u> Manufacturer: Jiangsu Webest Medical Products Co., Ltd, Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China. Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China. FSC: Free Sale Certificate (FSC) issued by China valid upto 05-07-2026. ISO 13485 validity date: 31-05-2026 LOA valid upto 01-05-2027	Secure Infusion Set with Burette Infusion Set with Burette Shelf Life 5 Year Class: C Codes: Not mentioned Fee vide slip No. 122216915064.: 50,000/-	Deferred for the following: FSC of the reference country and CE Certificates (FQA), Revised valid LOA, Form-7A duly signed with correct classification the product, Stability study data upto the claimed shelf life.
223.	S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan.	<u>Legal Manufacturer & Manufacturing Site:</u> Manufacturer: Jiangsu Webest Medical Products Co., Ltd,	Secure Extension Tube Extension Tube Shelf Life 3 Year Class: C	Deferred for the following: FSC of the reference country and CE Certificates (FQA), Revised valid LOA,

	ELI-00849	<p>Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China.</p> <p>Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China.</p> <p>FSC: Free Sale Certificate (FSC) issued by China valid upto 05- 07-2026.</p> <p>ISO 13485 validity date: 31- 05-2026</p> <p>LOA valid upto 01-05-2027</p>	<p>Codes/Pack size: LJG-01, LJG-02, LJG-03, LJG-04, LJG-05, LJG-06, (100mm,300mm,600mm,900 mm,1200,1500mm,2000mm)</p> <p>Fee vide slip No. 0746596381.: 50,000/-</p>	<p>Form-7A duly signed with correct classification the product, Stability study data upto the claimed shelf life.</p>
224.	<p>S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan.</p> <p>ELI-00849</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u></p> <p>Manufacturer: Jiangsu Webest Medical Products Co., Ltd, Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China.</p> <p>Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China.</p> <p>FSC: Free Sale Certificate (FSC) issued by China valid upto 05- 07-2026.</p> <p>ISO 13485 validity date: 31- 05-2026</p> <p>LOA valid upto 01-05-2027</p>	<p>Secure Sterile Syringes with Needle Sterile Syringes with Needle</p> <p>Shelf Life 5 Year Class: C</p> <p>Codes/Sizes: 1ml,2ml,3ml,5ml,10ml,20ml,5 0ml</p> <p>Fee vide slip No. 62107343909.: 50,000/-</p>	<p>Deferred for the following: FSC of the reference country and CE Certificates (FQA), Revised valid LOA, Form-7A duly signed with correct classification the product, Stability study data upto the claimed shelf life.</p>
225.	<p>S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan.</p> <p>ELI-00849</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u></p> <p>Manufacturer: Jiangsu Webest Medical Products Co., Ltd, Address:</p>	<p>Secure Three Way Stopcocks for Single Use Infusion Set with Burette</p> <p>Shelf Life 5 Year Class: C</p>	<p>Deferred for the following: FSC of the reference country and CE Certificates (FQA), Revised valid LOA, Form-7A duly signed with correct classification</p>

		<p>No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China.</p> <p>Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China.</p> <p>FSC: Free Sale Certificate (FSC) issued by China valid upto 05-07-2026.</p> <p>ISO 13485 validity date: 31-05-2026</p> <p>LOA valid upto 01-05-2027</p>	<p>Codes/Sizes: 3SC-P-I, 3SC-P-II</p> <p>Fee vide slip No. 97287441.: 50,000/-</p>	<p>the product, Stability study data upto the claimed shelf life.</p>
226.	<p>S.A Knitwear, Kothi No. 7, Teshi Kabirwala District Khanewal Pakistan.</p> <p>ELI-00849</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u></p> <p>Manufacturer: Jiangsu Webest Medical Products Co., Ltd, Address: No. 5, Yingchun Rd. Industrial Park Xuyi, Jiangsu Province Peoples Republic of China.</p> <p>Exporter: Qingdao Hiprove Medical Technologies Co., Ltd, Address: No.237, Wannianquan Road, 266199, Qingdao, China.</p> <p>FSC: Free Sale Certificate (FSC) issued by China valid upto 05-07-2026.</p> <p>ISO 13485 validity date: 31-05-2026</p> <p>LOA valid upto 01-05-2027</p>	<p>Secure Transfusion Set Infusion Set</p> <p>Shelf Life 5 Year Class: C</p> <p>Codes/Sizes: SXQ1, SXQ2</p> <p>Fee vide slip No. 71575003379.: 50,000/-</p>	<p>Deferred for the following: FSC of the reference country and CE Certificates (FQA), Revised valid LOA, Form-7A duly signed with correct classification the product, Stability study data upto the claimed shelf life.</p>
227.	<p>Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan.</p> <p>ELI-00186</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany.</p> <p>FSC:</p>	<p>RealStar Filovirus Screen RT-PCR Kit 1.0 Filovirus Screen RT-PCR Kit 1.0</p> <p>Shelf Life: 15 months Class: D</p>	<p>Deferred for the following: Stability study data & Design Examination CE Certificate</p>

		Germany Free Sale Certificate (FSC) issued on 22-06-2023. ISO 13485 validity date: 23-04-2026 LOA valid upto 31-12-2024.	Codes/Sizes: 441013 Fee vide slip No. 887919916.: 62,000/-	
228.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan. ELI-00186	<u>Legal Manufacturer & Manufacturing Site:</u> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany. FSC: Germany Free Sale Certificate (FSC) issued on 22-06-2023. ISO 13485 validity date: 23-04-2026 LOA valid upto 31-12-2024.	RealStar Zika Virus RT-PCR Kit 1.0 Zika Virus RT-PCR Kit 1.0 Shelf Life: 15 months Class: C Codes/Sizes: 591013 Fee vide slip No. 50517565737: Rs.62,000/-	Deferred for the following: Stability study data & Design Examination CE Certificate
229.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan. ELI-00186	<u>Legal Manufacturer & Manufacturing Site:</u> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany. FSC: Germany Free Sale Certificate (FSC) issued on 22-06-2023. ISO 13485 validity date: 23-04-2026 LOA valid upto 31-12-2024.	RealStar WNV RT-PCR Kit 2.0 West Nile virus (WNV) RT-PCR Kit 2.0 Shelf Life: 18 months Class: C Codes/Sizes: 322013 Fee vide slip No. 56126841590: Rs. 62,000/-	Deferred for the following: Stability study data & Design Examination CE Certificate
230.	Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore. ELI-00654	<u>Legal Manufacturer & Manufacturing Site:</u> Siare Engineering International Group SRL, Via Giulio Pastore, 18, 40053 Crespellano-Valsamoggia (BO), Italy.	Anesthesia Unit Morpheus ND Hybrid HYBRID anesthesia unit Shelf Life: N/A Class: C Codes/Sizes:	Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-

		<p>FSC: Italy Free Sale Certificate (FSC) issued vide No. DGDMF/3/P/I.5.e.1/2023/14 01</p> <p>EU Quality Management System Certificates (Technical sheets enclosed-7 pages) valid upto 19-02-2029.</p> <p>ISO 13485 validity date: 01-06-2027</p> <p>LOA valid upto 18-10-2025.</p>	<p>(MND. SE-T)</p> <p>Fee vide slip No. 57415278: Rs. 62,000/-</p>	
231.	<p>Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore.</p> <p>ELI-00654</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Siare Engineering International Group SRL, Via Giulio Pastore, 18, 40053 Crespellano-Valsamoggia (BO), Italy.</p> <p>FSC: Italy Free Sale Certificate (FSC) issued vide No. DGDMF/3/P/I.5.e.1/2023/14 01</p> <p>EU Quality Management System Certificates (Technical sheets enclosed-7 pages) valid upto 19-02-2029.</p> <p>ISO 13485 validity date: 01-06-2027</p> <p>LOA valid upto 18-10-2025.</p>	<p>Anesthesia Unit Morpheus E anesthesia unit</p> <p>Shelf Life: N/A Class: C</p> <p>Codes/Sizes: (OM3. SE-TS)</p> <p>Fee vide slip No. 466854127: Rs. 62,000/-</p>	<p>Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-</p>
232.	<p>Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore.</p> <p>ELI-00654</p>	<p><u>Legal Manufacturer & Manufacturing Site:</u> Siare Engineering International Group SRL, Via Giulio Pastore, 18, 40053 Crespellano-Valsamoggia (BO), Italy.</p> <p>FSC: Italy Free Sale Certificate (FSC) issued vide No. DGDMF/3/P/I.5.e.1/2023/14 01</p> <p>EU Quality Management System Certificates</p>	<p>Anesthesia Unit Morpheus M anesthesia unit</p> <p>Shelf Life: N/A Class: C</p> <p>Codes/Sizes: (OM3. S5-TS)</p> <p>Fee vide slip No. 825020855: Rs. 62,000/-</p>	<p>Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-</p>

		(Technical sheets enclosed-7 pages) valid upto 19-02-2029. ISO 13485 validity date: 01-06-2027 LOA valid upto 18-10-2025.		
233.	Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore. ELI-00654	<u>Legal Manufacturer & Manufacturing Site:</u> eVent Medical Ltd., 60 Empire Drive, Lake Forest, CA 92630, USA. FSC: USDFA CFG issued vide No.9354-52024-1 valid upto 27-05-2026. CE Certificate (FQA) valid upto 10-02-2023. ISO 13485 validity date: 10-02-2027 LOA valid upto 30-06-2025.	eVent Medical ICU Ventilators Inspiration 7i - 17 inch screen Shelf Life: N/A Class: C Codes/Sizes: 300000-7i-L Fee vide slip No. 1041263111: Rs. 62,000/-	Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-
234.	Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore. ELI-00654	<u>Legal Manufacturer & Manufacturing Site:</u> eVent Medical Ltd., 60 Empire Drive, Lake Forest, CA 92630, USA. FSC: USDFA CFG issued vide No.9354-52024-1 valid upto 27-05-2026. CE Certificate (FQA) valid upto 10-02-2023. ISO 13485 validity date: 10-02-2027 LOA valid upto 30-06-2025.	eVent Medical Inspiration 7i Flag Ship Ventilator Shelf Life: N/A Class: C Codes/Sizes: 300000-7i-F Fee vide slip No. 94349826779: Rs. 62,000/-	Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-
235.	Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore. ELI-00654	<u>Legal Manufacturer & Manufacturing Site:</u> eVent Medical Ltd., 60 Empire Drive, Lake Forest, CA 92630, USA. FSC: USDFA CFG issued vide No.9354-52024-1 valid upto 27-05-2026.	eVent Medical Evolution 3E Series Ventilator (12 in) Shelf Life: N/A Class: C Codes/Sizes: 300000-7i-S	Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-

		CE Certificate (FQA) valid upto 10-02-2023. ISO 13485 validity date: 10-02-2027 LOA valid upto 30-06-2025.	Fee vide slip No. 4661783767: Rs. 62,000/-	
236.	Eastern Medical Technology Services EMTS, 3-Aziz Avenue, Gulberg-5, Punjab, Lahore. ELI-00654	<u>Legal Manufacturer & Manufacturing Site:</u> eVent Medical Ltd., 60 Empire Drive, Lake Forest, CA 92630, USA. FSC: USDFA CFG issued vide No.9354-52024-1 valid upto 27-05-2026. CE Certificate (FQA) valid upto 10-02-2023. ISO 13485 validity date: 10-02-2027 LOA valid upto 30-06-2025.	eVent Medical Evolution 3E Ultra Ventilator Shelf Life: N/A Class: C Codes/Sizes: 300000-7i-S Fee vide slip No. 70874930: Rs. 62,000	Approved subject to submission of fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-
237.	Mezan International, 59BRH Opp DCO House Haji Meherban Road, Bilal Town Jhelum. ELI-00096	<u>Legal Manufacturer & Manufacturing Site:</u> Zhejiang Soudon Medical Technology Co., Ltd, Room 302-1, Floor 3, Building 4, No. 1 Nangonghe Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province, P.R. China. FSC: China FSC issued vide No.20230428 valid upto 29-07-2025. ISO 13485 validity date: 20-07-2025 LOA valid upto 30-06-2025.	Disposable Endoscope Injection Needle Shelf Life: Class: C Codes/Sizes: SD-04-A2321-4 SD-04-A2323-4 SD-04-A2325-4 SD-04-A1821-4 SD-04-A1823-4 SD-04-A1825-4 SD-04-B2321-4 SD-04-B2323-4 SD-04-B2325-4 SD-04-B1821-4 SD-04-B1823-4 SD-04-B1825-4 SD-04-A2321-6 SD-04-A2323-6 SD-04-A2325-6 SD-04-A1821-6 SD-04-A1823-6 SD-04-A1825-6 SD-04-B2321-6 SD-04-B2323-6 SD-04-B2325-6 SD-04-B1821-6 SD-04-B1823-6	Deferred for submission of the following: Stability Study data & revised Form7A with demanded shelf life, Reference country FSC or CE Certificates (FQA) along with fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-

			SD-04-B1825-6 Fee vide slip No. 68335360358: Rs. 62,000	
238.	Mezan Internationa, 59BR11 Opp DCO House Haji Meherban Road, Bilal Town Jhelum. ELI-00096	<u>Legal Manufacturer & Manufacturing Site:</u> Zhejiang Soudon Medical Technology Co., Ltd, Room 302-1, Floor 3, Building 4 & Room 505, Floor 5, Building 8, No. 1 Nangonghe Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province, P.R. China. FSC: China FSC issued vide No.20230428 valid upto 29- 07-2025. ISO 13485 validity date: 20- 07-2025 LOA valid upto 30-06-2025.	Disposable Guide Wire Shelf Life: Class: C Codes/Sizes: SD-06-89-A450S , SD-06-89- 4450J SD-06-89-A260S .SD- 06-89-A260J SD-06-81- A450S ,SD-06-81-A450J SD- 06-81-A260S ,SD-06-81- A260J SD-06-81-A150S ,SD- 06-81-A150J SD-06-63- A450S .SD-06-63-A450J SD- 06-63-A260S ,SD-06-63- A260J Fee vide slip No. 25410780: Rs. 62,000	Deferred for submission of the following: Stability Study data & revised Form7A with demanded shelf life, Reference country FSC or CE Certificates (FQA) along with fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-
239.	Mezan Internationa, 59BR11 Opp DCO House Haji Meherban Road, Bilal Town Jhelum. ELI-00096	<u>Legal Manufacturer & Manufacturing Site:</u> Zhejiang Soudon Medical Technology Co., Ltd, Room 302-1, Floor 3, Building 4 & Room 505, Floor 5, Building 8, No. 1 Nangonghe Road, Donghu Street, Linping District, Hangzhou City, Zhejiang Province, P.R. China. FSC: China FSC issued vide No.20230428 valid upto 29- 07-2025. ISO 13485 validity date: 20- 07-2025 LOA valid upto 30-06-2025.	Disposable Biopsy Forceps Shelf Life: Class: C Codes/Sizes: As per FSC Fee vide slip No. 486056794703: Rs. 62,000	Deferred for submission of the following: Stability Study data & revised Form7A with demanded shelf life, Reference country FSC or CE Certificates (FQA) along with fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs. 100,000/-
240.	Mezan Internationa, 59BR11 Opp DCO House Haji Meherban Road, Bilal Town Jhelum. ELI-00096	<u>Legal Manufacturer & Manufacturing Site:</u> Zhejiang Soudon Medical Technology Co., Ltd, Room 302-1, Floor 3, Building 4 & Room 505, Floor 5, Building 8, No. 1 Nangonghe Road, Donghu Street, Linping District,	Disposable Hemostatic Clips Shelf Life: Class: C Codes/Sizes: SD-02-165-9, SD-02-195-9 SD-02-230-9, SD-02-165-9C SD-02-195-9C, SD-02-230-9C	Deferred for submission of the following: Stability Study data & revised Form7A with demanded shelf life, Reference country FSC or CE Certificates (FQA) along with fee as per SRO.1324 (I)/2024 dated 30th August, 2024 which Rs.

		<p>Hangzhou City, Zhejiang Province, P.R. China.</p> <p>FSC: China FSC issued vide No.20230428 valid upto 29-07-2025.</p> <p>ISO 13485 validity date: 20-07-2025</p> <p>LOA valid upto 30-06-2025.</p>	<p>SD-02-165-11, SD-02-195-11 SD-02-230-11, SD-02-165-11C SD-02-195-11C, SD-02-230-11C</p> <p>SD-02-165-13, SD-02-195-13 SD-02-230-13. SD-02-165-13C SD-02-195-13C, SD-02-230-13C SD-02-165-16, SD-02-195-16 SD-02-230-16, SD-02-165-16C SD-02-195-16C, SD-02-230-16C SD-02-165-9-N, SD-02-195-9-N SD-02-230-9-N, SD-02-165-9C-N SD-02-195-9C-N. SD-02-230-9C-N</p> <p>SD-02-165-11-N. SD-02-195-11-N</p> <p>SD-02-230-11-N, SD-02-165-11C-N</p> <p>SD-02-195-11C-N, SD-02-230-11C-N</p> <p>SD-02-165-13-N, SD-02-195-13-N SD-02-230-13-N, SD-02-165-13C-N</p> <p>SD-02-195-13C-N. SD-02-230-13C-N</p> <p>SD-02-165-16-N. SD-02-195-16-N</p> <p>SD-02-230-16-N. SD-02-165-16C-N</p> <p>SD-02-195-16C-N, SD-02-230-16C-N</p> <p>Fee vide slip No. 71019169399: Rs. 62,000</p>	100,000/-
241.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<p><u>Legal Manufacturer & Site:</u></p> <p>Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy.</p> <p>Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025</p> <p>ISO 13485 validity date....03-04-2026</p> <p>EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028</p> <p>EU Technical Documentation Assessment Certificate validity date.. 26-01-2028</p>	<p>Neauvia Stimulate Hyaluronic acid hydrogels Cross-linked 26mg/ml</p> <p>Class- D (III in EU)</p> <p>Shelf life: ...3 Years</p> <p>Codes/Sizes: HY100P26 HY101P26</p> <p>Pack Size: in disposable syringe (1×1ml) (2×1ml)</p> <p>Fee vide slip No. 2358241139: Rs. 62,000</p>	Approved

		Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024		
242.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy. Italy Free Sale Certificate (FSC) No. DGD MF/3/P/i.5.1.e.1/2023/1 025 ISO 13485 validity date....03-04-2026 EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028 EU Technical Documentation Assessment Certificate validity date.. 26-01-2028 Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024	Neauvia Intense Rheology Hyaluronic acid hydrogels Cross-linked 22mg/ml Class- D (III in EU) Shelf life: ...3 Years Codes/Sizes: HY200P22 HY201P22 Pack Size: in disposable syringe (1×1ml) (2×1ml) Fee vide slip No. 05206827677: Rs. 62,000	Approved
243.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy. Italy Free Sale Certificate (FSC) No. DGD MF/3/P/i.5.1.e.1/2023/1 025 ISO 13485 validity date....03-04-2026 EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028 EU Technical Documentation Assessment Certificate validity date.. 26-01-2028	Neauvia Stimulate Man Hyaluronic acid hydrogels Cross-linked 28mg/ml Class- D (III in EU) Shelf life: ...3 Years Codes/Sizes: HY100P28 HY101P28 Pack Size: in disposable syringe (1×1ml) (2×1ml) Fee vide slip No. 2358241139: Rs. 62,000	Approved

		Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024		
244.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy. Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025 ISO 13485 validity date....03-04-2026 EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028 EU Technical Documentation Assessment Certificate validity date.. 26-01-2028 Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024	Neuvia Intense Hyaluronic acid hydrogels Cross-linked 28mg/ml Class- D (III in EU) Shelf life: ...3 Years Codes/Sizes: HY200P28A HY201P28A Pack Size: in disposable syringe (1×1ml) (2×1ml) Fee vide slip No. 1594336563: Rs. 62,000	Approved
245.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy. Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025 ISO 13485 validity date....03-04-2026 EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028 EU Technical Documentation Assessment Certificate validity date.. 26-01-2028 Design Examination Certificate: Not provided	Neuvia Intense Man Hyaluronic acid hydrogels Cross-linked 28mg/ml Class- D (III in EU) Shelf life: ...3 Years Codes/Sizes: HY200P28B HY201P28B Pack Size: in disposable syringe (1×1ml) (2×1ml) Fee vide slip No. 290082972352: Rs. 62,000	Approved

		Distribution agreement dated 8-11-2024		
246.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<p><u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy.</p> <p>Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025 ISO 13485 validity date...03-04-2026</p> <p>EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028</p> <p>EU Technical Documentation Assessment Certificate validity date.. 26-01-2028</p> <p>Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024</p>	<p>Neuvia Intense LV Hyaluronic acid hydrogels Cross-linked 26mg/ml</p> <p>Class- D (III in EU)</p> <p>Shelf life: ...3 Years</p> <p>Codes/Sizes: HY200P26A HY201P26A</p> <p>Pack Size: in disposable syringe (1×1ml) (2×1ml)</p> <p>Fee vide slip No. 54672297872: Rs. 62,000</p>	Approved
247.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<p><u>Legal Manufacturer & Site:</u> Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy.</p> <p>Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025 ISO 13485 validity date...03-04-2026</p> <p>EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028</p> <p>EU Technical Documentation Assessment Certificate validity date.. 26-01-2028</p> <p>Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024</p>	<p>Neuvia Intense Lips Hyaluronic acid hydrogels Cross-linked 24mg/ml</p> <p>Class- D (III in EU)</p> <p>Shelf life: ...3 Years</p> <p>Codes/Sizes: HY200P24 HY201P24</p> <p>Pack Size: in disposable syringe (1×1ml) (2×1ml)</p> <p>Fee vide slip No. 4247773953: Rs. 62,000</p>	Approved

248.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<p><u>Legal Manufacturer & Site:</u></p> <p>Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy.</p> <p>Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1 025</p> <p>ISO 13485 validity date....03-04-2026</p> <p>EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028</p> <p>EU Technical Documentation Assessment Certificate validity date.. 26-01-2028</p> <p>Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024</p>	<p>Neauvia Intense Flux Hyaluronic acid hydrogels Cross-linked 26mg/ml</p> <p>Class- D (III in EU)</p> <p>Shelf life: ...3 Years</p> <p>Codes/Sizes: HY200P26B HY201P26B</p> <p>Pack Size: in disposable syringe (1×1ml) (2×1ml)</p> <p>Fee vide slip No. 221603033: Rs. 62,000</p>	Approved
249.	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	<p><u>Legal Manufacturer & Site:</u></p> <p>Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy.</p> <p>Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1 025</p> <p>ISO 13485 validity date....03-04-2026</p> <p>EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028</p> <p>EU Technical Documentation Assessment Certificate validity date.. 26-01-2028</p> <p>Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024</p>	<p>Neauvia Hydro Delux Hyaluronic acid hydrogels Not-Cross-linked 18mg/ml</p> <p>Class- D (III in EU)</p> <p>Shelf life: ...3 Years</p> <p>Codes/Sizes: HY301P18 HY305S18</p> <p>Pack Size: (1×1ml) in one ml disposable plastic syringe. (2×2.5ml) in 3ml glass syringe</p> <p>Fee vide slip No. 13529319948: Rs. 62,000</p>	Approved
250.		<u>Legal Manufacturer & Site:</u>	Neauvia Hydro Delux Man	Approved

	M/S Schazoo SPL Consumer Healthcare (ELI- 00095)	Matex Lab S.p.A via Carlo Urbani 2, angolo Via E. Fermi 72100 Brindisi (Br) Italy. Italy Free Sale Certificate (FSC) No. DGDMF/3/P/i.5.1.e.1/2023/1025 ISO 13485 validity date....03-04-2026 EU Quality Management System Certificate along with technical sheet Certificate validity date.. 26-01-2028 EU Technical Documentation Assessment Certificate validity date.. 26-01-2028 Design Examination Certificate: Not provided Distribution agreement dated 8-11-2024	Hyaluronic acid hydrogels Not-Cross-linked 18mg/ml Class- D (III in EU) Shelf life: ...3 Years Codes/Sizes: HY301P18M HY305S18M Pack Size: (1×1ml) in one ml disposable plastic syringe. (2×2.5ml) in 3ml glass syringe Fee vide slip No. 0531834817: Rs. 62,000	
251.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd., Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026 LOA Validity: 31-10-2029	Hindering Malaria P.f/P.v Rapid Test Cassette Class: C MD group: Single Shelf life: 24 Months Codes & Sizes I041-4002 Fee Challan No.: 8940355491 PKR: 62,000/- Dated: 12-12-2024	Approved
252.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd., Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026	Hindering Malaria P.f/Pan Rapid Test Cassette Class: C MD group: Single Shelf life: 24 Months Codes & Sizes I040-4002, Fee Challan No.: 29701464 PKR: 62,000/- Dated: 12-12-2024	Approved

		LOA Validity: 31-10-2029		
253.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd., Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026 LOA Validity: 31-10-2029	Hindering Syphilis Rapid Test Cassette Class: C MD group: Single Shelf life: 24 Months Codes & Sizes I044-3001, I044-3002, I044-4001, I044-4002. Fee Challan No.: 91367313927 PKR: 62,000/- Dated: 12-12-2024	Approved
254.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd., Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026 LOA Validity: 31-10-2029	Hindering Dengue IgG/IgM Rapid Test Cassette Class: C MD group: Single Shelf life: 24 Months Storage condition: Room Temperature Codes & Sizes 1027-4002 Fee Challan No.: 717794234749 PKR: 62,000/- Dated: 12-12-2024	Approved
255.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd., Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026 LOA Validity: 31-10-2029	Hindering Dengue NS1 Rapid Test Cassette Class: C MD group: Single Shelf life: 24 Months Codes & Sizes 1028-4002 Fee Challan No.: 523891769 PKR: 62,000/- Dated: 12-12-2024	Approved
256.	M/s Zenith International,	Legal Manufacturer & Site: Hangzhou Tongzhou Biotechnology Co. Ltd.,	Hindering Typhoid IgG IgM Rapid Test Cassette	Approved

	Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China. FSC Validity 18-09-2026 (China) valid upto 18-09-2026 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 19-07-2026 LOA Validity: 31-10-2029	Class: C MD group: Single Shelf life: 24 Months Codes & Sizes: 1035-3002 Fee Challan No.: 211110861413 PKR: 62,000/- Dated: 12-12-2024	
257.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Zhejiang runqing Medical Instrument Co., Ltd Address as per Form-7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaxing City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaxing Xiuzhou District 314031 Jiaxing City, China FSC Validity 18-09-2026 (China) valid upto 26-03-2025 FSC (Spain) Date of Issuance 10-10-2024 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid upto 06-05-2023 LOA Validity: 29-04-2029	Perfect Disposable Spinal Needle (Quincke Bevel type Class: C MD group: Single Shelf life: 5 years Codes & Sizes: 18,19,20,21,22,23,24,25,26 & 27G. Fee Challan No.: 6193522908 PKR: 62,000/- Dated: 12-12-2024	Deferred for submission of revised Form7A with correct classification, valid Design Examination Certificate, Clarification of the address difference in the provided CE (FQA) & FSC (china).
258.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	Legal Manufacturer & Site: Wellong Instruments Co., Ltd Address (as per form-7A): 2F, 63 Linsen North Road Taipei, Taiwan. R.O.C. Address as per FSC: 5 th Floor No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, Republic of China. FSC Validity : 09-09-2025 (Taiwan) 09-03-2021 (France) ISO 13485 Certificate validity: 08-07-2027 EC (FQA) not provided Design Examination	BMI External Drainage Monitoring System Class: D MD group: Family Shelf life: Not mentioned Storage condition: Room Temperature Codes & Sizes: 06128, 06140, 08182 Fee Challan No.: 2516483568 PKR: 62,000/-	Deferred for submission of: Revised Form7A duly signed with demanded shelf life, Stability study data, valid Design Examination Certificate, Clarification of the address difference in the provided Form-7A & FSC, Valid FSC of the country of origin wherein the applied product “BMI External Drainage Monitoring System” shall be indicated on free sale.

		Certificate not provided. LOA Validity: 26-07-2026		
259.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block- 24, Karachi (ELI-00907)	Legal Manufacturer & Site: Wellong Instruments Co., Ltd Address (as per form-7A): 2F, 63 Linsen North Road Taipei, Taiwan. R.O.C. Address as per FSC: 5 th Floor No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, Republic of China. FSC Validity: 09-09-2025 (Taiwan) 09-03-2021 (France) ISO 13485 Certificate validity: 08-07-2027 EC (FQA) not provided Design Examination Certificate not provided. LOA Validity: 26-07-2026	BMI Shunting System Class: D MD group: Family Shelf life: Not mentioned Storage condition: Room Temperature Codes & Sizes: 06124, 06126, 06128, 06120, 06122, 06129,06140,06142, US-62 Fee Challan No.: 948088324 PKR: 62,000/-	Deferred for submission of: Revised Form7A duly signed with demanded shelf life, Stability study data, valid Design Examination Certificate, Clarification of the address difference in the provided Form-7A & FSC, Valid FSC of the country of origin wherein the applied product “BMI Shunting System” shall be indicated on free sale.
260.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block- 24, Karachi (ELI-00907)	Legal Manufacturer & Site: Zhejiang Runqiang Medical Instrument Co., Ltd Address as per Form-7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaxing City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaxing Xiuzhou District 314031 Jiaxing City, China FSC: (China) valid upto 26-03- 2025 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid upto 06-05-2023 Design Examination Certificate valid upto 11-12- 2022 LOA Validity: 22-08-2029	Safety Aero Disposable Anesthesia Filter-NRFIT Filter Class: D MD group: Single Shelf life: 5 years Codes & Sizes: AF-A-0.5 Fee Challan No.: 322123110 PKR: 62,000/-	Deferred for submission of, valid Design Examination Certificate, EC (FQA), Clarification of the address difference in the provided CE (FQA) & FSC (china).
261.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block- 24, Karachi (ELI-00907)	Legal Manufacturer & Site: Zhejiang Runqiang Medical Instrument Co., Ltd Address as per Form-7A & China FSC: 599 Ruifeng Street, Gaozhao	Safety Aero Disposable Anesthesia Needle -NRFIT Needle (Disposable Anesthesia Needle-NRFIT Needle) Class: D	Deferred for submission of, valid Design Examination Certificate, EC (FQA), Clarification of the address difference in the provided CE

		<p>District, Xiuzhou Jiaying City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaying Xiuzhou District 314031 Jiaying City, China FSC: (China) valid upto 26-03-2025 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid upto 06-05-2023 Design Examination Certificate valid upto 11-12-2022 LOA Validity: 22-08-2029</p>	<p>MD group: Family Shelf life: 5 years</p> <p>Codes & Sizes: AN-E, AN-S, AN-N,AN-E/SII</p> <p>Fee Challan No.: 82294572303 PKR: 62,000/-</p>	(FQA) & FSC (china).
262.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	<p>Legal Manufacturer & Site: Zhejiang Runqiang Medical Instrument Co., Ltd Address as per Form-7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaying City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaying Xiuzhou District 314031 Jiaying City, China FSC: (China) valid upto 26-03-2025 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid upto 06-05-2023 Design Examination Certificate valid upto 11-12-2022 LOA Validity: 22-08-2029</p>	<p>Safety Aero Anesthesia Epidural Puncture Kit Class: D MD group: Single Shelf life: 5 years</p> <p>Codes & Sizes: AS-E</p> <p>Fee Challan No.: 366814753 PKR: 62,000/-</p>	Deferred for submission of, valid Design Examination Certificate, EC (FQA), Clarification of the address difference in the provided CE (FQA) & FSC (china).
263.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	<p>Legal Manufacturer & Site: M/s Thai Nippon Rubber Industry Public Company Limited. 789/ 139 Moo 1 Pinthong Industrial estate Nonkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand validity 04-02-2026</p> <p>ISO 13485 Certificate validity: 07-02-2026 EU QMS Certificates (MDR)</p>	<p>Safe In (plain) Natural Rubber Latex Male Condom</p> <p>Class-C MD group: Single</p> <p>Shelf life: 5 years Codes: Fee Challan No.: 07108939511 PKR: 62,000/-</p>	Approved. The firm shall submit f CE (FQA) Certificate, LOA

		Certificate valid upto 06-05-2023 LOA Validity: 03-07-2029		
264.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. Original FSC: China. Validity: 20-06-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY Toxoplasma gondii IgM (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 62845269320 PKR: 62,000/-	Approved.
265.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. Original FSC: China. Validity: 04-05-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY Toxoplasma gondii IgG (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 04788061850 PKR: 62,000/-	Approved.
266.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. Original FSC: China. Validity: 23-04-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity:	MINDRAY Rubella Virus IgG (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 763443015510 PKR: 62,000/-	Approved.

		14-04-2027		
267.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. Original FSC: China. Validity: 20-06-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY Rubella Virus IgM (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 583615291087 PKR: 62,000/-	Approved.
268.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 04-05-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY Cytomegalovirus IgG (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 200418199 PKR: 62,000/-	Approved.
269.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 20-06-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY Cytomegalovirus IgM (CLIA) Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 2x50 (calibrators included) 2x100 (calibrators included) Fee Challan No.: 85557172 PKR: 62,000/-	Approved.
270.	MR Medical Pakistan Pvt Ltd,	Legal Manufacturer & Site: Shenzhen Mindray Bio-	MINDRAY ToRCH IgM Positive control	Approved.

	Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 20-06-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 3x1ml/vial, 6x1ml/vial, 1x3ml/vial, 3x3ml/vial, Fee Challan No.: 5777371666 PKR: 62,000/-	
271.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 26-05-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY ToRCH IgG Positive control Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 3x1ml/vial, 6x1ml/vial, 1x3ml/vial, 3x3ml/vial, Fee Challan No.: 9295205062 PKR: 62,000/-	Approved.
272.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 20-06-2026. ISO 13485 Certificate validity 31-08-2026 EU QMS Certificates (IVDR) Certificate valid upto 14-12-2025 LOA Validity: 14-04-2027	MINDRAY ToRCH IgG / IgM Negative control Class-C MD group: Kit Shelf life: 18 months (at 2-8C°) Codes: 3x1ml/vial, 6x1ml/vial, 1x3ml/vial, 3x3ml/vial, Fee Challan No.: 094650416618 PKR: 62,000/-	Approved.
273.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech	MINDRAY Prolactin kit (CLIA) with calibrator Class-C MD group: Cluster	Deferred for clarification of the class of the applied product & their categorization in cluster along with fee as per new

	Area, Islamabad Pakistan. ELI-01008 Date of Application: 30-12-2022	Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 29-03-2023. FSC Germany issued on 30-01-2021. ISO 13485 Certificate validity 31-08-2026 EC (FQA) not provided. LOA Validity: 14-04-2027	Shelf life: 24 months (at 2-8C°) Codes: Prolactin :2x30test, 2x50test, 2x100test Calibrator: 3 bottle each of 1x2mL, Fee Challan No.: 5398202593 PKR: 50,000/-	SRO.
274.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad Pakistan. ELI-01008 Date of Application: 30-12-2022	Legal Manufacturer & Site: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, Reople's Republic of China. FSC China. Validity: 29-03-2023. FSC Germany issued on 30-01-2021. ISO 13485 Certificate validity 31-08-2026 EC (FQA) not provided. LOA Validity: 14-04-2027	MINDRAY Reproductive multi control (CLIA) Class-C MD group: Cluster Shelf life: 16 months (at 2-8C°) Codes: L :6x5mL, 12x5mL, 1x5mL,3x5mL, H: 6x50mL, 12x5mL, 1x5mL,3x5mL Fee Challan No.: 39249204585 PKR: 50,000/-	Deferred for clarification of the class of the applied product & their categorization in cluster along with fee as per new SRO.
275.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	NFINI PREMIUM FILLER B Body Sodium hyaluronate...2% (20mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: 10 ml monophasic gel Fee Challan No.: 158286337332 PKR: 50,000/-	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.
276.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application:	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity	NFINI PREMIUM FILLER M Sodium hyaluronate...2.10% (21mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°)	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.

	11-07-2024	10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	Codes: One ml monophasic gel Fee Challan No.: 9920326634 PKR: 50,000/-	
277.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	NFINI PREMIUM FILLER S Sodium hyaluronate...2% (20mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: One ml monophasic gel Fee Challan No.: 71344219383 PKR: 50,000/-	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.
278.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	NFINI PREMIUM FILLER L Sodium hyaluronate..2.40% (24mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: One ml monophasic gel Fee Challan No.: 3629058612 PKR: 50,000/-	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.
279.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	NFINI PREMIUM FILLER XL Sodium hyaluronate..2.60% (26mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: One ml monophasic gel Fee Challan No.: 546352476800 PKR: 50,000/-	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.
280.	Crystolite Pharmaceuticals Health Care Division	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione	NFINI PREMIUM FILLER SOFT LIPS	Deferred for submission of the following: Valid Design

	Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	Sodium hyaluronate..2% (20mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: One ml monophasic gel Fee Challan No.: 9413707530 PKR: 50,000/-	Examination LOA issued by the product license holder in the country of origin.
281.	Crystolite Pharmaceuticals Health Care Division Flat No. 11, Haroon Plaza, I-9 Markaz, Islamabad. ELI-00917 Date of Application: 11-07-2024	Legal Manufacturer & Site: M/s VIDA SRL, Via Galileo Galilei 4, 56040 Frazione Lavoria Crespina (PI)- ITALY FSC: Italy Date of Issue:09/02/2023 ISO 13485 Certificate validity 10-05-2027 EC (FQA) not provided. Design Examination not provided. Distribution agreement dated 18-03-2024.	NFINI PREMIUM FILLER A Aquabooster Sodium hyaluronate..2% (20mg/ml) Class-D MD group: Single Shelf life: 3 years (at 5-25C°) Codes: One ml monophasic gel Fee Challan No.: 87612598918 PKR: 50,000/-	Deferred for submission of the following: Valid Design Examination LOA issued by the product license holder in the country of origin.
282.	Med Impex, 473-B Faisal Town Lahore. ELI-00301	Legal Manufacturer & Site: Hoffrichter GmbH, Mettenheimer Straße 12/14, 19061, Schwerin, Germany. Original FSC: Berlin Germany Date of Issuance: 06-11- 2023. ISO 13485 Certificate validity 28-04-2025 EC (FQA) valid upto 31-10- 2023 LOA valid upto 30-06-2026.	Trend III Bilevel ST BIPAP Class-C MD group: Not mentioned Shelf life: N/A Codes: 425031631-0053AW Fee Challan No.: 31414329647 PKR: 62,000/-	Approved
283.	Med Impex, 473-B Faisal Town Lahore. ELI-00301	Legal Manufacturer & Site: Hoffrichter GmbH, Mettenheimer Straße 12/14, 19061, Schwerin, Germany. Original FSC: Berlin Germany Date of Issuance: 06-11- 2023. ISO 13485 Certificate validity 28-04-2025 EC (FQA) valid upto 31-10- 2023	Point 3 Auto CPAP CPAP Class-C MD group: Not mentioned Shelf life: N/A Codes: 425031631-0082B5 Fee Challan No.: 41138421 PKR: 62,000/-	Approved

		LOA valid upto 30-06-2026.		
284.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi (ELI-00010)	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040 Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08- 2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	Liaison CA 15-3 Chemiluminescence Immunoassay CLIA Based Liaison CA 15-3 IVD Test Kit Class-C MD group: IVD Kit Shelf life: 18 months Codes: (Ref No. 314301) - Pack of 100 Tests Fee Challan No.: 4890947552 & 6070956311 PKR: 50,000/- Plus 12000/-	Approved
285.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi (ELI-00010)	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040 Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08- 2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	Liaison CA 19-9 Chemiluminescence Immunoassay CLIA Based Liaison CA 19-9, IVD Test Kit Class-C MD group: IVD Kit Shelf life: 12 months Codes: (Ref No. 314171) Pack of 100 Tests Fee Challan No.: 2620243773 & 4418085942 PKR: 50,000/- Plus 12000/-	Approved
286.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi (ELI-00010)	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040 Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08- 2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	Liaison Murex Anti-HEV IgM, Liaison Murex Control Anti- HEV IgM Chemiluminescence Immunoassay CLIA Based Liaison Murex Anti-HEV IgM IVD Test Kit & Liaison Murex Control Anti-HEV IgM Class-C MD group: IVD Kit Shelf life: 18 months & 24 months respectively Codes: (Ref No. 311280) Pack of 100 tests (Ref No. 311281) Fee Challan No.: 07213368721 & 78222250986 PKR: 50,000/- Plus 12000/-	Approved for Liaison Murex Anti-HEV IgM. The rest of the products shall be approved subject to the condition that the firm shall submit prescribed fee & application form (Form- 7A)
287.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal,	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040	Liaison Murex Anti-HEV IgG, Liaison Murex Control Anti-	Approved for Liaison Murex Anti-HEV IgG. The rest of the products shall be

	Karachi (ELI-00010)	Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08-2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	HEV IgG Chemiluminescence Immunoassay CLIA Based Liaison Murex Anti HEV IgG IVD Test Kit & Liaison Murex Control Anti HEV IgG. Class-C MD group: IVD Kit Shelf life: 18 months & 24 months respectively Codes: (Ref No. 311270) Pack of 100 tests (Ref No. 311271) Fee Challan No.: 659743977 & 831681183 PKR: 50,000/- Plus 12000/-	approved subject to the condition that the firm shall submit prescribed fee & application form (Form-7A)
288.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi (ELI-00010)	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040 Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08-2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	Liaison VZV IgG, Liaison Control VZV IgG Chemiluminescence Immunoassay CLIA Based Liaison VZV IgG IVD Text Kit & Liaison Control VZV IgG Class-C MD group: IVD Kit Shelf life: 21 months & 21 months respectively Codes: (ref No. 310850) & (ref No. 310851) Fee Challan No.: 394762971541 & 5474218257 PKR: 50,000/- Plus 12000/-	Approved for Liaison VZV IgG. The rest of the products shall be approved subject to the condition that the firm shall submit prescribed fee & application form (Form-7A)
289.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi (ELI-00010)	Legal Manufacturer & Site: Diasorin Italia S.p.A. Via Crescentino snc, 13040 Saluggia (VC, Italy) FSC: Italy Date of Issuance: 09-08-2022. ISO 13485 Certificate validity 06-02-2025 EC (FQA) Not provided LOA valid upto 31-12-2028.	Liaison VZV IgM, Liaison Control VZV IgM Chemiluminescence Immunoassay CLIA Based Liaison VZV IgM IVD Text Kit & Liaison Control VZV IgM Class-C MD group: IVD Kit Shelf life: 24 months & 21 months respectively Codes: (ref No. 310860) & (ref No. 310861) Fee Challan No.: 11130777508 & 078660338 PKR: 50,000/- Plus 12000/-	Approved for Liaison VZV IgM. The rest of the products shall be approved subject to the condition that the firm shall submit prescribed fee & application form (Form-7A)
290.	Unique Visual System, L-18m Block-17, Gulshan-E-Iqbal, Karachi (ELI-00449)	Legal Manufacturer & Site: Office address: Neo Vision Co., Ltd. Heungdeokjungang-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 120 U-Tower 17F, Korea. Factory: 129-1, Donghwagongdan-ro,	Optiano Clean NEO PLUS Contact Lens Multi-Purpose Solution (20% polyhexamethylene biguanide) Class-C MD group: Family Shelf life: Not mentioned Codes: 60mL & 130mL	Deferred for submission of revised Form-7A with correct demanded shelf life, LoA, Stability study data, valid EC(FQA) along with fee of Rs. 100,000/- as per new SRO.

		Munmak-eup, Wonju-si, Gangwon-do, Korea FSC: Korea Date of Issuance: 17-02-2023 ISO 13485 dated 25-08-2027. EC (FQA) valid upto 25-08-2023 LOA dated 15-07-2024.	Fee Challan No.: 82298189944 PKR: 62000/-	
291.	Unique Visual System, L-18m Block-17, Gulshan-E-Iqbal, Karachi (ELI-00449)	Legal Manufacturer & Site: M/s Chalice Solution PTE LT No. 6, Zhongxing Road, Yunyang street,High-tech zone, Danyang city, China FSC: China Date of Issuance: 08-05-2026 ISO 13485 dated 18-03-2027. EC (FQA) not provided LOA dated 15-07-2024.	Optiano" Multi-Purpose Solution Contact Lens Multi-Purpose Solution (20% polyhexamethylene biguanide) Class-C MD group: Family Shelf life: 3 years Codes: 100mL, 360mL & 500mL GXZZ20223160264 (Model. HA & HA-T) Fee Challan No.: 82298189944 PKR: 62000/-	Deferred for submission of LoA, valid EC(FQA)/FSC of reference country along with fee of Rs. 100,000/- as per new SRO.
292.	Claris Medical, Unit No. 01, Ground Floor, Rayyan Height Gangal East Service Road Islamabad. ELI-00269 Date of Application: 07-10-2024	Legal Manufacturer & Site: Scanlan International, Inc. One Scanlan Plaza, St Paul, MN 55107, United States. FSC: USA. Validity: 18-01-2026 ISO 13485 dated 02-11-2026. EC (FQA) valid upto 01-02-2023 LOA dated 31-12-2023. Design Examination Certificate not provided.	Surg-I-Loop Silicon Loops Silicon Loops Class-D MD group: Not specify Shelf life: not mentioned Codes: 1001-75 Red Mini 1001-76 Red Maxi 1001-77 Blue Mini 1001-78 Blue Maxi 1001-78A Blue Super Maxi 1001-78AC-24 Blue, Super Maxi 24 inches 1001-79 Yellow Mini 1001-80 Yellow Maxi 1001-81 White Mini 1001-81M White Micro 1001-82 White Maxi 1001-82C-30 White Maxi 30 inches SURG-I-LOOP® silicone loops 1001-80SC Yellow Maxi SURG-I-LOOP® Plus with blunt needle 1001-81P Light Green SURG-I-LOOP® Plus with semi-sharp needle 1001-82P Light Orange Single-use vein holders 1001-760 SCANLAN® Solem™ vein holder VASCU-STATT® clamps 1001-500 Midi Straight 1001-501 Midi Angled	Deferred for submission of the following: Revised Form7A with correct class along with prescribed fee as per the new SRO (if applicable), valid LOA, Stability study data upto the claimed shelf life. The board also advised to apply separately to each product or categorize the product in light MDR 2017 & submit fee as per the new SRO.

			1001-502 Mini Straight 1001-503 Mini Angled Fee Challan No.: 61069552152 PKR: 50,000/-	
293.	Sanyoh International, Office No. 2, Flat No. 8, Block No. 19, Allah Dad Plaza, G-8 Markaz, Islamabad. ELI-01179 Date of Application: 21-08-2024	Legal Manufacturer & Site: SCL Co., Ltd., 902, 903, Banpo Technopia, 186 Galmachi-ro, Jungwon- gu, Seongnam-si Gyeonggi- do, Korea. KS SUNG SUN INTERNATIONAL CO., LTD 164 Gonghang-daero, Gangseo-gu, Seoul, Republic of Korea. FSC: Korea. Issued date: 12-03-2024. ISO 13485 dated 10-04-2027. EC (FQA) valid upto 27-05- 2024. EC (Design Examination) valid upto 27-05-2024. LOA dated 21-04-2029	Caratfill Injectable Dermal Filler Caratfill KISS CE: HA contents ...24mg/ml, Lidocaine...0.3% Caratfill Deep CE: HA contents ...24mg/ml, Lidocaine...0.3% Caratfill SUB-Q CE: HA contents ...24mg/ml, Lidocaine...0.3% Class-D MD group: Family Shelf life: 24 months Codes: 1.1 mL each Fee Challan No.: 981338297474 PKR: 50,000/-	Approved subject to submission of fee of Rs. 100,000/- as per new SRO.
294.	M/s K.S. Agencies Office 210, 2 nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382)	Legal Manufacture & Site: (Cyprus site) Demophorius Ltd 196 Archbishop Makarios III Ave – 3030 Limassol – Cyprus (China site) Manufacturing site Huaiyin Medical Instruments Co., Ltd, No.8 West Ming Yuan Road, 223003, Huaiyin, China. FSC Validity of Cyprus site: 26-05-2024 (Cyprus) FSC (China) of china site valid upto 24-02-2025 FSC (MHRA) of china site expired on 06-11-2023 EC (FQA) of china site valid upto 28-04-2024. Design Examination Certificate of china site Validity	DTEK POLYGLACTIN PGLA (Polyglycolide-co-L-lactide) Class: D MD group: Single Shelf life: 5 years Codes & Sizes: 0, 1, 2, 2/0, 3/0,4/0,5/0,6/0 Fee Challan No.: 898131674 PKR: 62000/-	The product is approved from Cyprus site only subject to submission of fee of Rs. 100,000/-as per New SRO. Deferred the China site product for submission of the following: LOA issued by the product license holder, Stability Study data,

		<p>28-04-2024.</p> <p>ISO 13485 Certificate of China site: validity: 27-02-2025</p> <p>EC (FQA) Certificate validity of Cyprus site: 26-05-2024</p> <p>ISO 13485 Certificate of Cyprus site: validity: 04-12-2025</p> <p>Design Examination Certificate of Cyprus site Validity 26-05-2024 (extension letter attached) LOA Validity: 09-04-2029</p>		
295.	M/s K.S. Agencies Office 210, 2 nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382)	<p>Legal Manufacture & Site: (Cyprus site) Demophorius Ltd 196 Archbishop Makarios III Ave – 3030 Limassol – Cyprus (China site) Manufacturing site Huaiyin Medical Instruments Co., Ltd, No.8 West Ming Yuan Road, 223003, Huaiyin, China. FSC Validity of Cyprus site: 26-05-2024 (Cyprus)</p> <p>FSC (China) of china site valid upto 24-02-2025</p> <p>FSC (MHRA) of china site expired on 06-11-2023</p> <p>EC (FQA) of china site valid upto 28-04-2024.</p> <p>Design Examination Certificate of china site Validity 28-04-2024.</p> <p>ISO 13485 Certificate of China site: validity: 27-02-2025</p>	<p>DTEK POLYGLYCOLIC ACID PGA (Polyglycolic)</p> <p>Class: D MD group: Single Shelf life: 5 years</p> <p>Codes & Sizes: 0, 1, 2,3,4,5, 2/0, 3/0,4/0,5/0,6/0,7/0,8/0,9/0,10/0,11/0</p> <p>Fee Challan No.: 930557524 PKR: 62000/-</p>	<p>The product is approved from Cyprus site only subject to submission of fee of Rs. 100,000/-as per New SRO.</p> <p>Deferred the China site product for submission of the following: LOA issued by the product license holder, Stability Study data,</p>

		<p>EC (FQA) Certificate validity of Cyprus site: 26-05-2024</p> <p>ISO 13485 Certificate of Cyprus site: validity: 04-12-2025</p> <p>Design Examination Certificate of Cyprus site Validity 26-05-2024 (extension letter attached) LOA Validity: 09-04-2029</p>		
296.	M/s K.S. Agencies Office 210, 2 nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382)	<p>Legal Manufacture & Site: (Cyprus site) Demophorius Ltd 196 Archbishop Makarios III Ave – 3030 Limassol – Cyprus (China site) Manufacturing site Huaiyin Medical Instruments Co., Ltd, No.8 West Ming Yuan Road, 223003, Huaiyin, China. FSC Validity of Cyprus site: 26-05-2024 (Cyprus)</p> <p>FSC (China) of china site valid upto 24-02-2025</p> <p>FSC (MHRA) of china site expired on 06-11-2023</p> <p>EC (FQA) of china site valid upto 28-04-2024.</p> <p>Design Examination Certificate of china site Validity 28-04-2024.</p> <p>ISO 13485 Certificate of China site: validity: 27-02-2025</p> <p>EC (FQA) Certificate validity of Cyprus site: 26-05-2024</p> <p>ISO 13485 Certificate of</p>	<p>DTEK POLYDIOXANONE PDO (Polydioxanone)</p> <p>Class: D MD group: Single Shelf life: 5 years</p> <p>Codes & Sizes: 0, 1, 2, 2/0, 3/0,4/0,5/0,6/0,7/0 Fee Challan No.: 8827391611 PKR: 62000/-</p>	<p>The product is approved from Cyprus site only subject to submission of fee of Rs. 100,000/-as per New SRO.</p> <p>Deferred the China site product for submission of the following: LOA issued by the product license holder, Stability Study data,</p>

		<p>Cyprus site: validity: 04-12-2025</p> <p>Design Examination Certificate of Cyprus site Validity 26-05-2024 (extension letter attached) LOA Validity: 09-04-2029</p>		
297.	<p>M/s Life cares, M-20 Mezzanine Floor Falaknaz Plaza Main Shahra e faisal Karachi (ELI-00077)</p> <p>Date of Application: 19-09-2024</p>	<p>Legal Manufacture & Site: M/s Femtos GmbH, Universitätsstrabe 136 44799 Bochum, Germany FSC Issuance Date: (<i>country of origin</i>): 24-04-2023 (Germany) EC (FQA) Certificate validity: 11-03-2024</p> <p>ISO 13485 Certificate validity: 11-03-2025</p> <p>Design Examination Certificate validity: 26-05-2024 (expired at the time of submission)</p> <p>LOA Issuance Date: 04-05-2023</p>	<p>Pegasus Stent System Intracranial vascular stent</p> <p>Class: D MD group: Kit Shelf life: 05 Years</p> <p>Codes & Sizes PEGASUS-350-15 PEGASUS-350-15-HPC PEGASUS-350-20 PEGASUS-350-20-HPC PEGASUS-350-25 PEGASUS-350-25-HPC PEGASUS-350-30 PEGASUS-350-30-HPC PEGASUS-450-15 PEGASUS-450-15-HPC PEGASUS-450-20 PEGASUS-450-20-HPC PEGASUS-450-25 PEGASUS-450-25-HPC PEGASUS-450-30 PEGASUS-450-30-HPC Fee Challan No.: 022127774603 PKR: 50,000/-</p>	<p>Approved with 3 years shelf life subject to submission of fee as per new SRO & valid Design Examination Certificate.</p>
298.	<p>M/s Life cares, M-20 Mezzanine Floor Falaknaz Plaza Main Shahra e faisal Karachi (ELI-00077)</p>	<p>Legal Manufacture & Site: M/s Shanghai Wallaby Medical Technologies Co. Inc., Area C, No.3, Lane 299, Kangwei Road, Pudong New Area Shanghai 201315, China</p> <p>FSC Validity (country of origin): Not provided EC Certificate validity: 26-05-2024 (extension letter attached) ISO 13485 Certificate validity: 26-03-2027 Design Examination Certificate validity: 26-05-2024 (extension letter</p>	<p>Esperance Aspiration Catheter System Aspiration Catheter System</p> <p>Class: D MD group: System Shelf life: 03 Years</p> <p>Codes & Sizes: Not mentioned Fee Challan No.: 6195214291 PKR: 50,000/-</p>	<p>Deferred for submission of the following: Fee as per new SRO which is Rs.100, 000/-, Revised Form-7A with complete information along with the manufacturer name, FSC of the country of origin, FQA & design Examination Certificate of the china (from the product will be imported),LOA issued by the product license holder,</p>

		attached) LOA issuance date: Not mentioned but attestation data is 22-08-2023		
299.	M/s Life cares, M-20 Mezzanine Floor Falaknaz Plaza Main Shahra e faisal Karachi (ELI-00077)	Legal Manufacture & Site: M/s Shanghai Wallaby Medical Technologies Co. Inc., Area C, No.3, Lane 299, Kangwei Road, Pudong New Area Shanghai 201315, China FSC Validity (<i>country of origin</i>): Not provided EC Certificate validity: 26-05-2024 (extension letter attached) ISO 13485 Certificate validity: 26-03-2027 Design Examination Certificate validity: 26-05-2024 (extension letter attached) LOA issuance date: Not mentioned but attestation data is 22-08-2023	Paragon balloon guide catheter family Balloon guide catheter Class: D MD group: Kit Shelf life: 03 Years Codes & Sizes Not mentioned Fee Challan No.: 525307050450 PKR: 50,000/-	Deferred for submission of the following: Fee as per new SRO which is Rs.100, 000/-, Revised Form-7A with complete information along with the manufacturer name, FSC of the country of origin, FQA & design Examination Certificate of the china (from the product will be imported),LOA issued by the product license holder,
300.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity (<i>country of origin</i>): 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	EyeDIFF Plus Foldable Hydrophilic Acrylic Intraocular Lens (Sterile) Class: C MD group: Family Shelf life: 03 Years Codes & Sizes EyeDIFF-R, EyeDIFF-R1, EyeDIFF-R2, EyeDIFF-P, EyeDIFF-P1, EyeDIFF-P Fee Challan No.: 186603430046 PKR: 62000/-	Approved for EyeDIFF-R1, EyeDIFF-R2 (as family) subject to submission of fee of Rs. 100,000/- as per new SRO.
301.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026.	EyeGel 2% & EyeGel Plus 2.4% Hydroxypropyl Methyl Cellulose Ophthalmic Solution USP Class: C MD group: Family Shelf life: 03 Years Codes & Sizes EyeGel 2% (2mL PFS; 5mL vial) EyeGel Plus 2.4% (2mL PFS; 5mL vial)	Approved (as family) subject to submission of fee of Rs. 100,000/- as per new SRO.

		LOA Validity: 12-08-2026	Fee Challan No.: 7315074849 PKR: 62000/-	
302.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	Hiluron 1% and Hiluron 1.4% Sodium Hyaluronate Ophthalmic Solution Class: C MD group: Family Shelf life: 02 Years Codes & Sizes Hiluron 1% (1mL PFS), Hiluron 1.4% (1mL PFS) Fee Challan No.: 3450978204 PKR: 62000/-	Approved (as family) subject to submission of fee of Rs. 100,000/- as per new SRO.
303.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	Ultima Foldable Hydrophilic Acrylic Intraocular Lens (Sterile) Class: C MD group: Family Shelf life: 36 Months Codes & Sizes: Ultima Fee Challan No.: 7221505180 PKR: 62000/-	Approved.
304.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	Hyflex-Y Foldable Hydrophobic Acrylic Intraocular Lens (Sterile) Class: C MD group: Single Shelf life: 05 Years Codes & Sizes Hyflex Yellow (preloaded) Fee Challan No.: 36705241 PKR: 62000/-	Approved
305.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity:	Hyflex Foldable Hydrophobic Acrylic Intraocular Lens (Sterile) Class: C MD group: Single Shelf life: 05 Years Codes & Sizes Hyflex Aspherical	Approved

		extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	(preloaded) Fee Challan No.: 3870614869 PKR: 62000/-	
306.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	Gold Foldable Hydrophilic Acrylic Intraocular Lens (Sterile) Class: C MD group: Family Shelf life: 03 Years Codes & Sizes Gold, Gold (4L), Gold (4L6) Fee Challan No.: 2661187626 PKR: 62000/-	Approved
307.	M/s Akash Traders, 07 Hina Place, Hoshing Road, Civil Line, Clifton, Karachi (ELI-00585)	Legal Manufacture & Site: M/s Eyeol UK Ltd., 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB FSC Validity: 27-05-2025 (MHRA) EC Certificate validity: extension letter attached ISO 13485 Certificate validity: 21-08-2026. LOA Validity: 12-08-2026	Eyeol Foldable Foldable Hydrophilic Acrylic Intraocular Lens (Sterile) Class: C MD group: Family Shelf life: 03 Years Codes & Sizes LW6125, LW5752R, LW625A, LWMF, F611 Fee Challan No.: 92575688335 PKR: 62000/-	Approved
308.	M/s Sultan sons, 133 Kutchi Gali#1, Marriott Road, Karachi (ELI-00051)	M/s Zhanjiang Star Enterprise Co., Ltd., No.1, West Jinhua Road, Mazhang District, 524049 Zhanjiang and P.R. China FSC Validity <i>(country of origin):</i> 13-01-2025 (China) EC Certificate validity: 16-05-2024 extension letter attached ISO 13485 Certificate validity: 31-08-2025. LOA Validity: 31-12-2029	Classic Disposable Endotracheal Tube Sterile, Without Cuff Class: B MD group: Single Shelf life: 05 Years Codes & Sizes 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm 9.5mm, 10.0mm Fee Challan No.: 6655423693,PKR: 31000/-	Approved subject to submission of fee of Rs. 50,000/- as per new SRO.
309.	M/s Ontech Corporation, B-154, Block 13-D/2, Gulshan-e-Iqbal, Karachi	M/s CMR Surgical Limited, 1 Evolution Business Park, Milton Road, Impington, Cambridge CB24 9NG, UK	vLimelite [Surgeon Console, Camera Head with NIR Function, Endoscope 30 degree with NIR Function,	Approved as system.

	(ELI-00289)	FSC Validity: 14-03-2025 (MHRA) QMS Certificate (MDR) validity: 09-01-2028 ISO 13485 Certificate validity: 23-09-2024. LOA Validity: 31-03-2027	Endoscope 0 degree with NIR function, Light Source communication cable, Class: C MD group: System Shelf life: N/A Codes & Sizes: V-SS-1000, 90911, 90909,90910,90912/5,90912/10 Fee Challan No.: 025226268932 PKR: 100,000/-	
310.	M/s Taj Diagnostics Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi. (ELI-00589)	M/s GeneSign Biotech (Xiamen) Co., Ltd. Unit 03, 8th Floor, Building B14, Xiamen Biomedical Industrial Park, 2076 Wengjiao West Road, Haicang District, Xiamen 361022, P.R.China LOA Validity: 03-08-2028 FSC Validity <i>(China):</i> 24-10-2025 FSC Validity <i>(Spain):</i> Issued on 30-01-2024 EC Certificate Not provided ISO 13485 Certificate validity: 27-07-2024	Genesign (Genesign Malaria Pf/Pan Antigen Rapid Test) Class: C MD group: Kit Shelf life: 2 Years Codes & Sizes: GS110403 Fee Challan No.: 03337676 PKR: 50,000/-	Approved
311.	M/s Taj Diagnostics Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi. (ELI-00589)	M/s GeneSign Biotech (Xiamen) Co., Ltd. Unit 03, 8th Floor, Building B14, Xiamen Biomedical Industrial Park, 2076 Wengjiao West Road, Haicang District, Xiamen 361022, P.R.China LOA Validity: 03-08-2028 FSC Validity <i>(China):</i> 24-10-2025 FSC Validity <i>(Spain):</i>	Genesign (Respiratory Combo Antigen Rapid Test) Class: C MD group: Kit Shelf life: 2 Years Codes & Sizes: GS110403 Fee Challan No.: 747966260460 PKR: 50,000/-	Approved

		<p>Issued on 30-01-2024</p> <p>EC Certificate Not provided</p> <p>ISO 13485 Certificate validity: 27-07-2024</p>		
312.	<p>RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)</p> <p>Date of Application: 03-06-2024</p>	<p>United Orthopedic Co., Ltd No57, Park Ave.2 Science Park Hsinchu city Taiwan</p> <p>CFG (FSC issued by US FDA) valid till 04-03-2026.</p> <p>FSC of Taiwan issued on 25- 12-2023. & issued on 24-07- 2023</p> <p>FQA valid till 26-05-2024.</p> <p>ISO 13485 valid till 26-09- 2026.</p> <p>Design Examination Certificate valid till 26-05- 2024.</p> <p>LOA valid upto 31-12-2025</p>	<p>U-motion II Cementless/linear cups</p> <p>MD group: Family</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p> <p>Fee Challan No.: 3214037019 PKR: 50,000/-</p> <p>Sizes/Codes: As per FSC/CFG issued by USFDA</p>	<p>Approved in Class-D subject to submission of fee of Rs. 100,000/- as per the new SRO.</p>
313.	<p>RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)</p> <p>Date of Application: 03-06-2024</p>	<p>United Orthopedic Co., Ltd No57, Park Ave.2 Science Park Hsinchu city Taiwan</p> <p>CFG (FSC issued by US FDA) valid till 04-03-2026.</p> <p>FSC of Taiwan issued on 25- 12-2023. & issued on 24-07- 2023</p> <p>FQA valid till 26-05-2024.</p> <p>ISO 13485 valid till 26-09- 2026.</p> <p>Design Examination Certificate valid till 26-05- 2024.</p> <p>LOA valid upto 31-12-2025</p>	<p>U2-Hip Total Hip Replacement</p> <p>MD group: Family</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p> <p>Fee Challan No.: 214467829 PKR: 50,000/-</p> <p>Sizes/Codes: As per FSC/CFG issued by USFDA</p>	<p>Approved in Class-D subject to submission of fee of Rs. 100,000/- as per the new SRO.</p>
314.	<p>RECH International 247/B Block 6 PECHS Yaseen Suleman Street</p>	<p>Shandong Weigao Orthopedics Devices Company Limited</p>	<p>Cgaes Cgaes</p>	<p>Approved subject to submission of the following:</p>

	Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257	Address: NO.26 Xiangjiyang Road, tourist resort, Weihei city Shandong Province, China LOA submitted valid till 15- 11-2027. FSC (china) valid till 28-09- 2024. FQA provided valid till 26- 05-2024.	MD group: Family Class C Shelf life 5 Years Fee 50,000/- Fee Challan No.: 49559614099 PKR: 50,000/- Sizes/Codes: As per FSC	Clarification regarding the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017, Stability study data, valid ISO 13485
315.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257	Manufacturer (Legal & Manufacturing Site) Shandong Weigao Orthopedics Devices Company Limited Address: NO.26 Xiangjiyang Road, tourist resort, Weihei city Shandong Province, China LOA submitted valid till 15- 11-2027. FSC (china) valid till 20-08- 2025. FQA provided valid till 26- 05-2024. ISO 13485 expired on 30-04- 2024.	Intra Madulary Nail System MD group: Family Class C Shelf life 5 Years Fee 50,000/- Fee Challan No.: 779480179621 PKR: 50,000/- Sizes/Codes: As per FSC	Approved subject to submission of the following: Clarification regarding the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017, Stability study data, valid ISO 13485
316.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257	Manufacturer (Legal & Manufacturing Site) Arthrex Inc. 1370 Creekside Boulevard Naples 34108- 1945 USA LOA submitted valid till 31- 06-2027 FSC (CFG issued by USFDA) valid till 07-03- 2024. EU QMS (MDR) provided valid till 07-03-2027. FQA provided valid till 26- 05-2024. ISO 13485 expired on 21-11- 2025.	Button and sutures MD group: not mentioned Class C Shelf life 5 Years Fee 50,000/- Fee Challan No.: 9421425755 PKR: 50,000/- Sizes/Codes: As per FSC	Approved subject to submission of the following: Clarification regarding the the MD group, & mentioning the specific product name along with the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017, Stability study data, valid ISO 13485, LOA issued by the product license holder
317.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257	Manufacturer (Legal & Manufacturing Site) Arthrex Inc. 1370 Creekside Boulevard Naples 34108- 1945 USA LOA submitted valid till 30- 06-2027 FSC (CFG issued by USFDA) valid till 07-03- 2024. EU QMS (MDR) provided valid till 07-03-2027.	Orthopedic Surgical Devices and accessories Plates, Wedges and screw for orthopedic MD group: not mentioned Class C Shelf life Not mentioned Fee 50,000/- Fee Challan No.:	Approved subject to submission of the following: Clarification regarding the the MD group, & mentioning the specific product name along with the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017,

		FQA provided valid till 26-05-2024. ISO 13485 expired on 21-11-2025.	548782081166 PKR: 50,000/- Sizes/Codes: As per FSC	Stability study data, valid ISO 13485, LOA issued by the product license holder
318.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)	Manufacturer (Legal & Manufacturing Site) Arthrex Inc. 1370 Creekside Boulevard Naples 34108-1945 USA LOA submitted valid till 30-06-2027 FSC (CFG issued by USFDA) valid till 07-03-2024. EU QMS (MDR) provided valid till 07-03-2027. ISO 13485 expired on 21-11-2025. Design Examination Certificate valid till 26-05-2024	The Collateral Ligament Reconstruction Set (Bio Absorbable Screw and pins) MD group: not mentioned Class C Shelf life: Not mentioned Fee 50,000/- Fee Challan No.: 3407969169 PKR: 50,000/- Sizes/Codes: As per FSC	Approved subject to submission of the following: Clarification regarding the correct classification, specify the MD group, & mentioning the specific product name along with the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017, Stability study data, valid ISO 13485, LOA issued by the product license holder
319.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)	Manufacturer (Legal & Manufacturing Site) Arthrex Inc. 1370 Creekside Boulevard Naples 34108-1945 USA LOA submitted valid till 30-06-2027 FSC (CFG issued by USFDA) valid till 24-04-2024. FQA provided valid till 07-03-2027. ISO 13485 expired on 21-11-2025.	Electrosurgical Device MD group: Set Class C Shelf life: Not mentioned Fee 50,000/- Fee Challan No.: 3407969169 PKR: 50,000/- Sizes/Codes: As per FSC	Approved subject to submission of the following: Clarification regarding the correct classification, specify the MD group, & mentioning the specific product name along with the codes/sizes of the product as per the FSC along with justification for categorization as family as per MDR 2017, Stability study data, valid ISO 13485, LOA issued by the product license holder
320.	M/s Rech International, 247/B, Block 6, PECHS, Karachi (ELI-0257)	Legal Manufacturer & Site: Biomet France Plateau de Lautangne 26000 Valence France FSC (France) dated 06-05-2024. ISO 13485 valid 19-08-2027 LOA Validity: 14-10-2027 EC Certificate (FQA) validity: 26-05-2024 Design Examination Certificate valid till 26-05-2024	Refobacin Bone Cement Bone Cemen Class: D MD group: Family Shelf life: 05 Years Codes & Sizes as per FSC (France) Fee challan No.: 8874171983 PKR: 62,000/- Dated: 24-12-2024	Approved subject to submission of fee of Rs. 100,000/- as per new SRO and stability study data.
321.	(ELI-01225) Name: M/s Biocept Intl Co	Legal Manufacturer: AE Health Limited Manufacturing Site:	AE Health Reagents for Aerc-3 Hematology Analyzer (Diluent, Lyse Prob cleaner)	Approved.

	<p>Address: 28-29 A/EI Old FCC Gulberg 3, Lahore</p>	<p>Floor 11, Building 1B, BTR Technology Park, Longitan Street, Pingshan District, Shenzhen, P.R. China</p> <p>FSC: China Validity: 03-12-2026</p> <p>LOA Validity: 30-11-2026</p> <p>CE Certificate Validity: 15-04-2026</p> <p>ISO 13485: Validity: 02-06-2026</p>	<p>Class- B</p> <p>Shelf Life: 2 years</p> <p>Sizes:</p> <p>Diluent 20 L, Lyse 500 ml & 1L, Probe Cleaner 50ml,100ml,250ml</p>	
322.	<p>(ELI-01225)</p> <p>Name: M/s Biocept Intl Co</p> <p>Address: 28-29 A/EI Old FCC Gulberg 3, Lahore</p>	<p>Legal Manufacturer: AE Health Limited</p> <p>Manufacturing Site: Floor 11, Building 1B, BTR Technology Park, Longitan Street, Pingshan District, Shenzhen, P.R. China +86 176 88400403 https://m.aehealthgroup.com</p> <p>FSC: China Validity: 03-12-2026</p> <p>LOA Validity: 30-11-2026</p> <p>CE Certificate Validity: 15-04-2026</p> <p>ISO 13485: Validity: 02-06-2026</p>	<p>AE Health Reagents for Aerc-5 Hematology Analyzer (Diff Diluent, Diff Lyse, LH Lyse, Diff Cell Cleaner)</p> <p>Class- B</p> <p>Shelf Life: 2 years</p> <p>Sizes:</p> <p>Diluent 20 L, Lyse 500 ml & 1L, LH Lyse 50ml, 100ml & 200ml, Cell Cleaner 30ml, 50ml,100ml</p>	Approved.
323.	<p>(ELI-01225)</p> <p>Name: M/s Biocept Intl Co</p> <p>Address: 28-29 A/EI Old FCC Gulberg 3, Lahore</p>	<p>Legal Manufacturer: AE Health Limited</p> <p>Manufacturing Site: Floor 11, Building 1B, BTR Technology Park, Longitan Street, Pingshan District, Shenzhen, P.R. China +86 176 88400403 https://m.aehealthgroup.com</p> <p>FSC: China Validity: 03-12-2026</p>	<p>AE Health Aerc-3 Hematology Analyzer (Hematology Analyzer)</p> <p>Class- A</p> <p>Service Life: 10 Years</p> <p>Codes/Sizes:</p> <p>As per FSC</p>	Approved.

		<p><u>LOA</u> Validity: 30-11-2026</p> <p><u>CE Certificate</u> Validity: 15-04-2026</p> <p><u>ISO 13485:</u> Validity: 02-06-2026</p>		
324.	<p>(ELI-01225)</p> <p><u>Name:</u> M/s Biocept Intl Co</p> <p><u>Address:</u> 28-29 A/EI Old FCC Gulberg 3, Lahore</p>	<p><u>Legal Manufacturer:</u> AE Health Limited</p> <p><u>Manufacturing Site:</u> Floor 11, Building 1B, BTR Technology Park, Longitan Street, Pingshan District, Shenzhen, P.R. China +86 176 88400403 https://m.aehealthgroup.com</p> <p><u>FSC:</u> China Validity: 03-12-2026</p> <p><u>LOA</u> Validity: 30-11-2026</p> <p><u>CE Certificate</u> Validity: 15-04-2026</p> <p><u>ISO 13485:</u> Validity: 02-06-2026</p>	<p>AE Health Aerc-5 Hematology Analyzer</p> <p>(Hematology Analyzer)</p> <p><u>Class- A</u></p> <p><u>Service Life: 10 Years</u></p> <p><u>Codes/Sizes:</u> As per FSC.</p>	Approved.
325.	<p>(ELI-01225)</p> <p><u>Name:</u> M/s Biocept Intl Co</p> <p><u>Address:</u> 28-29 A/EI Old FCC Gulberg 3, Lahore</p>	<p><u>Legal Manufacturer:</u> Infitek Co Ltd</p> <p><u>Manufacturing Site:</u> Room 2014 Building 3, Ligaguojihuayuan No 1222, West Aoti Road, Lixia District, Jinan, Shandong, China</p> <p><u>FSC:</u> China Validity: 25-12-2026</p> <p><u>LOA</u> Validity: 06-12-2026</p> <p><u>CE Certificate</u> Validity: 15-07-2026</p> <p><u>ISO 13485:</u> Validity: 07-11-2026</p>	<p>Infitek HEMA D6190 Hematology Analyzer</p> <p><u>Class- A</u></p> <p><u>Service Life: 10 Years</u></p> <p><u>Codes/Sizes:</u> As per FSC.</p>	Approved.
326.	M/s MICROPORT SCIENTIFIC	<u>Legal Manufacturer:</u> <u>Name:</u>	<u>Name of Medical device</u> Toumai Endoscopic Surgical	Approved

<p>PAKISTAN (PRIVATE) LIMITED Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town</p> <p>(ELI-01182)</p> <p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 43852176312 PKR: 180000/-</p> <p>No of cat: 36</p>	<p>M/s Shanghai MicroPort MedBot (Group) Co., Ltd</p> <p>Room 101, Zone B, Building 1, No. 1601, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China</p>	<p>System- MT1000 with components</p> <p>Class: C MD group: System</p> <p>LOA Validity: 1-Sep-2029 FSC Validity: China- Date of validity 16-March-2026 Netherland- validity 18 June 2028</p> <p>Codes:</p> <p>Cat No:</p> <p>Endoscopic Surgical System-MT1000,Endoscope Adapter-ECO857,Surgeon console-MSS810, Patient Platform-SSS800, Vision Platform-VS820, Trocar Adapter-TRA8507, TRA8547, 3D Electronic Endoscope-EL824/30°, EL824/0°, ELW824/30°, Endoscopic Imaging Processor-MVS828, Single Use Scissors Tip Cover Accessory-UAS8543, Bipolar HF Instrument Cord-EID841C, Monopolar HF Instrument Cord- EIS841B, EIS2841G, Emergency Release Tool-IER8509, Instrument Sterilizing Tray-IST8544, Accessory Sterilizing Tray-AST8546, Endoscope Sterilizing Tray-EST8545, Needle driver-IN8031/8mm, Fenestrated Bipolar Forceps-IN8033/8mm, Monopolar Curved Scissors-IN8035/8mm, Maryland Bipolar Forceps-IN8036/8mm, Permanent Cautery Spatula-IN8037/8mm, Large Needle Driver-IN8038/8mm, Claw Forceps-IN8039/8mm, Cadiere Forceps-IN803A/8mm, Strong Cadiere Forceps-IN803B/8mm, Ultrasound Shears-IN803C/8mm, Tenaculum Forceps-IN803D/8mm, Small Scissors Needle Driver--IN803E/8mm, Large Scissors Needle Driver-IN803F/8mm, Medium-large</p>	
--	--	---	--

			<p>Clip Applier- IN803G/8mm, Large Clip Applier- IN803H/8mm, Small Monopolar Cautery Hook- IN803J/8mm, Micro Needle Driver- IN803M/8mm</p> <p>Shelf life: NA</p>	
327.	<p>M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE) LIMITED Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town</p> <p>(ELI-01182)</p> <p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 8536709702 PKR: 50000/-</p> <p>No of cat no: 16</p>	<p>Legal Manufacturer: Name: M/s Shanghai MicroPort MedBot (Group) Co., Ltd</p> <p>Address of manufacturer: Room 101, Zone B, Building 1, No. 1601, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China</p> <p>Site 1 for Design and development, Production, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, Zone A, 3rd basement, Building 11, No. 2585, Zuchongzhi Road, No. 1661, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China</p> <p>Site 2 for Design and Development, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, 2nd Floor, Building 4, No. 128, Dieqiao Road, Pudong New district Shanghai 201315 China</p>	<p><u>Toumai SURGICAL TROCAR</u></p> <p>Class: B MD group: Set</p> <p>LOA Validity: 1-Sep-2029 FSC Validity: China- Date of validity 16- March-2026 Netherland- validity 18 June 2028</p> <p>Codes:</p> <p>Force Presentation Trocar- TRF85D / 14mm Instrument Trocar Cannula- TFSP8529 95 112 Endoscope Trocar Cannula- TESP8530 11 107 Instrument Trocar Cannula, Long- TFLP8531 95 143 Endoscope Trocar Cannula, Long- TELP8532 11 138 Instrument Trocar Cannula (No Air Valve)- TFSPN8533 95 112 Instrument Trocar Cannula (No Air Valve), Long- TFLPN8534 95 143 Blunt Instrument Trocar Puncture Needle- TFSNO8537 Blunt Instrument Trocar Puncture Needle, Long- TFLNO8538 Blunt Endoscope Trocar Puncture Needle- TESNO8541 Blunt Endoscope Trocar Puncture Needle, Long- TELNO8542 Force Presentation Trocar Cannula- TRF85D Force Presentation Trocar Puncture Needle- TRFON8523 Instrument Trocar Sealing Cap (8 mm)- ISC8513</p>	Approved

			Endoscope Trocar Sealing Cap (10 mm)- ESC8514 Instrument Trocar Sealing Cap (5 mm)- ISC8524 Shelf life: NA	
328.	<p>M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE) LIMITED Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town (ELI-01182)</p> <p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 368544797 PKR: 6000/-</p>	<p>Legal Manufacturer: Name: M/s Shanghai MicroPort MedBot (Group) Co., Ltd</p> <p>Address of manufacturer: Room 101, Zone B, Building 1, No. 1601, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China</p> <p>Site 1 for Design and development, Production, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, Zone A, 3rd basement, Building 11, No. 2585, Zuchongzhi Road, No. 1661, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China</p> <p>Site 2 for Design and Development, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, 2nd Floor, Building 4, No. 128, Dieqiao Road, Pudong New district Shanghai 201315 China</p>	<p>DFVision Medical Cold Light Source</p> <p>Class: A MD group: Single</p> <p>LOA Validity: 1-Sep-2029 FSC Validity: China- Date of validity 16-March-2026 Netherland- validity 18 June 2028</p> <p><u>Code</u> Model- CLS-2000</p> <p><u>Expiry: 5 years</u></p>	Approved
329.	<p>M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE) LIMITED Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town (ELI-01182)</p>	<p>Legal Manufacturer: Name: M/s Shanghai MicroPort MedBot (Group) Co., Ltd</p> <p>Address of manufacturer: Room 101, Zone B, Building 1, No. 1601, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China</p>	<p>Toumai Column Sterile Drape</p> <p>Class: A MD group: Single</p> <p>LOA Validity: 1-Sep-2029 FSC Validity: China- Date of validity 16-March-2026 Netherland- validity 18 June 2028</p> <p><u>Code</u></p>	Approved

	<p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 49404707050 PKR: 6000/-</p>	<p>Site 1 for Design and development, Production, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, Zone A, 3rd basement, Building 11, No. 2585, Zuchongzhi Road, No. 1661, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China</p> <p>Site 2 for Design and Development, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, 2nd Floor, Building 4, No. 128, Dieqiao Road, Pudong New district Shanghai 201315 China</p>	<p>CB8502</p> <p><u>Expiry: 2.5 years</u></p>	
330.	<p>M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE) LIMITED Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town (ELI-01182)</p> <p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 3722119714 PKR: 6000/-</p>	<p>Legal Manufacturer: Name: M/s Shanghai MicroPort MedBot (Group) Co., Ltd</p> <p>Address of manufacturer: Room 101, Zone B, Building 1, No. 1601, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, 201203, China</p> <p>Site 1 for Design and development, Production, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01, Zone A, 3rd basement, Building 11, No. 2585, Zuchongzhi Road, No. 1661, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China</p> <p>Site 2 for Design and Development, manufacture and distribution: Shanghai MicroPort MedBot (Group) Co., Ltd. Room 01,</p>	<p>Toumai Instrument Arm Sterile Drape</p> <p>Class: A MD group: Single</p> <p>LOA Validity: 1-Sep-2029 FSC Validity: China- Date of validity 16-March-2026 Netherland- validity 18 June 2028</p> <p><u>Code</u> AB8501</p> <p><u>Expiry: 2.5 years</u></p>	Approved

		2nd Floor, Building 4, No. 128, Dieqiao Road, Pudong New district Shanghai 201315 China		
331.	<p>M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE) LIMITED</p> <p>Address of Importer Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton, Karachi, South, Saddar town</p> <p>(ELI-01182)</p> <p>R&I Dated: Submission date: 6-12-2024</p> <p>Fee Challan No.: 425329860 PKR: 100000/-</p>	<p>Legal Manufacturer: Name: M/s Shanghai MicroPort CardioFlow Medtech Co., Ltd</p> <p>Address of manufacturer: Room 1002, Area A and Area B of G Floor (Nominal Floor G Floor, Actual Floor 1 Floor), Area A of Second Floor (Nominal Floor 2 Floor, Actual Floor 3 Floor), Building 1, 1601 Zhangdong Road, Shanghai Free Trade Pilot Area, China</p>	<p>Name of Medical device VitaFlow Liberty™ Transcatheter Aortic Valve System</p> <p>Class: D MD group: System</p> <p>LOA Validity: 20-Feb-2028 FSC Validity: China- Date of validity June-22-2024 CE Attached- 1-April-2029</p> <p>Shelf life: 2 years Codes:</p> <p>Cat No:</p> <p>Vitaflow Liberty Aortic Valve TAV21, TAV24, TAV27, TAV30</p> <p>Vitaflow liberty delivery system (including battery and loading tool)</p> <p>Vitaflow liberty Delivery system DSR21, DSR24, DSR27, DSR30, DSR21-A, DSR24-A, DSR27-A, DSR30-A</p>	Approved
332.	<p>ELI 00373 Muslim Medical Services</p> <p>Office address: 1st Floor of Sky Star Travels,3-Syed Moj Darya Road, Lahore</p> <p>Warehouse address: Basement of Building, S60 R34- Mozang Road, Opp. Total Petrol Pump, Lahore.</p>	<p>Legal Manufacturer: Beurer Gmbh Germany</p> <p>Manufacturing Site: EPS biotechnology corp. No. 8, R&D III, Hsinchu science park, Hsinchu,Taiwan 30077, R.O.C</p> <p>FSC: China Issued on: 29-11-2022</p> <p>LOA Validity: 31-12-2023</p> <p>EC Certificate Validity: 07-04-2026</p>	<p>Beurer 463.04 strips (Blood Glucose test strips)</p> <p>Class C</p> <p>Shelf Life: 18 months</p> <p>Codes/Sizes: As per FSC.</p>	Approved

		ISO 13485 Validity: 29-11-2026		
333.	M/s Bio Sphere Marketing, House 2, Street 4 Adjacent to the best grammar school, Pak Town Chungi Amar Sidhu Lahore Pakistan (ELI-00922)	M/s AEHEALTH LIMITED Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen, China	Laffinite II HbA1c Analyzer Hemoglobin Analyzer HPLC Based Class A Shelf Life: 07 Years	Approved
334.	M/s Health Prior (SMC-Private) Limited, 502, Flat No.03, 5th Floor, Gulberg Green, Islamabad. (ELI-01006)	Legal Manufacturer: JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO..LTD Address: Baisheng Road No.1, Yuwell Industrial Park, DanYang, JiangSu Province, P.R.China, FSC: China Validity: 11-08-2025 LOA Validity: 09-07-2028 CE Certificate Validity: 31-12-2028 ISO 13485 Validity: 04-01-2027	SwiftGluco Strips (Glucose test strips) Class-C Shelf Life: 02 years Codes/Sizes: As per FSC.	Approved. Firm shall submit application form and fee for SwiftGluco Meter.
335.	Platinum Corporation Office address: F-10/7/6 Near Arfeen masjid Barrage Colony Sukkhar Warehouse address: F-10/7/6 Near Arfeen masjid Barrage Colony Sukkhar ELI 00443	Legal Manufacturer: M/s Guangdong Haiou Medical Apparatus Co., Ltd Manufacturing Site: M/s Guangdong Haiou Medical Apparatus Co., Ltd Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong, China Date of R&I 28-02-2024 Last reply submitted: FSC: Country of Origin Issued on: 20-11-2024	Brand Name: Globalseagull (Generic name) (Single use Sterile Syringe) Single Use Class D Shelf Life: 36 months Codes/Sizes: 1ML,2ML, 2.5ML,3ML,5ML, 10ML,20ML, 30ML & 50ML	Approved the product is WHO-Prequalified

		<p><u>FSC:</u> WHO PQS Certified</p> <p><u>LOA</u> Validity: 30-06-2026</p> <p><u>EC Certificate</u> Validity:</p> <p><u>ISO 13485</u> Validity: 17-10-2025</p>		
336.	<p>Platinum Corporation</p> <p>Office address: F-10/7/6 Near Arfeen masjid Barrage Colony Sukkhar</p> <p>Warehouse address: F-10/7/6 Near Arfeen masjid Barrage Colony Sukkhar ELI 00443</p>	<p><u>Legal Manufacturer:</u> M/s Guangdong Haiou Medical Apparatus Co., Ltd</p> <p><u>Manufacturing Site:</u> M/s Guangdong Haiou Medical Apparatus Co., Ltd</p> <p>Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong, China</p> <p><u>Date of R&I</u> 28-02-2024</p> <p><u>Last reply submitted:</u></p> <p><u>FSC:</u> Country of Origin Issued on: 20-11-2024</p> <p><u>FSC:</u> WHO PQS Certified</p> <p><u>LOA</u> Validity: 30-06-2026</p> <p><u>EC Certificate</u> Validity:</p> <p><u>ISO 13485</u> Validity: 17-10-2025</p>	<p>Brand Name: Globalseagull</p> <p>(Generic name)</p> <p>(Auto Disable Syringe with needle) Single Use</p> <p>Class D</p> <p>Shelf Life: 36 months</p> <p>Codes/Sizes: 0.05ML,0.1ML, 0.2ML,0.3ML,0.4ML,0.5 ML,</p>	Approved the product is WHO-Prequalified
337.	<p>Cure Connect Pakistan</p> <p>Plot No. B-204, First Floor, Sector 6-F,</p>	<p>Assure Tech (Hangzhou) Co., Ltd.</p> <p>Building No. 4,</p>	<p>Cure Sure Multifunction Monitor-I ()</p> <p>Class C</p>	Approved

	<p>Mehran Town, Korangi, Karachi Pakistan.</p> <p>(ELI - 01234)</p> <p>R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 2614187945</p>	<p>1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China</p> <p>Manufacturing Sites: Address: Assure Tech (Hangzhou) Co., Ltd 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China</p> <p>Address: Assure Tech (Hangzhou) Co., Ltd Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China</p>	<p>Shelf life: 3 years</p> <p>Codes: MSE-101</p> <p>LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025</p>	
338.	<p>Cure Connect Pakistan</p> <p>Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan.</p> <p>(ELI - 01234)</p> <p>R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 39861114</p>	<p>Assure Tech (Hangzhou) Co., Ltd.</p> <p>Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China</p> <p>Manufacturing Sites: Address: Assure Tech (Hangzhou) Co., Ltd 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China</p> <p>Address: Assure Tech (Hangzhou) Co., Ltd Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China</p>	<p>Cure Sure Immunodeficiency Virus (HIV) 1/2 Rapid Test</p> <p>Class D</p> <p>Shelf life: 3 years</p> <p>Codes & sizes: HIV-W23</p> <p>LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025</p>	Approved
339.	<p>Cure Connect Pakistan</p> <p>Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan.</p> <p>(ELI - 01234)</p> <p>R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 6496704468</p>	<p>Assure Tech (Hangzhou) Co., Ltd.</p> <p>Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China</p> <p>Manufacturing Sites: Assure Tech (Hangzhou) Co., Ltd Address: 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China</p>	<p>Cure Sure Typhoid Antibodies (IgG/IgM) Rapid Test</p> <p>Class C</p> <p>Shelf life: 3 years</p> <p>Codes & sizes: TYP-W23, TYP-P23, TYP-P11, TYP-W11</p> <p>LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025</p>	Approved

		Address: Assure Tech (Hangzhou) Co., Ltd Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China		
340.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234) R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 35975696552	Assure Tech (Hangzhou) Co., Ltd. Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China Manufacturing Sites: Assure Tech (Hangzhou) Co., Ltd Address: 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China Assure Tech (Hangzhou) Co., Ltd Address: Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China	Cure Sure Malaria P.f/Pan Rapid Test Class C Shelf life: 3 years Codes & sizes: MAL-W23M002, MAL- W11M002 LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025	Approved
341.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234) R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 65864004812	Assure Tech (Hangzhou) Co., Ltd. Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China Manufacturing Sites: Assure Tech (Hangzhou) Co., Ltd Address: 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China Assure Tech (Hangzhou) Co., Ltd Address: Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China	Cure Sure H.Pylori Antibodies Rapid Test Class C Shelf life: 3 years Codes & sizes as per FSC LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025	Approved
342.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F,	Assure Tech (Hangzhou) Co., Ltd. Building No. 4,	Cure Sure Dengue IgG/ IgM & NS1 COMBO RAPID TEST	Approved

	<p>Mehran Town, Korangi, Karachi Pakistan.</p> <p>(ELI - 01234)</p> <p>R&I details 18-12-2024 date Fee Rs. 62000/- Slip # 83874816788</p>	<p>1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang PR China</p> <p>Manufacturing Sites: Assure Tech (Hangzhou) Co., Ltd Address: 2-5 Floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang, P. R. China Assure Tech (Hangzhou) Co., Ltd Address: Floor 2-5, No. 66 Building 17, No. 2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang, P. R. China</p>	<p>Class C</p> <p>Shelf life: 3 years</p> <p>Codes & sizes: MI-W42M002</p> <p>LOA validity: 10-09-2029 FSC validity: 27-08-2026 ISO Validity: 28-11-2025</p>	
343.	<p>M/s. Bio Sphere Marketing ELI:00922</p>	<p>Legal Manufacturer: M/s JIANGSU AUDICOM MEDICAL TECHNOLOGY CO., LTD CHINA FSC: USA Validity: 17/10/2025 LOA Validity: 17/07/2028</p>	<p>AUDICOM AC6601 HbA1c Analyzer (HbA1c Analyzer Model AC6601)</p> <p>Class A</p> <p>Service Life: 05 years</p>	Approved.
344.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 12th March 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>FSC: Embassy attested FSC of Germany Issuance date 11.07.2022 17.01.2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 14-12-2025</p> <p>ISO Certificate: Validity 29-06-2026</p>	<p>Elecsys AMH Plus Test Kit</p> <p>Class: C Fees: 50,000/-</p> <p>Shelf life: 15 months at 2 - 8°C</p> <p>1. Elecsys AMH Plus CAT #: 10059516190 Pack size: 100 Tests Shelf life: 15 months at 2 - 8°C</p> <p>2. Elecsys AMH Plus CAT #: 10059524190 Pack size: 100 Tests Shelf life: 15 months at 2 - 8°C</p> <p>3. Calset AMH Plus CAT #: 07957203190 Pack size: 4 x 1.0ml Shelf life: 15 months at 2 - 8°C</p> <p>4. PreciControl AMH Plus CAT #: 07957211190 Pack size: 4 x 2.0 ml Shelf life: 15 months</p>	Approved The firm will submit valid FSc

			at 2 - 8°C	
345.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 18th April 2024</p>	<p>Legal Manufacturer: Roche Diabetes Care GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diabetes Care Inc., 9115 Hague road Indianapolis, Indiana 46250 USA</p> <p>FSC: Sacn copy of embassy attested FSC of Germany Issuance date 22.09.2023 08.01.2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 26-06-2025</p> <p>ISO Certificate: Validity Legal - 31-10-2027 Physical – 01-08-2025</p>	<p>Accu-Chek Instant Test Strips</p> <p>Class: C Fees: 50,000/-</p> <p>Shelf life: 21 months at 4 - 30°C</p> <p>1. Accu-Chek Instant (10 Tests) CAT #: 07819366023 Pack size: 10 Tests Shelf life: 21 months at 4 - 30°C</p> <p>2. Accu-Chek Instant (25 Tests) CAT #: 07819374023 Pack size: 25 Tests Shelf life: 21 months at 4 - 30°C</p> <p>3. Accu-Chek Instant (50Tests) CAT #: 07819382023 Pack size: 50 Tests Shelf life: 21 months at 4 - 30°C</p> <p>4. Accu-Chek Instant (100 Tests) CAT #: 07819404023 Pack size: 100 Tests Shelf life: 21 months at 4 - 30°C</p>	<p>Approved The firm will submit valid FSc</p>
346.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 18th April 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>FSC: FSC of Germany Issuance date 17.01.2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity</p>	<p>Elecsys Anti-HEV IgM Test Kit</p> <p>Class: C Fees: 50,000/-</p> <p>Shelf life: 15 months at 2 - 8°C</p> <p>1. Elecsys Anti-HEV IgM CAT #: 09056246190 Pack size: 100 Tests Shelf life: 15 months at 2 - 8°C</p> <p>2. Elecsys Anti-HEV IgM CAT #: 09056254190 Pack size: 300 Tests Shelf life: 15 months at 2 - 8°C</p>	<p>Approved The firm will submit valid FSc</p>

		14-12-2025 ISO Certificate: Validity 29-06-2027	3. PreciControl Anti-HEV IgM CAT #: 09056289190 Pack size: 16 x 1.0ml Shelf life: 15 months at 2 - 8°C	
347.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 18 th April 2024	<u>Legal Manufacturer:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany <u>Manufacturing Site:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance 17.01.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity 29-06-2027	Elecsys Anti-HEV IgG Test Kit Class: C Fees: 50,000/- Shelf life: 15 months at 2 - 8°C 1. Elecsys Anti-HEV IgG CAT #: 09044639190 Pack size: 100 Tests Shelf life: 15 months at 2 - 8°C 2. Elecsys Anti-HEV IgG CAT #: 09044647190 Pack size: 300 Tests Shelf life: 15 months at 2 - 8°C 3. PreciControl Anti-HEV IgG CAT #: 09044655190 Pack size: 16 x 1.3ml Shelf life: 15 months at 2 - 8°C	Approved The firm will submit valid FSc
348.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)	<u>Legal Manufacturer:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany <u>Manufacturing Site:</u> Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA Date of R&I 24 th May 2024 FSC: FSC of Germany Issuance date 29-03-2023 LOA: Validity 17-01-2026 CE Certificate: Validity	Cobas MTB-RIF/INH Class: C Fees: 50,000/- Shelf life: 24 months at 2 - 8°C 1. Cobas MTB-RIF/INH CAT #: 09040617190 Pack size: 192 Tests Shelf life: 24 months at 2 - 8°C 2. Cobas MTB-RIF/INH Positive Control Kit CAT #: 09040625190 Pack size: 16 x 1 ml Shelf life: 24 months at 2 - 8°C	Approved The firm will submit valid FSc

		14-12-2025 ISO Certificate: Validity Legal - 29-06-2027 Physical – 30-06-2027		
349.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 11 th July 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 02-05-2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity 29-06-2027	MTX (Methotrexate) Class: C Fees: 50,000/- Shelf life: 12 months at 2 - 8°C 1. MTX CAT #: 09230815190 Pack size: 100 Tests Shelf life: 12 months at 2 - 8°C 2. MTX CAT #: 09230785190 Pack size: 100 Tests Shelf life: 12 months at 2 - 8°C 3. MTX Calibrator CAT #: 09533699190 Pack size: 2 x 5 ml Shelf life: 12 months at 2 - 8°C	Approved The firm will submit valid FSc
350.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 09 th Aug 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 22.05.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 23-09-2026 13-03-2028 ISO Certificate: Validity	Roche Cardiac POC NT-proBNP Class: C Fees: 50,000/- Shelf life: 1. 12 months at 2 - 8°C 2. 18 months at 2 - 8°C 1. Roche Cardiac POC NT-proBNP CAT #: 09213074190 Pack size: 10 Tests Shelf life: 12 months at 2 - 8°C 2. Roche Cardiac POC NT-proBNP Control CAT #: 09302344190 Pack size: 2 x 1.0ml Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc

		29-06-2027		
351.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 03rd Oct 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA</p> <p>FSC: FSC of Germany Issuance date 13-06-2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 14-12-2026</p> <p>ISO Certificate: Validity Legal - 29-06-2027 Physical – 30-06-2027</p>	<p>Cobas PIK3CA Mutation Test</p> <p>Class: C Fees: 50,000/-</p> <p>Shelf life: 24 months at 2 - 8°C</p> <p>1. Cobas PIK3CA Mutation Test CAT #: 07003986190 Pack size: 24 Tests Shelf life: 24 months at 2 - 8°C</p>	<p>Approved subject to the for submission of deiffrential fee of RS 12000/- and claricaftion of the manufacturing site as per FSC</p>
352.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 15th Nov 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China</p> <p>FSC: FSC of Germany Issuance date 22.05.2024 22.03.2023</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 14-12-2025</p>	<p>Elecsys CA 15-3 II</p> <p>Class: C Fees: 62,000/-</p> <p>Shelf life: 18 months at 2 - 8°C</p> <p>1. Elecsys CA 15-3 II CAT #: 09755594190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C</p> <p>2. Elecsys CA 15-3 II CAT #: 07027001214 Pack size: 300 Tests Shelf life: 18 months at 2 - 8°C</p>	<p>Approved The firm will submit valid FSc</p>

		ISO Certificate: Validity Legal - 29-06-2027 Physical – 20-10-2025		
353.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: FSC of Germany Issuance date 22.05.2024 06.11.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity Legal - 29-06-2027 Physical – 20-10-2025	Elecsys CA 72-4 Class: C Fees: 62,000/- Shelf life: 21 months at 2 - 8°C 1. Elecsys CA 72-4 CAT #: 09744525190 Pack size: 100 Tests Shelf life: 21 months at 2 - 8°C 2. Elecsys CA 72-4 CAT #: 09005706214 Pack size: 300 Tests Shelf life: 21 months at 2 - 8°C	Approved The firm will submit valid FSc
354.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Validity 22-05-2024 LOA: Validity 17-01-2026 CE Certificate: Validity	Elecsys proBNP II Class: C Fees: 62,000/- Shelf life: 18 months at 2 - 8°C 1. Elecsys proBNP II CAT #: 09744959190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc

		14-12-2025 ISO Certificate: Validity 29-06-2027		
355.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: FSC of Germany Issuance date 22.05.2024 22.03.2023 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity Legal - 29-06-2027 Physical – 20-10-2025	Elecsys total PSA Class: C Fees: 62,000/- Shelf life: 18 months at 2 - 8°C 1. Elecsys total PSA CAT #: 09744860190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 2. Elecsys total PSA CAT #: 08791732214 Pack size: 300 Tests Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc
356.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 15 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 22.05.2024 LOA: Validity 17-01-2026 CE Certificate:	Elecsys Troponin T hs Class: C Fees: 62,000/- Shelf life: 18 months at 2 - 8°C 1. Elecsys Troponin T hs CAT #: 09744754190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc

		Validity 14-12-2025 ISO Certificate: Validity 29-06-2027		
357.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 22.05.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity 29-06-2027	Elecsys Anti-HAV IgM Class: C Fees: 62,000/- Shelf life: 12 months at 2 - 8°C 1. Elecsys Anti-HAV IgM CAT #: 09744991190 Pack size: 100 Tests Shelf life: 12 months at 2 - 8°C	Approved The firm will submit valid FSc
358.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 22-05-2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity 29-06-2027	Elecsys CA 125 II Class: C Fees: 62,000/- Shelf life: 18 months at 2 - 8°C 1. Elecsys CA 125 II CAT #: 09755586190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc

359.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 15th Nov 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China</p> <p>FSC: FSC of Germany Issuance date 22.05.2024 09.03.2022 06.11.2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 14-12-2025</p> <p>ISO Certificate: Validity Legal - 29-06-2027 Physical – 20-10-2025</p>	<p>Elecsys AFP</p> <p>Class: C Fees: 62,000/-</p> <p>Shelf life: 21 months at 2 - 8°C</p> <p>1. Elecsys AFP CAT #: 09731385190 Pack size: 100 Tests Shelf life: 21 months at 2 - 8°C</p> <p>2. Elecsys AFP CAT #: 09015086190 Pack size: 200 Tests Shelf life: 21 months at 2 - 8°C</p> <p>3. Elecsys AFP CAT #: 09015124214 Pack size: 300 Tests Shelf life: 21 months at 2 - 8°C</p>	<p>Approved The firm will submit valid FSc</p>
360.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 13th Nov 2024</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>FSC: FSC of Germany Issuance date 22.05.2024</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity 14-12-2025</p> <p>ISO Certificate:</p>	<p>ISE Internal Standard Gen. 2 conc.</p> <p>Class: C Fees: 62,000/-</p> <p>Shelf life: 24 months at 15 - 25°C</p> <p>1. ISE Internal Standard Gen. 2 conc. CAT #: 09137742190 Pack size: 1 x 510 ml Shelf life: 24 months at 15 - 25°C</p>	<p>Approved The firm will submit valid FSc</p>

		Validity 29-06-2027		
361.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 03 rd Dec 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: FSC of Germany Issuance date 22.05.2024 06.11.2024 LOA: Validity 17-01-2028 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity Legal - 29-06-2027 Physical – 20-10-2025	Elecsys HCG+β Class: C Fees: 62,000/- Shelf life: 18 months at 2 - 8°C 1. Elecsys HCG+β CAT #: 09744428190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 2. Elecsys HCG+β CAT #: 07251025214 Pack size: 300 Tests Shelf life: 18 months at 2 - 8°C	Approved The firm will submit valid FSc
362.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 03 rd Dec 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Issuance date 13.09.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 03-11-2026	Anti-p40 (SP225) Rabbit Monoclonal Primary Antibody Class: C Fees: 62,000/- Shelf life: 24 months at 2-8°C 1. Anti-p40 (SP225) Rabbit Monoclonal Primary Antibody CAT #: 09929649001 Pack size: 50 Tests Shelf life: 24 months at 2-8°C	Approved The firm will submit valid FSc

		ISO Certificate: Validity 29-06-2027		
363.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 24 th Dec 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: FSC of Germany Validity 13.09.2024 LOA: Validity 17-01-2026 CE Certificate: Validity 14-12-2025 ISO Certificate: Validity 29-06-2027	Ventana Kappa and Lambda Dual ISH mRNA Probe Cocktail Class: C Fees: 62,000/- Shelf life: 24 months at 2 - 8°C 1. Ventana Kappa and Lambda Dual ISH mRNA Probe Cocktail CAT #: 08507023001 Pack size: 30 Tests Shelf life: 24 months at 2 - 8°C	Approved The firm will submit valid FSc and stability studies
364.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I: 12 th March 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Molecular Systems, Inc. 1080 US Highway 202, Branchburg, NJ 08876-3771 USA FSC: FSC of Germany Issuance date 31.01.2024 LOA: Validity 17-01-2026 EU technical assessment doc CE Certificate: Validity EU QMS: 28-04-2026 EU Tech.: 08-01-2028 ISO Certificate: Validity	Cobas HEV Test Kit Class: D Fees: 50,000/- Shelf life: 25 months at 2 - 8°C 1. Cobas HEV CAT #: 09040986190 Pack size: 192 Tests Shelf life: 25 months at 2 - 8°C 2. Cobas HEV Control Kit CAT #: 09040889190 Pack size: 16 Kits Shelf life: 25 months at 2 - 8°C	Approved The firm will submit valid FSc including the clarification of brand name

		29-06-2027 30-06-2027		
365.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 09th Sep 2024</p>	<p><u>Legal Manufacturer:</u> Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA</p> <p><u>Manufacturing Site:</u> Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA</p> <p>FSC: FSC of Germany Validity EUA Letter</p> <p>LOA: Validity 17-01-2026</p> <p>CE Certificate: Validity N/A</p> <p>ISO Certificate: Validity 29-06-2027 30-06-2027</p>	<p>Cobas MPXV</p> <p>Class: D Fees: 50,000/-</p> <p>Shelf life: 1. 11 months at 2 - 8°C 2. 12 months at 2 - 8°C</p> <p>1. Cobas MPXV CAT #: 09863338190 Pack size: 192 Tests Shelf life: 11 months at 2 - 8°C</p> <p>2. Cobas MPXV Control Kit CAT #: 09863320190 Pack size: 16 x 1.0 ml Shelf life: 12 months at 2 - 8°C</p>	<p>Deferred for submission of differential fee of RS 12000/- provision of the FSC in the country of origin and design examination certificate</p>
366.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>Date of R&I 03rd Oct 2024</p>	<p><u>Legal Manufacturer:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p><u>Manufacturing Site:</u> Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA</p> <p>FSC: FSC of Germany Validity 12.06.2024</p> <p>LOA: Validity 17-01-2026</p> <p>EU technical documentation CE Certificate: Validity EU QMS: 28-04-2026 EU Tech.: 30-10-2028</p>	<p>Cobas MPX</p> <p>Class: D Fees: 50,000/-</p> <p>Shelf life: 24 months at 2 - 8°C</p> <p>1. Cobas MPX CAT #: 09288538190 Pack size: 24 Tests Shelf life: 24 months at 2 - 8°C</p>	<p>Approved The firm will submit valid FSC</p>

		ISO Certificate: Validity 29-06-2027 30-06-2027		
367.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 13 th Nov 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA FSC: FSC of Germany Issuance date 17.07.2024 LOA: Validity 17-01-2026 EU tech doc CE Certificate: Validity EU QMS: 28-04-2026 EU Tech.: 14-05-2029 ISO Certificate: Validity 29-06-2027	Cobas Malaria Class: D Fees: 62,000/- Shelf life: 1. upto 24 months at 2 - 8°C 2. upto 18 months at 2 - 8°C 1. Cobas Malaria - 192 CAT #: 09352511190 Pack size: 192 Tests Shelf life: upto 24 months at 2 - 8°C 2. Cobas Malaria Control Kit CAT #: 09352520190 Pack size: 4 Kits Shelf life: upto 18 months at 2 - 8°C	Approved subject to submission of 18 months stability studies and FSC in country of origin
368.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I 03 rd Dec 2024	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA FSC: FSC of Germany Issuance date 18.12.2023 LOA: Validity 17-01-2028 CE Certificate: Validity EU QMS: 28-04-2026 EU Tech.: 30-05-2028 ISO Certificate:	Cobas CHIKV/DENV Class: D Fees: 62,000/- Shelf life: upto 24 months at 2 - 8°C 1. Cobas CHIKV/DENV-480 CAT #: 09040650190 Pack size: 480 Tests Shelf life: upto 24 months at 2 - 8°C 2. Cobas CHIKV/DENV Control Kit CAT #: 09040668190 Pack size: 16 Kits Shelf life: upto 24 months at 2 - 8°C	Approved The firm will submit valid FSc

		Validity 29-06-2027		
369.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Embassy attsted FSC: USA valid till 29-03-2024 (LIFECODES LSA Class I) ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	LIFECODES Class I ID Class C Shelf Life: 12 months Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
370.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 29-03- 2024 (LIFECODES LSA Class I) ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	LIFECODES Class II IDv2 Class C Shelf Life: 12 months Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
371.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 29-03- 2024 ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	LIFECODES LSA Class I Class C Shelf Life: 12 months Code:- 265100 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc

372.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 29-03- 2024 (LIFECODES LSA Class I) ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	LIFECODES LSA Class II Class C Shelf Life: 12 months Code:- 265200 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
373.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 29-03- 2024 (LIFECODES LSA Class I) ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	LIFECODES LifeScreen Deluxe Class C Shelf Life: 1PAK2 months Code:- 268215 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
374.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Embassy attstes ed FSC: USA valid till 03-04-2024 ISO valid till 03-01-2024 FQA/CE: N/A LOA valid till 09-07-2027	PF4 IgG assay Class C Shelf Life: 24 months Code:- HAT13G, HAT45G Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
375.	M/s Labserv,	Manufacturer:	LIFECODES HLA-A eRES	Approved

	House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 07-07- 2024 ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	SSO Typing Kit Class C Shelf Life: 24 months Code:- 628913 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	The firm will submit valid FSc
376.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 07-07- 2024 (LIFECODES HLA-A eRES SSO Typing Kit) ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	LIFECODES HLA-B eRES SSO Typing Kit Class C Shelf Life: 24 months Code:- 628917 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
377.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 07-07- 2024 (LIFECODES HLA-A eRES SSO Typing Kit) ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	LIFECODES HLA-C eRES SSO Typing Kit Class C Shelf Life: 24 months Code:- 628921 Date of Submission: 23-01- 2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
378.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA.	LIFECODES HLA-DPA1/B1 SSO Typing Kit Class C Shelf Life: 24 months	Approved The firm will submit valid FSc

	Lic. No. ELI-00105	Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 07-07-2024 (LIFECODES HLA-A eRES SSO Typing Kit) ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	Code:- 628936 Date of Submission: 23-01-2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	
379.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Embassy attested FSC: USA valid till 07-07-2024 (LIFECODES HLA-A eRES SSO Typing Kit) ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	LIFECODES HLA-DQA1/B1 SSO Typing Kit Class C Shelf Life: 24 months Code:- 628930 Date of Submission: 23-01-2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
380.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. Manufacturing Site: Immucor GTI Diagnostics Inc. 20925 Crossroads Circle, Waukesha, WI 53186, USA. FSC: USA valid till 07-07-2024 (LIFECODES HLA-A eRES SSO Typing Kit) ISO valid till 03-01-2024 FQA/CE: 26-05-2025 LOA valid till 09-07-2027	LIFECODES HLA-DRB1 eRES SSO Typing Kit Class C Shelf Life: 24 months Code:- 628925 Date of Submission: 23-01-2024 Fee submitted: Rs. 50,000/- Storage temperature: Keep away from light and Temperature range from 2°C to 8°C	Approved The firm will submit valid FSc
381.	Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. ELI-00105 Date of	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site:	EUROLINE Anti-TO.R.C.H. Profile (IgM) DN 2410-1601-4 M, DN 2410-5001-4 M, DN 2410-6401-4 M Class C	Deferred for submission of the valid FSC along with valid FQA and LOA

	issue:	EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notarsied ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Shelf life 12 months Fee 50000/-	
382.	Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. ELI-00105	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notarsied ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Hepatitis E Virus (HEV) ELISA (IgM) EI 2525-9601 M Class C Shelf life 12 months Fee 50000/-	Deferred for submission of the valid FSC along with valid FQA and LOA
383.	Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. ELI-00105	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notarsied ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Cardiolipin ELISA (IgG) EA 1621-9601 G Class C Shelf life 12 months Fee 50000/-	Deferred for submission of the valid FSC along with valid FQA and LOA
384.	Labserv. House No. B-165/2 Block 3A Gulistan e	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG,	Anti-Dengue Virus Type 1-4 ELISA (IgM) EI 266a-9601-1 M	Deferred for submission of valid FSC along with valid FQA and LOA

	Jauhar, Scheme 36, Karachi. ELI-00105	Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Class C Shelf life 15 months Fee Rs 50000/-	
385.	Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. ELI-00105 Date of issue: 03/08/2018 and valid till 03/08/2023 (5 years). Renewal submitted on 02/08/2023	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025 .	Dengue Virus NS1 ELISA EQ 266a-9601-1 Class C Shelf life 12 months Fee Rs 50000/-	Deferred for submission of the valid FSC along with valid FQA and LOA
386.	Labserv.House No. B- 165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.ELI-00105	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till	Anti-Cardiolipin ELISA (IgM)EA 1621-9601 M Class C Shelf life 12 months Fee 50000/-	Deferred for submission of the valid FSC along with valid FQA and LOA

		26.05.2025		
387.	<p>Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105 Date of issue: 03/08/2018 and valid till 03/08/2023 (5 years). Renewal submitted on 02/08/2023</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024.</p> <p>Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025</p>	<p>Anti-Dengue Virus Type 1-4 ELISA (IgG) EI 266a-9601-1 G Class C Shelf life 15 months Fee 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA</p>
388.	<p>Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of expired FSc of Germany issued on 19.03.2019 Notarsied LOA valid till 31.12.2024.</p> <p>Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025</p>	<p>Anti-EBV-CA ELISA (IgG) EI 2791-9601-1 G Class C Shelf life 12 months Fee Rs 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA. Clarify the brand name as per FSC</p>
389.	<p>Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105 Date of issue: 03/08/2018 and valid till 03/08/2023 (5 years). Renewal submitted on 02/08/2023</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024</p>	<p>Anti-Cardiolipin ELISA (IgA) EA 1621-9601 A Class C Shelf life 12 months Fee Rs 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA</p>

		<p>Notarsied LOA valid till 31.12.2024.</p> <p>Notasried ISO valid till 18.05.2026</p> <p>Copy of FQA valid till 26.05.2025</p>		
390.	<p>Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105 Date of</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024.</p> <p>Notasried ISO valid till 18.05.2026</p> <p>Copy of FQA valid till 26.05.2025</p>	<p>Anti-Chikungunya Virus ELISA (IgG) El 293a-9601 G Class C Shelf life 15 months Fee Rs 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA</p>
391.	<p>Labserv.House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.ELI-00105</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024.</p> <p>Notasried ISO valid till 18.05.2026</p> <p>Copy of FQA valid till 26.05.2025</p>	<p>Anti-β2-Glycoprotien 1 ELISA (IgG) EA 1632-9601 G Class C Shelf life 12 months Fee Rs 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA</p>
392.	<p>Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105 Date of</p>	<p>Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.</p> <p>Manufacturing Site:</p>	<p>Anti-VZV ELISA (IgG) El 2650-9601 G Class C Shelf life 12 months Fee Rs 50000/-</p>	<p>Deferred for submission of the valid FSC along with valid FQA and LOA</p>

	issue: 03	EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 13.03.2019 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025		
393.	Labserv. House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. ELI-00105 Date of issue:	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-β2-Glycoprotien 1 ELISA (IgM) EA 1632-9601 M Class C Shelf life 12 months Fee Rs 50000/-	Deferred for submission of the valid FSC along with valid FQA and LOA
394.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	Legal manufacturer Medtron AG located at Hauptstra be 255 66128 Saarbrücken Germany Manufacturing Site: Medtron AG located at Kreisstraße 152, 66128 Saarbrücken, Germany Date of R&I: 12.02.2024 Embassy attested FSC: Country: Germany Issued on 07.09.2022 (No validity date) FSC: Reference Country: Germany Issued on 07.09.2022 (No validity date) LOA	Accutron HP Model 832 (Contrast Media Injector) Class C Shelf Life: 10 years (service life) Codes/Sizes: 57997 (GMDN Code)	Deferred for submission of valid LOA and service life certfacte

		<p>Validity: issuance date 07.02.2024</p> <p><u>EC Certificate of conformity</u> Validity: 20.01.2024</p> <p><u>ISO 13485</u> Validity: 20.01.2025</p>		
395.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer</u> Medtron AG located at Hauptstra be 255 66128 Saarbrücken Germany</p> <p><u>Manufacturing Site:</u> Medtron AG located at Kreisstraße 152, 66128 Saarbrücken, Germany</p> <p><u>Date of R&I:</u> 12.02.2024</p> <p><u>Embassy attested FSC:</u> Country: Germany Issued on 07.09.2022 (No validity date)</p> <p><u>LOA</u> Validity: issuance date 07.02.2024</p> <p><u>EC Certificate of conformity</u> Validity: 20.01.2024</p> <p><u>ISO 13485</u> Validity: 20.01.2025</p>	<p>Accutron HP-D Model 833 (Contrast Media Injector)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37291 (GMDN Code)</p>	Deferred for submission of notarsied and valid LOA and service life certfacte
396.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Site:</u> Progetti S.R.L. located at Strada Del Rondello, 5-10028 Trofarello, Italy</p> <p><u>Date of R&I:</u> 15.08.2024</p> <p><u>Embassy attested FSC:</u> Country: Italy Issuance date 22.04.2022 (No validity date)</p> <p><u>Notarized LOA</u> Validity: 31.05.2025</p> <p><u>Notarized CE Certificate</u> Validity: 31.12.2028</p>	<p>Rescue SAM (External Defibrillator AED)</p> <p>Class C</p> <p>Shelf Life: 7 years (service life)</p> <p>Codes/Sizes: 17882 (GMDN Code)</p>	Approved

		<u>Notarized ISO 13485</u> Validity: 06.06.2026		
397.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Site:</u> Progetti S.R.L. located at Strada Del Rondello, 5-10028 Trofarello, Italy Date of R&I: 15.08.2024 <u>FSC:</u> Country: Italy Issuance date 22.04.2022 (No validity date) <u>LOA</u> Validity: 31.05.2025 <u>Apostille FOA Certificate</u> Validity: 31.12.2028 <u>ISO 13485</u> Validity: 06.06.2026	PG-907s (Syringe Pump) Class C Shelf Life: 5 years (service life) Codes/Sizes: 13215 (GMDN Code)	Approved
398.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Site:</u> Progetti S.R.L. located at Strada Del Rondello, 5-10028 Trofarello, Italy Date of R&I: 15.08.2024 <u>FSC:</u> Country: Italy Issuance date 22.04.2022 (No validity date) <u>LOA</u> Validity: 31.05.2025 <u>Apostille FOA Certificate</u> Validity: 31.12.2028 <u>ISO 13485</u> Validity: 06.06.2026	PG-807i (Infusion Pump) Class C Shelf Life: 5 years (service life) Codes/Sizes: 13215 (GMDN Code) Fee 50000/-	Approved
399.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.	<u>Legal manufacturer & Site:</u> Progetti S.R.L. located at Strada Del Rondello, 5-10028 Trofarello, Italy Date of R&I: 12.02.2024 <u>FSC:</u>	Rescue Life (External Cardiac Defibrillator) Class C Shelf Life: 10 years (service life)	Approved subject to submission of evidence of Fee of RS 50000/-

	Establishment Licence No.: ELI-000263	Country: Italy Issuance date 22.04.2022 (No validity date) <u>LOA</u> Validity: 31.05.2025 <u>FQA Certificate</u> Validity: 27.05.2024 <u>ISO 13485</u> Validity: 06.06.2026	Codes/Sizes: 17882 (GMDN Code)	
400.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Site:</u> Progetti S.R.L. IStrada Del Rondello, 5-10028 Trofarello, Italy Date of R&I: 12.02.2024 <u>FSC:</u> Country: Italy Issuance date 22.04.2022 (No validity date) <u>LOA</u> Validity: 31.05.2024 <u>FQA Certificate</u> Validity: 27.05.2024 <u>ISO 13485</u> Validity: 06.06.2026	Rescue Life ⁹ (External Cardiac Defibrillator) Class C Shelf Life: 10 years (service life) Codes/Sizes: 17882 (GMDN Code)	Approved subject to submission of the service life certificate
401.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Site:</u> GE Medical Systems LLC, located at 3000 North Grandview Blvd, Waukesha, WI 53188, U.S.A. Date of R&I: 10.01.2024 <u>Embassy attested FSC:</u> Country: U.S.A. Validity: 10.08.2025. <u>Notarized LOA</u> <u>Issue date 3.10.2023</u> Validity: 30.11.2025 <u>CE Certificate</u> Validity: 07.11.2026 <u>ISO 13485</u>	Revolution Apex Plus (Full body CT system) Class C Shelf Life: 30 years (service life) Codes/Sizes: 37618 (GMDN Code)	Approved

		Validity: 17.12.2026		
402.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Site:</u> GE Medical Systems LLC, located at 3000 North Grandview Blvd, Waukesha, WI 53188, U.S.A.</p> <p>Date of R&I: 29.04.2024</p> <p><u>FSC:</u> Country: U.S.A. Validity: 10.08.2025.</p> <p>FSC: Reference Country: U.S.A. Validity: 10.08.2025.</p> <p><u>LOA</u> Validity: 30.11.2025</p> <p><u>Notarized CE Certificate</u> Validity: 07.11.2026</p> <p><u>ISO 13485</u> Validity: 17.12.2026</p>	<p>Revolution Apex Elite (Full body CT system)</p> <p>Class C</p> <p>Shelf Life: 30 years (service life)</p> <p>Codes/Sizes: 37618 (GMDN Code)</p>	Approved
403.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer</u> GE Hangwei Medical Systems Co. Ltd. located at West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, Beijing 100176 China</p> <p>Manufacturing Site GE Medical Systems LLC, located at 3000 North Grandview Blvd, Waukesha, WI 53188, U.S.A.</p> <p>Date of R&I: 29.10.2024</p> <p><u>FSC:</u> Country: Apostille U.S.A. Validity: 10.08.2025.</p> <p>FSC: Reference Country: U.S.A. Validity: 10.08.2025.</p> <p><u>LOA</u> Validity: 30.11.2025</p>	<p>Revolution Apex Select (Full body CT system)</p> <p>Class C</p> <p>Shelf Life: 30 years (service life)</p> <p>Codes/Sizes: 37618 (GMDN Code)</p> <p>Fee 100000/-</p>	Approved subject to submission o the legalized FSC of USFDA , notarsied and valid LOA and ISO 13485or clarify if already submitted

		<p><u>CE Certificate</u> Validity: 12.01.2026</p> <p><u>ISO 13485</u> Validity: 12.11.2026 (China)</p> <p>Validity: 17.12.2026 (U.S.A.)</p>		
404.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Manufacturing Site</u> GE Medical Systems SCS located at 283 Rue De La Miniere 78530 Buc, France</p> <p>Date of R&I: 12.02.2024</p> <p><u>FSC:</u> Country: France Issued on 28.04.2022 (No validity date)</p> <p><u>FSC:</u> Reference Country: embassy attested France Issued on 28.04.2022 (No validity date)</p> <p><u>LOA</u> Validity: 30.11.2025</p> <p><u>CE Certificate</u> Validity: 15.04.2026</p> <p><u>ISO 13485</u> Validity: 20.12.2026</p>	<p>Allia IGS 3 (Stationary Angiographic X-Ray System, digital)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37623 (GMDN Code)</p>	<p>Approved subject to submission o the legalized FSC of USFDA , notarsied and valid LOA and ISO 13485, Ce certfcaite or clarify if already submitted</p>
405.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Site</u> GE Medical Systems SCS located at 283 Rue De La Miniere 78530 Buc, France</p> <p>Date of R&I: 24.04.2024</p> <p><u>Copy of FSC:</u> Country: France Issued on 03.01.2022 (No validity date)</p> <p><u>Copy of LOA</u> Validity: 30.11.2025</p> <p><u>Notarsied CE Certificate</u> Validity: 15.04.2026</p> <p><u>Notarised ISO 13485</u></p>	<p>Allia IGS 7 OR (Stationary Angiographic X-Ray system, Digital)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37623 (GMDN Code)</p>	<p>Approved subject to submission of valid FSC of France and valid LOA</p>

		Validity: 20.12.2026		
406.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Site</u> GE Healthcare Finland Oy located at Kuortaneenkatu 2, FI-00510 Helsinki, Finland.</p> <p>Date of R&I: 09.07.2024</p> <p><u>Embassy attested FSC:</u> Country: Finland Issued on 31.07.2023 (No validity date)</p> <p>Apotille FSC: Reference Country: U.S.A. Validity: 17.07.2025</p> <p><u>Notarised LOA</u> Validity: 30.11.2025</p> <p><u>Notarised CE Certificate</u> Validity: 08.02.2027</p> <p><u>Notarised ISO 13485</u> Validity: 11.11.2026</p>	<p>Carescape Canvas 1000</p> <p>(Single Patient physiologic monitoring system)</p> <p>Class C</p> <p>Shelf Life: 07 years (service life)</p> <p>Codes/Sizes: 33586 (GMDN Code)</p>	Approved
407.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Site</u> GE Healthcare Finland Oy located at Kuortaneenkatu 2, FI-00510 Helsinki, Finland.</p> <p>Date of R&I: 09.07.2024</p> <p><u>Copy of FSC:</u> Country: Finland Issued on 31.07.2023 (No validity date)</p> <p>Copy of FSC: Reference Country: U.S.A. Validity: 17.07.2025</p> <p><u>LOA</u> Validity: 30.11.2025</p> <p><u>CE Certificate</u> Validity: 08.02.2027</p> <p><u>ISO 13485</u> Validity: 11.11.2026</p>	<p>Carescape Canvas Smart Display</p> <p>(Single Patient physiologic monitoring system)</p> <p>Class C</p> <p>Shelf Life: 07 years (service life)</p> <p>Codes/Sizes: 33586 (GMDN Code)</p>	Approved
408.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal,</p>	<p><u>Legal manufacturer & Manufacturing Site</u> GE Hualun Medical Systems Co. Ltd. located at No.1 Yong Chang North Road Beijing Economic Technological Development</p>	<p>Definium Tempo Pro</p> <p>(Stationary basic diagnostic X-Ray System, digital)</p> <p>Class C</p>	Approved subject to submission of valid LOA and ISO 13485, CE certfcaite

	Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	Zone, 100176 Beijing, China Date of R&I: 29.04.2024 <u>Embassy attested d FSC:</u> Country: China Validity: 03.12.2024 Copy FSC: Reference Country: France Issued on 09.11.2021 (No validity date) <u>LOA</u> Validity: 30.11.2025 <u>CE Certificate</u> Validity: 05.12.2026 <u>ISO 13485</u> Validity: 12.11.2026	Shelf Life: 10 years (service life) Codes/Sizes: 37645 (GMDN Code) Fee 50000/-	
409.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Manufacturing Site</u> GE Hualun Medical Systems Co. Ltd. located at No.1 Yong Chang North Road Beijing Economic Technological Development Zone, 100176 Beijing, China Date of R&I: 29.04.2024 <u>FSC:</u> embassy attested Country: China Validity: 03.12.2024 Embassy attested FSC: Reference Country: France Issued on 25.07.2023 (No validity date) <u>LOA</u> Validity: issued on 27.07.20223 Expiry not mentioned <u>Notarized ISO 13485</u> Validity: 12.11.2026	Definium Pace Select (Stationary basic diagnostic X- Ray System, digital) Class C Shelf Life: 10 years (service life) Codes/Sizes: 37645 (GMDN Code)	Approved subject to submission of service life and valid FQA
410.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal,	<u>Legal manufacturer & Manufacturing Site</u> GE Hualun Medical Systems Co. Ltd. located at No.1 Yong Chang North Road Beijing Economic Technological Development	Optima IGS 330 (Stationary angiographic X- ray system, digital) Class C	Approved subject to submission of the FSC of reference country

	<p>Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p>Zone, 100176 Beijing, China</p> <p>Date of R&I: 15.08.2024</p> <p><u>Embassy attested FSC:</u> Country: China Validity: 14.08.2024</p> <p>Copy of FSC: Reference Country: France Issued on 25.10.2021 (No validity date)</p> <p><u>Copy LOA</u> Validity: 30.11.2025</p> <p><u>CE Certificate</u> Validity: 31.12.2028</p> <p><u>ISO 13485</u> Validity: 12.11.2026</p>	<p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37623 (GMDN Code)</p>	
411.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer</u> GE Medical Systems Information Technologies Inc. located at 9900 Innovation Drive, Wauwatosa WI 53226, U.S.A.</p> <p>Manufacturing site: GE Medical Systems (China) Co. Ltd. Located at No.19, ChangJiang Road Wuxi National Hi-tech Development Zone, Jiangsu, China</p> <p>Date of R&I: 25.04.2024</p> <p><u>Embassy attested FSC:</u> Country: France Issued on 28.09.2023 (No validity date)</p> <p>FSC: Reference Country: France Issued on 28.09.2023 (No validity date)</p> <p><u>Notarized LOA</u> Validity: 30.11.2025</p> <p><u>CE Certificate</u> Validity: 30.10.2025</p> <p><u>Notarized ISO 13485 Legal Manufacturer</u></p>	<p>Portrait VSM (Multiple vital physiological parameters monitoring system)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 36872 (GMDN Code)</p>	<p>Approved subject to calrifcaiton of the brand name as per FSC</p>

		Validity: 03.04.2026 Manufacturing Site Validity: 07.05.2026		
412.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer & Site</u> GE OEC Medical Systems Inc. located at 384 Wright Brothers Dr Salt Lake City, UT 84116, U.S.A. Date of R&I: 24.04.2024 <u>FSC:</u> Country: U.S.A. Validity: 14.09.2025 FSC: Reference Country: U.S.A. Validity: 14.09.2025 <u>Notarized LOA</u> Validity: 30.11.2025 <u>Notarized CE Certificate</u> Validity: 26.05.2024 <u>Notarized ISO 13485</u> Validity: 25.09.2024	OEC 3D (Mobile general purpose fluoroscopic X-Ray system, Digital) Class C 22 years (service life) Codes/Sizes: 37646 (GMDN Code)	Approved
413.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	<u>Legal manufacturer</u> Datex Ohmeda Inc. located at 3030 Ohmeda Drive, P.O Box 7550, Madison WI 3707-7550, U.S.A. <u>Manufacturing Site</u> GE Medical Systems (China) Co. Ltd. located at No.19, ChangJiang Road Wuxi National Hi-tech Development Zone, Jiangsu, China Date of R&I: 24.04.2024 <u>FSC:</u> Embassy attested Country: U.S.A. Validity: 23.05.2025 Copy of certificate for exportation Country: China Validity: 20.04.2024 FSC:	Carestation 750c (Anaesthesia Workstation, general purpose) Class C Shelf Life: 07 years (service life) Codes/Sizes: 37710 (GMDN Code)	Deferred for submission of valid noarsied LOA , ISO 13485, FQA and service life

		<p>Reference Country: U.S.A. Validity: 23.05.2025</p> <p><u>Notarized LOA</u> Issuance date Validity: 15.09.2023 (portrait vsm)</p> <p><u>CE FQA Certificate</u> Validity: 26.05.2024</p> <p><u>ISO 13485</u> Validity: 10.07.2024 (U.S.A.)</p> <p>Validity: 07.05.2026 (China)</p>		
414.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Manufacturing Site</u> GE Medical Systems LLC located at 3000 North Grandview Blvd Waukesha, WI 53188, USA</p> <p>Date of R&I: 20.02.2024</p> <p><u>FSC USFDA Apostille:</u> Country: U.S.A. Validity: 10.08.2025</p> <p>FSC: Reference Country: U.S.A. Validity: 10.08.2025</p> <p><u>LOA</u> Validity: 30.11.2025</p> <p><u>Eu Quality Management Certificate</u> Validity: 07.11.2026</p> <p><u>ISO 13485</u> Validity: 17.12.2026</p>	<p>AMX Navigate (X-Ray System, mobile, digital)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37647 (GMDN Code)</p>	<p>Approved subject to submission of attested/notarized and valid LOA</p>
415.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Manufacturing Site</u> Technix S.p.A. located at Via E. Fermi, 45-24050, Grassobbio BG - Italy</p> <p>Date of R&I: 20.02.2024</p> <p><u>Copy of FSC:</u> Country: Italy Issued in 2018 (No validity date)</p>	<p>Traveller (Mobile basic diagnostic X-Ray System, analogue)</p> <p>Class C</p> <p>Shelf Life: 10 years (service life)</p> <p>Codes/Sizes: 37626 (GMDN Code)</p>	<p>Approved subject to submission of the legalized and vlnid FSC and service life certificate for the calimed shelf life</p>

		<p><u>Notarized LOA</u> <u>Issuance date</u> <u>26.01.2024</u> Validity: 30.11.2025</p> <p><u>CE Certificate</u> Validity: 26.05.2024</p> <p><u>ISO 13485</u> Validity: 03.04.2026</p>		
416.	<p>Shirazi Trading Company Private Limited</p> <p>114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Establishment Licence No.: ELI-000263</p>	<p><u>Legal manufacturer & Manufacturing Site</u> Lemer Pax located at 72, Rue De Lorraine 44240 La Chapelle Sur Erdre France</p> <p><u>Date of R&I:</u> 25.04.2024</p> <p><u>Embassy attested FSC:</u> Country: France Issued on 21.01.2023 (No Validity date)</p> <p><u>Notarized LOA</u> Validity: 31.12.2023</p> <p><u>Notarized CE Certificate</u> Validity: 20.04.2027</p> <p><u>Notarized ISO 13485</u> Validity: 17.04.2025</p>	<p>Posijet</p> <p>(Auto FDG Injector)</p> <p>Class C</p> <p>Shelf Life: 06 years (service life)</p> <p>Codes/Sizes: Z1102909 (GMDN Code)</p>	<p>Deferred for the submission of the valid and notarsied LOA</p>
417.	<p>NI Healthcare Products (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi</p> <p>(ELI-01117)</p>	<p>Vincent Medical and Manufacturing Co. Ltd. Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon Hong Kong</p> <p>Vincent medical dongguan technology company limited Address EM 101 and 201 block 10 ist taoyun road songhsan lake zone Dongguan Guangdong PR china Copy of FQA expiry 26.05.2024 Copy of ISO 13485 valid till 16.04.2027 Copy of Apostille certificate for exportation of the medical products valid till 16.02.2025</p>	<p>Vincent / Inspired Humidifier VHB10A</p> <p>Humidifier</p> <p>Class C Shelf life 5 Years Fee 62,000/-</p>	<p>Approved subject to the submission of notarized LoA</p>

		Copy of LOA issued on 1 st December 2024 valid for two years		
418.	NI Healthcare Products (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Vincent Medical and Manufacturing Co. Ltd. Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon Hong Kong Vincent medical dongguan technology company limited Address EM 101 and 201 block 10 1st taoyun road songhsan lake zone Dongguan Guangdong PR china Copy of FQA expiry 26.05.2024 Copy of ISO 13485 valid till 16.04.2027 Original Apostille copy titled certificate for exportation of the medical products valid till 16.02.2025 Notarized LOA issued on 1st December 2024 valid for two years	Vincent / Inspired Heated Wire Breathing Circuits and Kits Heated Breathing Circuits Class C Shelf life 5 Years Fee 62,000/-	Approved subject to the submission of notarized LoA
419.	NI Healthcare Products (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Vincent Medical and Manufacturing Co. Ltd. Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon Hong Kong	Vincent / inspired Humidifier VBH20 Humidifier Class C Shelf life 5 Years Fee 62,000/-	Deferred for clarification of the brand name as per FSC and applied name Also provide FQA. Submit legalized FSC having the applied code
420.	NI Healthcare Products (Pvt) Ltd., A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi	Bio-Med Devices Inc. 61 Soundview Road Guilford, CT 06437, USA Embassy Attested FSC of USFDA valid till 9 th Feb 2025 Notarized LOA valid till 31 dec 2027 ISO valid till 27.7.2025 EU QMS Valid till 8.11.2027	Air/Oxygen Blenders 2002F70D Blender Class C Service life 15 Years Fee 50,000/-	Approved The firm will submit clarification of the brand name as per FSC and applied name And FQA
421.	NI Healthcare Products (Pvt) Ltd., A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi	Bio-Med Devices Inc. 61 Soundview Road Guilford, CT 06437, USA Embassy Attested FSC of USFDA valid till 9 th Feb 2025	Air/Oxygen Blenders 2003 Blender Class C Service life 15 Years Fee 50,000/-	Approved The firm will submit clarification of the brand name as per FSC and applied name And FQA and submit stability studies

		Notarsied LOA valid till 31 dec 2027 ISO valid till 27.7.2025 EU QMS Valid till 8.11.2027		
422.	TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN (ELI-00247)	Shenzhen Le Medical Technology Co., Ltd. 5F, Block A, XInYongFeng Industrial Park, No. 2, TianBao Road, YongrenShi Community, Shiyan Sub- District, Baoan District, Shenzhen, Guangdong Province China Apostille copy titled certificate for exportation of the medical products valid till 05.05.2025 Copy of FSC of Germany issuance date 08.12.2023 Copy of LOA valid till September 2028 Copy of ISO valid till 17.02.2025 FQA valid till 27.05.2024	LE MEDICAL PM 12B PM 12D Patient Monitor Class C Shelf life 3 Years Fee 100,000/-	Approved both model separately subject to submission of legalised and submission of applicable fee and application.
423.	S. Ejazuddin & Co. P.O. Box 5629, 237-B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00078	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain Apostille FSC Of Spain Issue in 30.09.2024 Notarized LOA valid till 30 .09.2025 ISO 13485 23.09.2025 EU QMS Valid till 28.09.2026 EU tech doc 17.01.2028	Serascan Diana 4 Reagent Red Blood Cells used in gel technique for the screening of unexpected antibodies Class D Shelf life 60 days Fee 62,000/-	Approved The firm will submit valid FSC
424.	S. Ejazuddin & Co. P.O. Box 5629, 237-B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00079	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain Apostille FSC Of Spain Issue in 30.09.2024 Notarized LOA valid till 30 .09.2025 ISO 13485 23.09.2025	DG Gel Neutral Gel Card for gel technique for saline and enzymatic tests and as a control microtube. Class C Shelf life 12 Months Fee 62,000/-	Approved The firm will submit valid FSC

		EU QMS Valid till 28.09.2026		
425.	S. Ejazuddin & Co. P.O. Box 5629, 237-B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00080	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain Apostille FSC Of Spain Issue in 30.09.2024 Notarized LOA valid till 30 .09.2025 ISO 13485 23.09.2025 EU QMS Valid till 28.09.2026 EU tech doc 09.05.2028	DG Gel Confirm Gel card for gel technique for confirming the blood groups of the ABO and rh(D) systems in human blood samples. Class D Shelf life 25 Months Fee 62,000/-	Approved The firm will submit valid FSC
426.	S. Ejazuddin & Co. P.O. Box 5629, 237-B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00081	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain Apostille FSC Of Spain Issue in 30.09.2024 Notarized LOA valid till 30 .09.2025 ISO 13485 23.09.2025 EU QMS Valid till 28.09.2026 EU tech doc 17.01.2028	Identisera Diana Reagent Red Blood Cells used in gel technique for the identification of unexpected antibodies, in human blood samples. Class D Shelf life 60 Days Fee 62,000/-	Approved The firm will submit valid FSC
427.	S. Ejazuddin & Co. P.O. Box 5629, 237-B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00082	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain Apostille FSC Of Spain Issue in 30.09.2024 Notarized LOA valid till 30 .09.2025 ISO 13485 23.09.2025 EU QMS Valid till 28.09.2026 EU tech doc 17.01.2028	DG Gel ABO-Rh (2D) Gel card for gel technique for determining the antigens of the ABO and Rh(D) systems and the reverse ABO group, in human blood samples. Class D Shelf life 25 Months When stored at 5°C Fee 62,000/-	Approved subject to submission of valid and notasried Eu tech documentation
428.	Zam Zam Corporation, Suit No. 205, 206,	Laboratorio Innoaesthetics S.L.	INNO-CE BI_DENS 2.5, MOIST 1.5,	Deferred for submission of the separate application for

	Beamount Plaza 6-CL-10, Beamount Road, karachi (ELI-00412)	C/ Point Reixat 3, 08960 Sant Just Desvern Barelona Spain Manufacturer name Laboratorio Innoaesthetics S.L. Carretera de madrid km 261, 4900 Espana Notarized LOA valid till 30.11.2026 Notasried ISO 13485 15.03.2027 Notarsied FQA 27.5.2024 Design examination certificate valid 27.05.2024 Having extension letter	MESHA DEEP, MESHA INTENSE, MESHA ESSENCE, MESHA SMILE and MESHA SCARS Sodium Hyaluronate for intra-dermal use Form: Crosslinked Sodium Hyaluronate 20mg/ml, Sodium Hyaluronate 25mg/ml and 15mg/ml Route of administration: Intradermal Injections Class D Shelf life 3 Years Fee 62,000/-	each code as per MDR 2017 and submit stability studies
429.	3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)	SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021 Notarized LOA valid till 31.12.2026 Notarized ISO 13485 valid till 23.10.2025 EU FQA Valid til 26.05.2024	SGS Double connection conical implant As per FSc P7D-O3.5 P7D-O3.75 P7D-O4.2 P7D-O4.5 P7D-O5 P7D-O6.0 Class C Shelf life N/A Fee 170,000/-	Approved subject to submission of the legalsied and valid FSC and noatrsied FQA
430.	3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)	SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021 Notarized LOA valid till 31.12.2026 Notarized ISO 13485 valid till 23.10.2025 EU FQA Valid til 26.05.2024	SGS Double connection implant As per FSc P5D-O3.5 P5D-O3.75 P5D-O4.2 P5D-O4.5 P5D-O5 P5D-O6.0 Class C Shelf life N/A Fee 170,000/-	Approved subject to submission of the legalsied and valid FSC and noatrsied FQA

431.	<p>3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)</p>	<p>SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary</p> <p>Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021</p> <p>Notarized LOA valid till 31.12.2026</p> <p>Notarized ISO 13485 valid till 23.10.2025</p> <p>EU FQA Valid til 26.05.2024</p>	<p>SGS</p> <p>Ball attachment straight abutment</p> <p>S3</p> <p>Class C</p> <p>Shelf life N/A</p> <p>Fee 100,000/-</p>	<p>Approved subject to submission of the legalised and valid FSC and noatrsied FQA</p>
432.	<p>3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)</p>	<p>SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary</p> <p>Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021</p> <p>Notarized LOA valid till 31.12.2026</p> <p>Notarized ISO 13485 valid till 23.10.2025</p> <p>EU FQA Valid til 26.05.2024</p>	<p>SGS</p> <p>S2</p> <p>Antirotaation Straight Abutment</p> <p>S1</p> <p>Class C</p> <p>Shelf life N/A</p> <p>Fee 100,000/-</p>	<p>Approved subject to submission of the legalised and valid FSC and noatrsied FQA</p>
433.	<p>3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)</p>	<p>SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary</p> <p>Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021</p> <p>Notarized LOA valid till 31.12.2026</p> <p>Notarized ISO 13485 valid till 23.10.2025</p> <p>EU FQA Valid til 26.05.2024</p>	<p>SGS</p> <p>Angular Abutment</p> <p>S2</p> <p>Class C</p> <p>Shelf life N/A</p> <p>Fee 100,000/-</p>	<p>Approved subject to submission of the legalised and valid FSC and noatrsied FQA</p>
434.	<p>3C International, • 1620, Main Double</p>	<p>SGS International Kft. 1047, Budapest, Karolyi</p>	<p>SGS</p>	<p>Approved subject to submission of the legalised</p>

	Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)	Istvan utca 1-3. Hungary Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021 Notarized LOA valid till 31.12.2026 Notarized ISO 13485 valid till 23.10.2025 EU FQA Valid til 26.05.2024	One Piece Implant P9S-Ø2.4-10mm P9S-Ø3.0-8mm P9S-Ø3.2-8mm P9S-Ø3.5-8mm P9S-Ø4.2-8mm P9S-05.0-6mm Class C Shelf life N/A Fee 150,000/-	and valid FSC and noatrsied FQA
435.	3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)	SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021 Notarized LOA valid till 31.12.2026 Notarized ISO 13485 valid till 23.10.2025 EU FQA Valid til 26.05.2024	SGS Narrow Conical Implant P7N-03.0 P7N-03.2 Class C Shelf life N/A Fee 150,000/-	Approved subject to submission of the legalsied and valid FSC and noatrsied FQA
436.	3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad • Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)	SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary Notarized FSC Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021 Notarized LOA valid till 31.12.2026 Notarized ISO 13485 valid till 23.10.2025 EU FQA Valid til 26.05.2024	SGS Healing cap for Implant H Class C Shelf life N/A Fee 100,000/-	Approved subject to submission of the legalsied and valid FSC and noatrsied FQA
437.	3C International, • 1620, Main Double Road, Sector I-10/1, Islamabad	SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3. Hungary Notarized FSC	SGS Transfer T1	Approved subject to submission of the legalsied and valid FSC and noatrsied FQA

	<p>• Office 9, First Floor Awan Plaza G8 Makaz Islamabad Pakistan ,46000 (ELI-00752)</p>	<p>Of Hungary issued by the national institute of pharmacy and nutrition issued on 12.09.2021</p> <p>Notarized LOA valid till 31.12.2026</p> <p>Notarized ISO 13485 valid till 23.10.2025</p> <p>EU FQA Valid til 26.05.2024</p>	<p>T4 T5 T6 T8</p> <p>Class C Shelf life N/A Fee 100,000/-</p>	
438.	<p>Ophthalmic-Tec, Shahrah-e-liaquat haji fazal Ellahi Building opp Women College Karachi</p> <p>(ELI-00310)</p>	<p>Ophthalmic Experts Limited UK, 50 Ripple Road,Barking, Essex, 1G11 7PG, United Kingdom</p> <p>Copy of Notarized MHRA FSC Issuance date 7.01.2019</p> <p>LOA issued 09.12.2023 Valid for 05 years ISO 13485 expired</p>	<p>Xpert</p> <p>PMMA Intra ocular lens Class C Shelf life 5 Years Fee 62,000/-</p>	<p>Deferred for submission of the differential fee of RS 38000/- and noatrsied FQA Clarify the brand anme as per FSC and applied name Submit stability studies Submit legalsied and valid FSC or clarify</p>
439.	<p>Ophthalmic-Tec, Shahrah-e-liaquat haji fazal Ellahi Building opp Women College Karachi</p> <p>(ELI-00310)</p>	<p>Ophthalmic Experts Limited UK, 50 Ripple Road,Barking, Essex, 1G11 7PG, United Kingdom</p> <p>Copy of Notarized MHRA FSC Issuance date 7.01.2019</p> <p>LOA issued 09.12.2023 Valid for 05 years ISO 13485 expired</p>	<p>Xpert</p> <p>Hydrophilic Intraocular IOL</p> <p>Class C Shelf life 5 Years Fee 62,000/-</p>	<p>Deferred for submission of the differential fee of RS 38000/- and noatrsied FQA and ISO 13485 Clarify the brand anme as per FSC and applied name Submit stability studies Submit legalsied and valid FSC or clarify</p>
440.	<p>Ophthalmic-Tec, Shahrah-e-liaquat haji fazal Ellahi Building opp Women College Karachi</p> <p>(ELI-00310)</p>	<p>Ophthalmic Experts Limited UK, 50 Ripple Road,Barking, Essex, 1G11 7PG, United Kingdom</p> <p>Copy of Notarized MHRA FSC Issuance date 7.01.2019</p> <p>LOA issued 09.12.2023 Valid for 05 years ISO 13485 expired before submission</p>	<p>Mestro</p> <p>Hydrophobic Intraocular Lens</p> <p>Class C Shelf life 5 Years Fee 62,000/-</p>	<p>Deferred for submission of the differential fee of RS 38000/- and noatrsied FQA Clarify the brand anme as per FSC and applied name Submit stability studies Submit legalsied and valid FSC or clarify</p>
441.	<p>Sure Bio-Diagnostics & Pharmaceuticals EE-IO, Defence View</p>	<p>Redcell Byoteknoloji A.S. Serifali Mah. BEYIT SOK. No: 66/4 Umraniye / istanbul</p>	<p>Red Cell Blood Grouping Gel Systems</p>	<p>Disposed of as already decided in 76th meeting.</p>

	Phase 11, Near Iqra University, Shaheed-e-Millat Express Way, Karachi (ELI-00084)	Turkiye Notarized LOA Valid till 8 th December 2025 Embassy attested FSC of turkey Issuance date 25.01.2023 Valid for three years. Notarized FQA Valid till 27.05.2024 Notarized Design examination certificate 27.05.2024 Notarized ISO 13485 valid till 22.06.2026	1. Comp / Cross 2. Forward / Reverse Donor 3. Forward AB Plus 4. Forward ABO Patient 5. Newborn 6. Cell reverse A1/B (2x10ml) 7. Rh Phenotype 8. Forward / Reverse 9. Rh Phenotype Plus 10. IgG 11. Neutral / AHG 12. AHG 13. Cell Screen 1-2-3 (3x5ml) 14. Cell ID (11x3ml) Class D Shelf life As per stability study Fee 62,000/-	
442.	Sure Bio-Diagnostics & Pharmaceuticals EE-IO, Defence View Phase 11, Near Iqra University, Shaheed-e-Millat Express Way, Karachi (ELI-00084)	Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Notarized LOA Valid till 31 st December 2025 Notarized by UK and FSC(copy) of France issued on 05.06.2024 Notarized ISO 13485 valid till 17.09.2026 Notarized EU quality management system Valid till 06.06.2027 Notarized EU tech Doc Valid till 28.11.2027	Ortho-Clinical Diagnostics, Inc. Ortho BioVue System Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-D (DVI) (Anti-RH1) (Monoclonal) ABD (DVI) Donor Confirmation Cassettes Ortho Bio Vue System Blood Grouping Reagents Anti-A (Anti-ABO1) (Monoclonal) Anti-B (Anti-ABO2) (Monoclonal) Anti-A,B (Anti-ABO3) (Monoclonal) Anti-D (Anti-RH1) (Monoclonal) Anti-D(DVI) (Anti-RH1) (Monoclonal) Control (DVI) Grouping Cassette) Class D Shelf life As per stability study Fee 62,000/-	Approved
443.	Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)	Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru Notarized LOA valid till 27-10-2025.	Glicosorb Polyglycolic Acid Multifilament Absorbable Sterile Synthetic Sutures Premium Tagum / Glicosorb	Deferred for submission of the notarized FQA and design examination certificate

		<p>Apostille FSC of Peru valid till 30-10-2023.</p> <p>Notarized ISO 13485 valid till 25-10-2024.</p>	<p>Sutures, Synthetic, Absorbable, Polyglycolic Acid</p> <p>Class D Shelf life 5 Years Fee 50,000/-</p>	
444.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru</p> <p>Notarized LOA valid till 27-10-2025.</p> <p>Apostille FSC of Peru valid till 30-10-2023.</p> <p>Notarized ISO 13485 valid till 25-10-2024.</p>	<p>Tagum Braided Polyester Nonabsorbable Sterile Sutures Premium</p> <p>Sutures, Synthetic, Nonabsorbable, Polyester</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of the FQA certificate</p>
445.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru</p> <p>Notarized LOA valid till 27-10-2025.</p> <p>Apostille FSC of Peru valid till 09-02-2023.</p> <p>Notarized ISO 13485 valid till 25-10-2024.</p>	<p>Tagum Chromic Catgut Absorbable Sutures Sterile Premium</p> <p>Sutures, Natural, Absorbable, Surgical Gut</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of the FQA certificate</p>
446.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru</p> <p>Notarized LOA valid till 27-10-2025.</p> <p>Apostille FSC of Peru valid till 23-08-2023.</p> <p>Notarized ISO 13485 valid till 25-10-2024.</p>	<p>Tagum Braided Silk with Silicon Coating Non-Absorbable Sterile Sutures Premium</p> <p>Sutures, Natural, Non-absorbable, Silk</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of the FQA certificate</p>
447.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru</p> <p>Notarized LOA valid till 27-10-2025.</p> <p>Apostille FSC of Peru valid till 04-08-2023.</p> <p>Notarized ISO 13485 valid till 25-10-2024.</p>	<p>Tagum Braided Polyglactin Acid Absorbable Sterile Synthetic Sutures with Premium Needle</p> <p>Sutures, Synthetic, Absorbable, Polyglactin</p> <p>Class D Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of the FQA certificate</p>
448.	<p>Noor International Noor House 29-D</p>	<p>Tagumedica S.A., Av. Maquinarias No. 2414,</p>	<p>Tagum Stainless Steel Non-Absorbable Sterile Sutures</p>	<p>Approved subject to submission of the FQA certificate</p>

	Block 6 PECHS Karachi -75400 (ELI-00061)	Lima- Peru. Notarized LOA valid till 27-10-2025. Apostille FSC of Peru valid till 09-02-2023. Notarized ISO 13485 valid till 25-10-2024.	with Premium Needle Sutures, Metallic, Stainless Steel Class C Shelf life 5 Years Fee 50,000/-	certificate
449.	Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)	Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru Notarized LOA valid till 27-10-2025. Apostille FSC of Peru valid till 26-08-2023. Notarized ISO 13485 valid till 25-10-2024.	Tagum Polypropylene Monofilament Sterile Non-absorbable Sutures with Premium Needle. Tagum Sutures, Synthetic, Nonabsorbable, Polypropylene Class C Shelf life 5 Years Fee 50,000/-	Approved subject to submission of the FQA certificate
450.	Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)	Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand Notarized LOA valid till 27-02-2025. Apostille Free Sale of Medical Device issued by MEDSAFE New Zealand Medicines & Medical Device Safety Authority issued on 13-11-2023. Notarized Certificate of Free Sale of Australia TGA. Notarized ISO 13485 valid till 13-11-2024. Notarized FQA valid till 26-05-2024. Notarized EU Quality Management System valid till 05-12-2026.	Fisher & Paykel 820 Respiratory Humidification system Humidification system Class C Shelf life 7 Years Fee 50,000/-	Approved subject to submission of clarification of the brand name and as per FSC and applied name Submit stability studies or clarify
451.	Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)	Keewell Medical Technology Co, Ltd., Xiananyi Industry Zone, Pingzhou Babhai District Foshan City Guangdong Province 528251 P.R. China.	FT-1800 Blood and Infusion warmer Class C Shelf life 5 Years	Approved subject to submission of clarification of the brand name and as per FSC and applied name Submit stability studies or clarify

		<p>Notarized LOA valid till 04-01-2027.</p> <p>Apostille Certificate for Exportation of Medical Products valid till 16-07-2024.</p> <p>Notarized ISO 13485 valid till 25-09-2025.</p> <p>Notarized EC Certificate of Conformity valid till 27-05-2024.</p>	Fee 50,000/-	
452.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Keewell Medical Technology Co, Ltd., Xiananyi Industry Zone, Pingzhou Babhai District Foshan City Guangdong Province 528251 P.R. China</p> <p>Notarized LOA valid till 04-01-2027.</p> <p>Apostille Certificate for Exportation of Medical Products valid till 16-07-2024.</p> <p>Notarized ISO 13485 valid till 25-09-2025.</p> <p>Notarized EC Certificate of Conformity valid till 27-05-2024.</p>	<p>FT-2800</p> <p>Blood and Infusion warmers</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of clarification of the brand name and as per FSC and applied name Submit stability studies or clarify</p>
453.	<p>Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061)</p>	<p>Fisher & Paykel Healthcare Limited, 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand.</p> <p>Notarized LOA valid till 27-02-2025.</p> <p>Apostille Free Sale of Medical Device issued by MEDSAFE New Zealand Medicines & Medical Device Safety Authority issued on 16-08-2022.</p> <p>Apostille Certificate of Free Sale of Australia TGA issued on 28-09-2022.</p> <p>Notarized ISO 13485 valid till 13-11-2024.</p>	<p>Fisher & Paykel Airvo 3 Respiratory Support System</p> <p>Respirator Gas Delivery System and Heated humidifier</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved subject to submission of clarification of the brand name and as per FSC and applied name Submit stability studies or clarify</p>

		<p>Notarized FQA valid till 26-05-2024.</p> <p>Notarized EU Quality Management System valid till 05-12-2026.</p>		
454.	<p>Pulse Surgicals, Suite No. 113, 1st Floor, Almas Height, 190/1, Block 2 PECHS, Karachi (ELI-000578)</p>	<p>Argon Medical Devices, INC. 1445 Flat Creek Road, Athens, Texas 75751 USA</p> <p>Notarized LOA valid till 20-03-2029. Copy of CFG valid till 25-02-2026.</p> <p>Notarized ISO 13485 valid till 28-04-2025.</p> <p>Notarized FQA valid till 26-05-2024.</p> <p>Notarized Design Examination Certificate valid till 16-02-2024. Extension letter also provided.</p>	<p>Option ELITE Vena Cava Filter System</p> <p>Option Elite Retrievable Vena Cava Filter System</p> <p>352506070E Option Elite Retrievable Vena Cava Filer System</p> <p>352506100E Option Elite Retrievable Vena Cava Filer System 100cm</p> <p>Class D Shelf life 3 Years Fee 50,000/-</p>	<p>Approved subject to submission of the FSC and clarification of the brand name as per FSC and applied name</p>
455.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)</p>	<p>United Orthopedic Corp., Ltd No. 57, Park Ave.2 Science Park, Hsinchu City, 30075 Taiwan</p> <p>Notarized & valid LOA valid till 31-12-2025.</p> <p>The firm has submitted CFG notarized and apostille valid till 04-03-2026.</p> <p>Notarized FSC of Taiwan valid issued on 02-05-2023.</p> <p>Notarized FQA valid till 26-05-2024.</p> <p>Notarized ISO 13485 valid till 26-09-2026.</p> <p>Notarized Design Examination Certificate valid till 26-05-2024.</p>	<p>GTF stem II, Ø9mm, 45mm, 160mm GTF stem II, Ø9mm, 55mm, 130mm GTF stem II, Ø9mm, 55mm, 160mm GTF stem II, Ø11mm, 45mm, 130mm GTF stem II, Ø11mm, 45mm, 160mm GTF stem II, Ø11mm, 55mm, 130mm GTF stem II, Ø11mm, 55mm, 160mm</p> <p>Femoral Hip Stem</p> <p>Class C Shelf life 5 Years Fee 50,000/-</p>	<p>Approved as class D product subject to submission of required differential fee and clarification of the brand name as per FSC</p>
456.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)</p>	<p>Beijing Libeier Bio-engineering Institute Co., Ltd. 12 Chuangxin Road, Changping Science and Technology park, Changping Area, Beijing P.R.China</p>	<p>HK01</p> <p>Cannulated Screw, Nuts, Washer, Screw Plugs</p> <p>Class C</p>	<p>Deferred for submission of valid FSC, notarized LOA, ISO 13485, FQA and clarification of the multiple application as per MDR 2017.</p>

		<p>Expired embassy attested certificate for exportation submitted valid till 29.02.2024</p> <p>Expired Notarized LOA submitted valid till 31 Dec 2023</p> <p>Copy of ISO 13485 valid till 4.08.2026</p> <p>Expired FQA submitted valid till 26.05.2024</p>	<p>Shelf life As per stability study</p> <p>Fee 50,000/-</p>	
457.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi</p> <p>(ELI-00257)</p>	<p>Tipmed Medical devices Manufacturing Ltd. Kamalpasa Mahallesi 7401/1SOK. No. 16 Bornova/izmir/Turkey</p> <p>Notarized LOA submitted.</p> <p>Copy of Turkey notarized FSC issued on 23-02-2021 valid for three years. (Expired FSC submitted).</p> <p>Valid ISO submitted However expired after submission on 13-07-2024. Expired after submission. Notarized FQA valid till 26-05-2024. Expired after submission.</p>	<p>Tipmed</p> <p>Internal metallic bone fixation devices</p> <p>Class C</p> <p>Shelf life As per stability study</p> <p>Fee 50,000/-</p>	<p>Deferred for submission of valid FSC and notarsied LOA, ISO 13485, FQA and clarfcaition of the brand name and the manufacturre name as per the FSC and also Submit stability studies</p>
458.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi</p> <p>(ELI-00257)</p>	<p>Tipmed Medical devices Manufacturing Ltd. Kamalpasa Mahallesi 7401/1SOK. No. 16 Bornova/izmir/Turkey.</p> <p>Notarized LOA submitted.</p> <p>Copy of Turkey notarized FSC issued on 23-02-2021 valid for three years. (Expired FSC submitted). Notarized FQA valid till 26-05-2024. Expired after submission.</p> <p>Notarized ISO submitted valid 13-07-2024. Copy of FQA submitted till 26-05-2024.</p> <p>Notarized design examination certificated</p>	<p>Tipmed</p> <p>Primary Hip prosthesis sys</p> <p>Class C</p> <p>Shelf life As per stability study</p> <p>Fee 50,000/-</p>	<p>Deferred for submission of LOA, ISO 13485, design examination certificate, FQA and clarfcaition of the brand name manufacturre name as per FCS</p>

		submitted. Expired after submission on 26-05-2024.		
459.	Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)	United Orthopedic Corp., Ltd No. 57, Park Ave.2 Science Park, Hsinchu City, 30075 Taiwan. Notarized & valid LOA valid till 31-12-2025. The firm has submitted CFG notarized and apostille valid till 04-03-2026. Notarized FSC of Taiwan valid till 03-12-2024. Notarized FQA valid till 26- 05-2024. Notarized ISO 13485 valid till 26-09-2026. Notarized Design Examination Certificate valid till 26-05-2024.	UCP Stem Class C Shelf life As per stability study Fee 50,000/-	Approved subject to clarification of the class of the product as per DOC
460.	Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)	SERF : 85 Avenue des Bruyères, 69150 DECINES- CHARPIEU, FRANCE Copy of LOA valid till 05- 10-2027. Copy of FSC provided issued on 23-12-2020.	SERF Femoral Head RM-30100001 RM-30100002 RM-30100003 RM-30100006 RM-30100006 RM-30100007 Class C Shelf life 5 Years Fee 50,000/-	Deferred for submission of LOA, ISO 13485, design examination certificate, FQA and clarification of the brand name manufacture name as per FCS
461.	RECH International 247/B Block 6 PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)	Shandong Weigao Orthopedics Devices Company Limited Address: NO.26 Xiangjiyang Road, tourist resort, Weihei city Shandong Province, China Copy of LOA submitted valid till 15-11-2027. Apostille Certificate for Exportation of Medical Products provided valid till 20-08-2025.	Bone Screw Bone Screw Class C Shelf life 5 Years Fee 50,000/-	Deferred for submission of valid FSc, ISO 13485, design examination certificate, FQA and clarification of the brand name manufacture name as per FCS

		Copy of FQA provided valid till 26-05-2024.		
462.	Tri Tech International 10-C 1st , 2nd , 3rd floor, Sunset Commercial Lane, Phase II Ext, DHA, Karachi ELI no. 00247	Beijing Eternity Electronic Technology Co. Ltd No. 502-1 & 502-2, F5, Building 1, Yard 19, Pingguoyuan Xixiao Street, Sheijinhshan District Beijing, China Notarized LOA valid till 17-12-2028. Apostille Certificate for Exportation of Medical Products valid till 19-04-2024. Notarized ISO 13485 valid till 17-07-2024. Extension letter also provided. CE/FQA not provided only extension letter provided.	Eshero Anesthesia Machine (AM834) Class C Service Life 8 Years Fee 50,000/-	Approved
463.	Pulse Surgicals, Suite No. 113, 1st Floor, Almas Height, 190/1, Block 2 PECHS, Karachi (ELI-000578)	Argon Medical Devices, INC. 1445 Flat Creek Road, Athens, Texas 75751 USA. Notarized LOA valid till 20-03-2029. Copy of CFG valid till 25-02-2026. Notarized ISO 13485 valid till 28-04-2025. Notarized FQA valid till 26-05-2024.	Skater™ All Purpose and Nephrostomy Drainage Set-Locking Drainage Catheter Set 756606025 756608025 756610025 756612025 756614025 756616025 Class C Shelf life 5 Years Fee 50,000/-	Approved subject to submission of valid FSc and clarify the barnd anme in the FSC and applied
464.	Pulse Surgicals, Suite No. 113, 1st Floor, Almas Height, 190/1, Block 2 PECHS, Karachi (ELI-000578)	Argon Medical Devices, INC. 1445 Flat Creek Road, Athens, Texas 75751 USA. Notarized LOA valid till 20-03-2029. Copy of CFG valid till 25-02-2026. Notarized ISO 13485 valid till 28-04-2025.	Cleaner15™ Rotational Thrombectomy System Cleaner Rotational Thrombectomy System 700015 Cleaner 7F X 65cm 15mm amplitude 700115 Cleaner 7F X 135cm 15mm amplitude	Approved subject to submission of valid FSc and clarify the barnd anme in the FSC and applied

		Notarized FQA valid till 26-05-2024.	Class C Shelf life 3 Years Fee 50,000/-	
465.	Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U., Shahra-e-Faisal Karachi (ELI-00347) R&I Date: 12-02-2024	Haemokinesis Pty Ltd, 16 Technology Circuit, Hallam Victoria 3803. Australia. Embassy attested FSC Switzerland valid till 24-06-2025. Copy of LOA valid till 01-12-2025. Copy of FQA valid till 26-05-2025 Copy of ISO valid till 13-01-2027. Notarized Design Examination Certificate valid till 26-05-2025	Stargel 10 Group Check (Patient) A-B-DVI—A-B-DVI- (ID.n°: GT 2004) Order ref. Number: 1x 10 Cards GT2004-10 1x100 Cards GT2004-100 3822.1900 Class D Shelf life 16 Months Fee 50,000/-	Approved subject to submission of clarification of the barnd anme in the FSC and applied and stability studies
466.	Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U., Shahra-e-Faisal Karachi (ELI-00347) R&I Date: 12-02-2024	Haemokinesis Pty Ltd, 16 Technology Circuit, Hallam Victoria 3803. Australia. Embassy attested FSC Switzerland valid till 24-06-2025. Copy of LOA valid till 01-12-2025. Copy of FQA valid till 26-05-2025 Copy of ISO valid till 13-01-2027.	Status 1 – Reverse A1 and B Cells Cat # RC5000 TT1003(Buffer) 3822.13.00 Class C Shelf life 8 Weeks Fee 50,000/-	Approved subject to submission of clarification of the barnd anme in the FSC and applied and stability studies
467.	Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U., Shahra-e-Faisal Karachi (ELI-00347) R&I Date: 12-02-2024	Haemokinesis Pty Ltd, 16 Technology Circuit, Hallam Victoria 3803. Australia. Embassy attested FSC Switzerland valid till 24-06-2025. Copy of LOA valid till 01-12-2025. Copy of FQA valid till 26-05-2025 Copy of ISO valid till 13-01-2027.	Stargel₁₀ Newborn A-B-AB-DVI+-Ctl-AHG (ID. n°: GT2007) Order ref. Number: 1x10 Cards GT2007-10 1x100 Cards GT2007-100 3822.1900 Class D Shelf life 16 Months Fee 50,000/-	Approved subject to submission of clarification of the barnd anme in the FSC and applied and stability studies

		Notarized Design Examination Certificate valid till 26-05-2025		
468.	Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U., Shahra-e-Faisal Karachi (ELI-00347) R&I Date: 12-02-2024	Haemokinesis Pty Ltd, 16 Technology Circuit, Hallam Victoria 3803. Australia. Embassy attested FSC Switzerland valid till 24-06-2025. Copy of LOA valid till 01-12-2025. Copy of FQA valid till 26-05-2025 Copy of ISO valid till 13-01-2027. Notarized Design Examination Certificate valid till 26-05-2025	Status 1- Blood Grouping Reagent ABO /D system for Reverse and Forward grouping Status 1 – Blood Grouping Reagent ABO /D for Reverse and Forward grouping TT1000 Class D Shelf life 16 Months Fee 50,000/-	Approved subject to submission of clarification of the brand name in the FSC and applied and stability studies
469.	Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U., Shahra-e-Faisal Karachi (ELI-00347) R&I Date: 12-02-2024	Haemokinesis Pty Ltd, 16 Technology Circuit, Hallam Victoria 3803. Australia. Copy of FSC Switzerland valid till 26-06-2025. Copy of LOA valid till 01-12-2025. Copy of FSC of Australia Copy of ISO valid till 13-01-2027. Copy of Design Examination Certificate valid till 26-05-2025	Status 1- Group Check TT 1001 (reagent TT1003 (Buffer)) Status 1 Group Check Gel Card 3822.13.00 Class D Shelf life 18 Months Fee 50,000/-	Approved subject to submission of clarification of the brand name in the FSC and applied and stability studies
470.	Name HOSPICARE SYSTEMS Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350 Date of R& I 14 MAY 2024	(LEGAL MANUFACTURER) Masimo corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618 FSC US FDA: Copy of CFG- 12-Sep-2024 Marketing Authorization Letter:	RD SET DCI (Red Set Reusable Sensor) 4050 Fee Rs. 50,000/- Class C Shelf Life: useful life 1 year	Approved

		<p>Loa Valid till 04-12-2024</p> <p>Copy of Production Quality Management System Certificate (Copy of ISO 13485) Valid till 20-12-2024</p> <p>Copy of Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p>		
471.	<p>Name HOSPICARE SYSTEMS</p> <p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p>	<p>(LEGAL MANUFACTURER) Masimo corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618</p> <p>FSC US FDA: Copy of CFG- 12-Sep-2024</p> <p>Marketing Authorization Letter: Loa Valid till 04-12-2024</p> <p>Copy of Production Quality Management System Certificate (Copy of ISO 13485) Valid till 20-12-2024</p> <p>Copy of Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p>	<p>NomoLine ISA CO2</p> <p>9921</p> <p>Fee Rs. 50,000/- Class C Shelf Life: N/A</p>	Approved
472.	<p>Name HOSPICARE SYSTEMS</p> <p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p>	<p>(LEGAL MANUFACTURER) Masimo Corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618</p> <p>FSC US FDA: Copy of CFG- 12-Sep-2024</p> <p>Marketing Authorization Letter: Loa Valid till 04-12-2024</p> <p>Copy of Production Quality Management System Certificate (Copy of ISO 13485) Valid till 20-12-2024</p>	<p>RAD-G REUSABLE YI SENSOR</p> <p>4653</p> <p>Fee Rs. 50,000/- Class C Shelf Life: N/A</p>	Approved subject to clarification on barnd name and code as per FSC

		Copy of Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided		
473.	<p>Name HOSPICARE SYSTEMS</p> <p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p>	<p>(LEGAL MANUFACTURER) Masimo corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618 Fsc: CFG- 12-Sep-2024 Marketing Authorization Letter: Loa Valid till 04-12-2024</p> <p>Production Quality Management System Certificate (Iso 13485) Valid till 20-12-2024</p> <p>Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p>	<p>RAD-G REUSABLE YI SENSOR</p> <p>4653</p> <p>Fee Rs. 50,000/- Class C Shelf Life: Usefule life: 1 year</p>	Approved
474.	<p>Name HOSPICARE SYSTEMS</p> <p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p>	<p>(LEGAL MANUFACTURER) Masimo corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618 FSC US FDA: Copy of CFG- 12-Sep-2024</p> <p>Marketing Authorization Letter: Loa Valid till 04-12-2024</p> <p>Copy of Production Quality Management System Certificate (Copy of ISO 13485) Valid till 20-12-2024 Copy of Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p>	<p>RD SET DBI (RD Set Reusable Sensor) 4052</p> <p>Fee Rs. 50,000/- Class C Shelf Life: N/A</p>	Approved
475.	<p>Name HOSPICARE SYSTEMS</p>	<p>(LEGAL MANUFACTURER) Masimo corporation (Manufacturing site)</p>	<p>RD SET NEO (RD Set Disposable Sensor)</p>	Approved

	<p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p>	<p>Masimo corporation 52 discovery Irvine, California, United states 92618 FSC US FDA: Copy of CFG- 12-Sep-2024</p> <p>Marketing Authorization Letter: Loa Valid till 04-12-2024</p> <p>Copy of Production Quality Management System Certificate (Copy of ISO 13485) Valid till 20-12-2024 Copy of Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p>	<p>4003</p> <p>Fee Rs. 50,000/- Class C Shelf Life: 3 Year</p>	
476.	<p>Name HOSPICARE SYSTEMS</p> <p>Address of Importer 9th Floor, Emarah Suites, Plot 8-B Block A ,SMCHS Shahrah-e-Faisal Karachi, 75350</p> <p>Date of R& I 14 MAY 2024</p> <p>Fee</p>	<p>(LEGAL MANUFACTURER) Masimo Corporation (Manufacturing site) Masimo corporation 52 discovery Irvine, California, United states 92618</p> <p>Fsc: Copy of CFG US FDA- 12-Sep-2024 Marketing Authorization Letter: Copy of LOA Valid till 04-12-2024</p> <p>Production Quality Management System Certificate (ISO 13485) Valid till 20-12-2024</p> <p>Full Quality Assurance Certificate Or Equivalent: Validity Up To: 15-7-2023 extension letter provided</p> <p>Design Examination N/A</p> <p>Declaration of Conformity (Doc): provided</p>	<p>Root with NIBP, Temp 9695 (Physiological Monitoring System)</p> <p>Rs. 50,000/- Class C</p>	<p>Approved subject to submission of brand name clarification as per FSC</p>
477.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission</p>	<p>Legal Manufacturer: Abbott Ireland Diagnostic Division Finisklin Business</p>	<p>ARCHITECT iValproic Acid Class: C</p>	<p>Approved</p>

	<p>Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Park Sligo, Ireland</p> <p><u>Manufacturing Site</u> Denka Co., Ltd Kagamida Factory 1359-1, Kagamida, Kigoshi Gosen-shi Niigata, 959-1695, Japan</p> <p>Date of R&I 06-May-2024</p> <p><u>Apostilled FSC:</u> Sligo Ireland Date of Issuance 21 November 2023. Validity: not mentioned</p> <p><u>LOA</u> Validity: N/A (Abbott is operating directly)</p> <p><u>ECCertificate</u> EU QMSC IVDR Ireland, Date of Validity 26-09 2026</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>	<p>Shelf Life: 18 Months</p> <p>Codes/Sizes: ARCHITECT iValproic Acid Reagent Kit 1P3525</p> <p>ARCHITECT iValproic Acid Calibrator Kit 1P3501</p>	
478.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland</p> <p><u>Manufacturing Site</u> Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645-1905, USA</p> <p>Date of R&I 27-June-2024</p> <p><u>Apostilled FSC:</u> Ireland Date of Issuance 23-Feb-2024. Validity: N/A</p> <p><u>LOA</u> Validity: Date of Issuance 23-Jan- 2024 (Abbott is operating directly)</p> <p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 26-09 2026</p>	<p>ARCHITECT STAT CK-MB</p> <p>Class: C</p> <p>Shelf Life: ARCHITECT STAT CK-MB Reagent Kit 18 Months ARCHITECT STAT CK-MB Calibrators 18 Months ARCHITECT STAT CK-MB Controls 36 Months</p> <p>Codes/Sizes: ARCHITECT STAT CK-MB Reagent Kit 2K42-28 2K42-38</p> <p>ARCHITECT STAT CK-MB Calibrators 2K42-01</p> <p>ARCHITECT STAT CK-MB Controls 2K42-10</p>	Approved

		ISO 13485 Validity: 24-03-26		
479.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland</p> <p><u>Manufacturing Site</u> Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645-1905, USA</p> <p>Date of R&I 27-June-2024</p> <p><u>Apostilled FSC:</u> Ireland Date of Issuance 23-Feb-2024. Validity: N/A</p> <p><u>LOA</u> Date of Issuance 23-Jan-2024 (Abbott is operating directly)</p> <p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 26-09 2026</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>	<p>ARCHITECT STAT Myoglobin</p> <p>Class: C</p> <p>Shelf Life: ARCHITECT STAT Myoglobin Reagent Kit 18 Months</p> <p>ARCHITECT STAT Myoglobin Calibrators 18 Months</p> <p>ARCHITECT STAT Myoglobin Controls 36 Months</p> <p>Codes/Sizes: ARCHITECT STAT Myoglobin Reagent Kit 2K43-25</p> <p>ARCHITECT STAT Myoglobin Calibrators 2K43-01</p> <p>ARCHITECT STAT Myoglobin Controls 2K43-10</p>	Approved
480.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p><u>Manufacturing Site</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p>Date of R&I 27-June-2024</p> <p><u>FSC:</u> Ireland Date of Issuance 08-Apr-2024. Validity: N/A</p> <p><u>LOA</u> Issuance date 28.03.2024</p>	<p>Amylase2</p> <p>Class: C</p> <p>Shelf Life: 15 Months</p> <p>Codes/Sizes: Amylase2 04S8920</p>	Approved

		<p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 25-11 2026</p> <p><u>ISO 13485</u> Validity: 31-08-26</p>		
481.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p><u>Manufacturing Site</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p><u>Date of R&I</u> 27-June-2024</p> <p><u>FSC:</u> Ireland Date of Issuance 08-Apr-2024. Validity: N/A</p> <p><u>LOA</u> Issuance date 28.03.2024</p> <p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 25-11 2026</p> <p><u>ISO 13485</u> Validity: 31-08-26</p>	<p>Amylase2</p> <p>Class: C</p> <p>Shelf Life: 15 Months</p> <p>Codes/Sizes: Amylase2 04T8520</p>	Approved
482.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p><u>Manufacturing Site</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p><u>Date of R&I</u> 11-Dec-2024</p> <p><u>FSC:</u> Embassy attested Italy Date of Issuance: 26-Sep-24 Validity: not mentioned</p> <p><u>LOA</u></p>	<p>Alinity c HBDH Reagent Kit</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: Alinity c HBDH Reagent Kit 01R0122</p> <p>Fee 62000/-</p>	Approved

		<p>Notarized Issuance: 14-Oct-24 Validity: 5 Years</p> <p><u>ECCertificate</u> Notarized EU QMSC IVDR . Date of Validity 05-02 2028</p> <p><u>Notarized ISO 13485</u> Validity: 24-03-26</p>		
483.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p><u>Manufacturing Site</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p>Date of R&I 11-Dec-2024</p> <p><u>FSC:</u> Italy Date of Issuance: 26-Sep-24 Validity: not mentioned</p> <p><u>LOA</u> Issuance: 14-Oct-24 Validity: 5 Years</p> <p><u>ECCertificate</u> EU QMSC IVDR . Date of Validity 05-02 2028</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>	<p>HBDH</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: 6K23-30</p>	Approved
484.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p><u>Manufacturing Site</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p>Date of R&I 11-Dec-2024</p> <p><u>FSC:</u> Italy Date of Issuance: 26-Sep-24</p>	<p>Alinity c Pancreatic Amylase Reagent Kit</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: 01R0422</p>	Approved

		<p>Validity: N/A</p> <p><u>LOA</u> Issuance: 14-Oct-24 Validity: 5 Years</p> <p><u>ECCertificate</u> EU QMSC IVDR . Date of Validity 05-02 2028</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>		
485.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p><u>Manufacturing Site</u> SENTINEL CH. S.p.A. Via Robert Koch, 2, 20152-MILANO, Italy</p> <p>Date of R&I 11-Dec-2024</p> <p><u>FSC:</u> Embassy attested Italy Date of Issuance: 26-Sep-24 Validity: not mentioned</p> <p><u>LOA</u> Issuance: 14-Oct-24 Validity: 5 Years</p> <p><u>ECCertificate</u> EU QMSC IVDR . Date of Validity 05-02 2028</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>	<p>Pancreatic Amylase</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: 6K22-30</p>	Approved
486.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany</p> <p><u>Manufacturing Site</u> Biokit, S.A. Av. Can Montcau 7 08186 Lliçà d'Amunt Barcelona, Spain</p> <p>Date of R&I 06-May-2024</p>	<p>ARCHITECT DHEA-S</p> <p>Class: C</p> <p>Shelf Life: 15 Months</p> <p>Codes/Sizes: ARCHITECT DHEA-S Reagent Kit 8K27-27</p>	Approved

		<p>FSC: Germany Date of Issuance 07-Feb-2024. Validity: N/A</p> <p>LOA Issuanc eadte 10.01.2024</p> <p>ECCertificate EU QMSC IVDR Date of Validity 11-08 2026</p> <p>ISO 13485 Validity: 30-09-24</p>	<p>ARCHITECT DHEA-S Calibrators 8K27-02</p> <p>ARCHITECT DHEA-S Controls 8K27-11</p>	
487.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Legal Manufacturer: Abbott GmbH Max-Planck- Ring 2 65205 Wiesbaden Germany</p> <p>Manufacturing Site Biokit, S.A. Av. Can Montcau 7 08186 Lliçà d'Amunt Barcelona, Spain</p> <p>Date of R&I 06-May-2024</p> <p>FSC: Germany Date of Issuance 07-Feb- 2024. Validity: N/A</p> <p>LOA Issuanc eadte 10.01.2024</p> <p>ECCertificate EU QMSC IVDR Date of Validity 11-08 2026</p> <p>ISO 13485 Validity: 30-09-24</p>	<p>Alinity i DHEA-S</p> <p>Class: C</p> <p>Shelf Life: 15 Months</p> <p>Codes/Sizes: Alinity i DHEA-S Reagent Kit 09P3720</p> <p>Alinity i DHEA-S Calibrators 09P3701</p> <p>Alinity i DHEA-S Controls 09P3710</p>	Approved
488.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Legal Manufacturer: Abbott GmbH Max-Planck- Ring 2 65205 Wiesbaden Germany</p> <p>Manufacturing Site Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA, 19355, USA</p> <p>Date of R&I</p>	<p>Alinity i Thyroglobulin</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: Alinity i Thyroglobulin Reagent Kit 09P4922</p>	Approved

		<p>27-June-2024</p> <p><u>FSC:</u> Germany Date of Issuance 03-Apr-2024. Validity: not mentioned</p> <p><u>LOA</u> Issuance date 22.03.2024</p> <p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 11-08 2026</p> <p><u>ISO 13485</u> Validity: 30-09-24</p>	<p>09P4932</p> <p>Alinity i Thyroglobulin Calibrators 09P4901</p> <p>Alinity i Thyroglobulin Controls 09P4910</p>	
489.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden Germany</p> <p><u>Manufacturing Site</u> Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA, 19355, USA</p> <p><u>Date of R&I</u> 27-June-2024</p> <p><u>FSC:</u> Germany Date of Issuance 03-Apr-2024. Validity: not mentioned</p> <p><u>LOA</u> Issuance date 22.03.2024</p> <p><u>ECCertificate</u> EU QMSC IVDR Date of Validity 11-08 2026</p> <p><u>ISO 13485</u> 05.02.2025</p>	<p>ARCHITECT Thyroglobulin</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: ARCHITECT Thyroglobulin Reagent Kit 5P20-25 5P20-35</p> <p>ARCHITECT Thyroglobulin Calibrators 5P20-01</p> <p>ARCHITECT Thyroglobulin Controls 5P20-10</p>	Approved
490.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Rapid Dx Galway Parkmore East Business Park Ballybrit, Galway Ireland</p> <p><u>Manufacturing Site</u> Abbott Diagnostics Korea Inc. 65, Borahagal-ro, Giheung-</p>	<p>Panbio™ COVID-19/Flu A&B Panel (Nasal)</p> <p>Class: C</p> <p>Shelf Life: 25 Months</p> <p>Fee 50000/- Codes/Sizes:</p>	Approved

		<p>gu, Yongin-si Gyeonggi-do 17099, Republic of Korea & 46, Hagal-ro 15beon-gil, Giheung-gu Gyeonggi-do 17099, Republic of Korea</p> <p>Date of R&I 23-Apr-2024</p> <p>FSC: Ireland Date of Issuance 08-Jan-2024. Validity: not mentioned</p> <p>LOA Validity: not mentioned Issuance date 16.01.2024</p> <p>ECCertificate EU QMSC IVDR Date of Validity 23-07 2028</p> <p>ISO 13485 Validity: 23-07-26</p>	<p>Panbio™ COVID-19/Flu A&B Panel (Nasal) 62FK31 62FK41</p>	
491.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Legal Manufacturer: M/s Abbott Diagnostics Medical Co., Ltd. 357 Matsuhidai, Matsudo-shi, Chiba 270-2214 Japan</p> <p>Date of R&I 17-May-2024</p> <p>FSC: Japan Date of Issuance 30-Aug-2023. Validity: N/A</p> <p>LOA Validity:5 years Date of Issue: 16-Jan-2024</p> <p>ECCertificate Original Notarized EU Technical Documentation Assessment Certificate EU QMSC IVDR Date of Validity 20-10 2027</p> <p>ISO 13485 Validity: 12-09-24</p>	<p>Determine™ HIV Controls</p> <p>Class: D</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: Determine™ HIV Controls 7D2253</p>	<p>Approved subject to clarification of the FSC from the regulatory authority</p>

492.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Date of R&I</u> 09-Sep-2024</p> <p><u>FSC:</u> Germany Date of Issuance 13. Oct.2023 Validity: not mentioned</p> <p><u>LOA</u> Validity: N/A Date of Issue: 24-Jan-2024</p> <p><u>ECCertificate</u> Memo Provided of No DEC and FQA. Issuance Date: 24-01 2023</p> <p><u>ISO 13485</u> Validity: 15-12-26</p>	<p>Vysis CDKN2A/CEP 9 FISH Probe Kit</p> <p>Class: C</p> <p>Shelf Life: 24 Months</p> <p>Codes/Sizes: Vysis CDKN2A/CEP 9 FISH Probe Kit 04N61-020</p>	<p>Approved subject to submission of Diffrentail fee of Rs 12000/-</p>
493.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Date of R&I</u> 09-Sep-2024</p> <p><u>FSC:</u> Germany Date of Issuance 14-Nov-2023. Validity: not mentioned</p> <p><u>LOA</u></p>	<p>Vysis RARA Break Apart FISH Probe Kit</p> <p>Class: C</p> <p>Shelf Life: 24 Months</p> <p>Codes/Sizes: Vysis RARA Break Apart FISH Probe Kit 05N46-020</p>	<p>Approved subject to submission of Diffrentail fee of Rs 12000/-</p>

		<p>Validity: N/A Date of Issue: 24-Jan-2024</p> <p><u>ECCertificate</u> Memo Provided of No DEC and FQA. Issuance Date: 24-01 2023</p> <p><u>ISO 13485</u> Validity: 15-12-26</p>		
494.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p>Date of R&I 19-Jan-2024</p> <p><u>FSC:</u> USA Validity: 12-Sep-2023</p> <p><u>LOA</u> Validity: N/A Date of Issue: 28-Oct-2022</p> <p><u>ECCertificate</u> Memo of No DEC and FQA. Date of Issue: 26-01-23</p> <p><u>ISO 13485</u> Validity: 15-12-26</p>	<p>VP 2000 Protease I (250mg*2) Class: C</p> <p>Shelf Life: N/A (Memo Attached)</p> <p>Codes/Sizes 02J08-032 Fee 50000/-</p>	Approved
495.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p>Date of R&I</p>	<p>Vysis SRY Probe - LSI SRY SpectrumOrange Probe</p> <p>Class: C</p> <p>Shelf Life: N/A (Memo Attached)</p> <p>Codes/Sizes 05J27-079</p>	Approved

		<p>19-Jan-2024</p> <p><u>FSC:</u> USA Validity: 01-Aug-2024</p> <p><u>LOA</u> Validity: N/A Date of Issue: 28-Oct-2022</p> <p><u>ECCertificate</u> Memo of No DEC and FQA. Date of Issue: 26-01-23</p> <p><u>ISO 13485</u> Validity: 15-12-26</p>		
496.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Date of R&I</u> 19-Jan-2024</p> <p><u>FSC:</u> USA Validity 14 Sep 2023</p> <p><u>LOA</u> Validity: N/A Date of Issue: 28-Oct-2022</p> <p><u>ECCertificate</u> Memo of No DEC and FQA. Date of Issue: 26-01-23</p> <p><u>ISO 13485</u> Validity: 15-12-26</p>	<p>Vysis LSI N-MYC SpectrumGreen/CEP 2 SpectrumOrange Probes</p> <p>Class: C</p> <p>Shelf Life: N/A (Memo Attached)</p> <p>Codes/Sizes: 07J72-001 Fee 50000/-</p>	Approved
497.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p><u>Manufacturing Site</u> Abbott Molecular Inc. 1300 East Touhy Avenue Des</p>	<p>Vysis IntelliFISH Hybridization Buffer</p> <p>Class: C</p> <p>Shelf Life: N/A (Memo Attached)</p> <p>Codes/Sizes 08N87-001</p>	Approved

		<p>Plaines, IL 60018 USA</p> <p>Date of R&I 19-Jan-2024</p> <p>FSC: USA Validity: 01-Aug-2024</p> <p>LOA Validity: N/A Date of Issue: 28-Oct-2022</p> <p>ECCertificate Memo of No DEC and FQA. Date of Issue: 26-01-23</p> <p>ISO 13485 Validity: 15-12-26</p>		
498.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Legal Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p> <p>Date of R&I 12-Sep-2023</p> <p>FSC: USA Validity: 01-08-2024</p> <p>LOA Validity: N/A (Abbott is operating directly)</p> <p>ECCertificate Memo is provided of No DEC and FQA</p> <p>ISO 13485 Validity: 15-12-2023</p>	<p>Vysis IntelliFISH Universal FFPE Tissue Pretreatment Protease</p> <p>Class: C</p> <p>Shelf Life: Not Applicable</p> <p>Codes/Sizes: 08N85-010 08N85-015</p>	Approved
499.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p>	<p>Legal Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA</p>	<p>Vysis IntelliFISH Hybridization Buffer</p> <p>Class: C</p> <p>Shelf Life: Not Applicable</p>	Approved.

	(ELI-00019)	<p>Date of R&I 20-Dec-2023</p> <p>FSC: USA Validity: 01.08.2024</p> <p>LOA Validity: N/A (Abbott is operating directly)</p> <p>ECCertificate Memo is provided of No DEC and FQA</p> <p>ISO 13485 Validity: 16-12-2026</p>	<p>Codes/Sizes:</p> <p>08N87-005</p>	
500.	<p>New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161)</p> <p>[4930] Evaluator: DD-</p>	<p>Legal Manufacturer & Site: Nantong Egens Biotechnology Co., Ltd. Block A Fifteenth, Factory Building No. 1692 Xinghu Avenue, nantong Economic & Technological Development Zone, Nantong CHINA</p>	<p>ACCURATE PREGNANCY TEST KIT Class: B Shelf Life 3 Years</p>	<p>Disposed of as already decided in 75 MDB.</p>
501.	<p>New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161)</p> <p>[4469] Evaluator: DD-</p>	<p>Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China.</p>	<p>KBM Auto-Disable Syringe Class B Shelf life: 05 Years Sizes: 3ml, 5ml</p>	<p>Disposed of as already decided in 75 MDB.</p>
502.	<p>New Pakistan Traders. Office no 306/1, trade tower altaf hussain road, new challi, karachi (ELI-00161) [3933-C] Evaluator: DD-</p>	<p>Zibo Eastmed HealthCare Products Co., Ltd no 118, Huaguang Road, Zhangdian District Zibo 25500 Shandong China</p> <p>Copy of china FSc vvalid till 2027</p>	<p>Comfort Care IV Flow Regulator (DIA FLOW) Class: B Shelf Life:5-years</p>	<p>Deferred for submission of valid and notasried LOA with attachment as mentioned in the letter . Calrify the brand name as per FSC Provide undertaking on the stamp paper and proof of fee submission</p>
503.	<p>M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi</p>	<p>(Legal Manufacteurer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular</p>	<p>Perfusion Cannula/ Vessel Cannula Class-B Fsc: FSC (FDA): Validity: 12/10/2024</p>	<p>Approved with model and descripton given below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and</p>

	Date of R& I 08.06.2023 Fee Rs. 25,000/ through slip no.33196147, dated 07.06.2023	2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505 DOC validity: 25/10/2024	LOA validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Declaration of conformity.
	Sterile PN	Non-Sterile		
	PER-3001S	PER-3001		
	PER-3003S	PER-3003		
	PER-3006S	PER-3006/PER-3006-1000		
	PER-3007S	PER-3007		
	PER-3008S	PER-3008		
	PER-3009S Tip	PER-3009		
	PER-3015S	PER-3015		
504.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ through slip no.44444543484, dated 07.06.2023	(Legal Manufactureur & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505 DOC validity: 25/10/2024	ALPINE Femoral Venous Cannula Class-B Fsc: FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 Models: FEM-V1020 (20 FR) FEM-V1022 (22 FR) FEM-V1024 (24 FR) FEM-V1026 (26 FR) FEM-V1028 (28 FR) ISO 13485 Validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
505.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ through slip no.9849248822, dated 07.06.2023	(Legal Manufactureur & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505 DOC Validity: 25/10/2024	PEAK Left Ventricular Vent Cannula Class-B Fsc: FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 Models: LVV-016S (16 FR) LVV-018S (18 FR) LVV-020S (20 FR) Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.

506.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Slip No. 2844750084 Rs.5000 dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Coronary Artery Retraction Clips Class-A Fsc: FSC (FDA): Validity: 12/10/2024 LOA validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 Models: CAR-1613S (3mm) CAR-1615S (5mm) Shelf life: 03 years Storage conditions: 15°C and 30°C DOC Validity: 25/10/2024	Approved. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
507.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ through slip no.40695430 dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Antegrade Cardioplegia Cannula Class-B Fsc: FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO 13485 validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C DOC Validity: 25/10/2024	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
Sterile PN		Non sterile		
ANT-1012S		ANT-1012		
ANT-1014S		ANT-1014		
ANT-2012S		ANT-2012		
ANT-2014S		ANT-2014		
ANT-4012S Needle		ANT-4012		
ANT-4014S Needle		ANT-4014		
ANT-3012S		ANT-3012		
ANT-3014S		ANT-3014		
508.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ through slip no.0698410196 dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge	Perfusion Sets Class-B FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 DOC Validity: 25/10/2024 Shelf life:	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.

		2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	05 years Storage conditions: 15°C and 30°C	
	Sterile PN	Non Sterile		
	PER-1001S	PER-1001		
	PER-1003S	PER-1003		
	PER-1004S	PER-1004		
	PER-1005S	PER-1005		
	PER-1006S			
	PER-1400S	PER-1400		
	PER-1401S	PER-1401		
	PER-1407S			
	PER-1408S			
509.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.5,000/ through slip no.548760178714 dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Tubing Organizer Class-A Fsc: FSC (FDA): Validity: 12/10/2024 LOA validity: 21/12/2027 ISO: Issuance Date: 25/10/2021 - Validity Date: 25/10/2024 DOC Validity: 25/10/2024 Shelf life: 05 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
	Sterile PN	Non sterile		
	003NS	10-Hole Tubing		
	213-002			
	213-003	213-003NS		
	213-004	213-004NS		
510.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ through slip no.536020034, dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Cardiac Suckers Class-B FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 DOC Validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
	Sterile PN	Non sterile		
	SUC-4300S	SUC-4300		
	SUC-4991S	SUC-4991		
	SUC-0804S			
511.	M/s ACP Systems 13&23 Navel Fleet	(Legal Manufacturer & Product owner)	Tourniquets	Approved for models and description mention in table

	Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.5,000/ through slip no.982287045699, dated 07.06.2023	Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Class-A FSC (FDA): Issuance Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO 13485 Validity: 25/10/2024 DOC Validity: 25/10/2024 Shelf life: 05 years Storage conditions: 15°C and 30°C	below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
	Sterile PN	Non Sterile		
	TOU-79038/TOU-79038-100	TOU-7903		
	TOU-7904S	TOU-7904		
	TOU-79055			
	TOU-7906S	TOU-7906		
	TOY-7907			
	TOU-7908S			
512.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Fee Rs.25,000/ slip no.122541523, dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Cardiac Insulation Pads Class-B Fsc: FSC (FDA): Validity: 12/10/2024 LOA Validity: 21/12/2027 ISO13485 validity: 25/10/2024 DOC validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
	Sterile PN	Non sterile		
	ACIP	ACIPNS		
	PCIP	PCIPNS		
	PNP	PNPNS		
513.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Rs.25,000/ slip no.8026326580, dated 07.06.2023	((Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Retrograde Cardioplegia Cannula (Manual Inflate) Class-B FSC (FDA): Validity: 12/10/2024 LOA validity: 21/12/2027 ISO 13485 validity: 25/10/2024 DOC validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.

Sterile PN				
RMH-0015S				
RMH-1015S				
RMH-T015S				
RMR-0015S				
RMR-1015S				
RMG-0015S				
RMG-1015S				
RMG-T015S				
RMN-T015S				
514.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Rs. 25,000/ slip.78568674555, dated 7.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	Retrograde Cardioplegia Cannula (Self Inflate) Class-B FSC (FDA): Validity: 12/10/2024 LOA validity: 21/12/2027 ISO 13485 validity: 25/10/2024 DOC validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
Sterile PN				
RSH-M014S				
RSH-M014SL				
RSH-T014S				
RSH-T014SL				
RSR-M014S				
RSR-M014SL				
RSR-T014S				
RSR-T014SL				
RSG-M014S				
RSG-M014SL				
RSG-T014S				
RSG-T014SL				
RSN-M014SL				
515.	M/s ACP Systems 13 &23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 08.06.2023 Rs. 25,000/ slip 2669268564, Dated 07.06.2023	(Legal Manufacturer & Product owner) Name: MED MICHIGEN HOLDINGS LLC doing business as Surge Cardiovascular 2140 Oak Industrial Drive NE Grand Rapids, MI USA 49505 Contract Manufacturer Medisurge 2140 Oak Industrial Dr. NE Grand Rapids, MI, USA 49505	MicroSurge® BlowMister Model: BLM-22150 Class-B FSC (FDA): Validity: 12/10/2024 LOA validity: 21/12/2027 ISO 13485 validity: 25/10/2024 DOC validity: 25/10/2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved for models and description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485 certificate and Declaration of conformity.
516.	M/s ACP Systems	(Legal Manufacturer)	Cor – Knot MICRO®	Approved for models and

	13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 27.07.2023 Rs.25,000/ slip no. 39735004538 Dated 26.07.2023	LSI Solutions INC. 7796 VICTOR-MENDON RD. Victor NY, USA – 14564 LOA validity: 27/03/2026 ISO validity: 20/12/2024 EU-QMSC: (EU-QMS Certificate) Validity: 07/02/2028	Device Class B FSC (USA) Validity: 13/06/2024 EU –TDAC: (EU- Technical Documentation Assessment Certificate) Validity: 07/02/2028 Shelf life: 03 years Storage conditions: 15°C and 30°C	description mention in table below. Registration letter shall be issued after provision of valid Free sale certificate, ISO 13485.
517.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 26.10.2023 Fee Rs.5,000/ through slip no. 370132537 dated 24.10.2023	(Legal Manufacturer) WEXLER SUGICAL, INC. 11333 CHIMNEY ROCK RD, SUITE#110-120, Houston, TX USA -77035 DOC (MDD-93/42/EEC): Validity: 26/05/2024	MIS Forceps Class A FSC (USA): Validity: 13/03/2025 LOA validity: 27/03/2026 ISO (USA): Validity: 17.12.2026 By Orion Register Inc. Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved
518.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 26.10.2023 Fee Rs.5,000/ through slip no. 64982378654 dated 24.10.2023	(Legal Manufacturer) WEXLER SUGICAL, INC. 11333 CHIMNEY ROCK RD, SUITE#110-120, Houston, TX USA -77035 ISO: (USA): Validity: 17.12.2026 by Orion Register Inc. DOC (MDD-93/42/EEC): Validity Date: 26/05/2024	Multi-Purpose Clamps Class A FSC (USA): Validity: 13/03/2025 LOA validity: 27/03/2026 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved
519.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 26.10.2023 Fee Rs.5,000/ through slip no. 3072371762 dated 24.10.2023	(Legal Manufacturer) WEXLER SUGICAL, INC. 11333 CHIMNEY ROCK RD, SUITE#110-120, Houston, TX USA -77035 DOC (MDD-93/42/EEC): Issuance Date: 25/05/2021 - - Validity Date: 26/05/2024	VATS Scissors Class A FSC (USA): Validity: 13/03/2025 LOA Validity: 27/03/2026 ISO: (USA): Validity: 17.12.2026 by Orion Register Inc. Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved
520.	M/s ACP Systems	VITALITEC INT'L., INC.	CygNet - Flexible Vascular	Approved

	<p>13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi</p> <p>Date of R& I 28.11.2023</p> <p>Fee Rs.5,000/ through slip no. ,693400400511 dated 05.06.2023</p>	<p>Doing business as Peters Surgical, USA 10 CORDAGE PARK CIRCLE, SUITE # 200/100 Plymouth, MA USA 02360</p>	<p>Clamps</p> <p>Model: V-10143, V-10151 V-10152, V-10183 VR10152, VS00055 VS00056, VS00057 VS00060, VS00062 VS00063, VSAY00061</p> <p>Class A</p> <p>FSC (USA): Validity: 27/04/2024 LOA validity: 21/12/2027 ISO Validity Date: 09/03/2026 EC-FQAS Validity: 26/05/2024 DOC: Issuance Date: 07/04/2023</p> <p>Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	
521.	<p>M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi</p> <p>Date of R& I 28.11.2023</p> <p>Fee Rs.25,000/ through slip no. 4955351349 , dated 05.06.2023</p>	<p>VITALITEC INT'L., INC. Doing business as Peters Surgical, USA 10 CORDAGE PARK CIRCLE, SUITE # 200/100 Plymouth, MA USA 02360</p> <p>EC-FQAS Validity: 26/05/2024</p> <p>DOC: Issuance Date: 07/04/2023</p>	<p>Greyhound Adjustable Spring Clips</p> <p>Model: N-10108, N-10112, N-10113 Class B</p> <p>FSC (USA): Validity: 27/04/2024 LOA validity: 21/12/2027 ISO 13485 validity: 09/03/2026 Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved
522.	<p>M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi</p> <p>Date of R& I 28.11.2023</p> <p>Fee Rs.25,000/ through slip no. 80239248274 , dated 05.06.2023</p>	<p>VITALITEC INT'L., INC. d/b/a Peters Surgical, USA 10 CORDAGE PARK CIRCLE, SUITE # 200/100 Plymouth, MA USA 02360</p> <p>EC-FQAS: Issuance Date: 12/04/2021 - Validity Date: 26/05/2024</p> <p>DOC: Issuance Date: 07/04/2023</p>	<p>InTrack Ultra Insert Sets</p> <p>Class B FSC (USA): Validity: 27/04/2024 LOA validity: 21/12/2027 ISO 13485 validity: 09/03/2026</p> <p>Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved Registration letter shall be issued after provision of valid Free sale.

523.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.25,000/ through slip no. ,14223056 dated 02.03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Congor Hydrophilic Guidewire</p> <p>Class: B FSC (Netherlands) Validity: 26.5.2024 FSC (country of origin) Expiry - 31.12.2027</p> <p>LOA Validity: 1/12/2027</p> <p>ISO 13485 validity: 21.8.2025</p> <p>CE FQA expiry: 27.5.2024 DOC: 24.10.2022</p> <p>Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved
524.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.25,000/ through Rs.25,000/ through slip no. ,56559598279 dated 02.03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Introducer Sheath Sets</p> <p>Class: B FSC (Netherlands) Validity: 26-5-2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity: 21/12/2027</p> <p>ISO 13485 validity: 21-08-2025</p> <p>CE FQA validity: 27-05-2024</p> <p>DOC 24-10-2022 Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved
525.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd.</p>	<p>Connecting Tubes</p> <p>Class B FSC (Netherlands) Validity: 26-05-2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity Date: 21/12/2027</p>	Approved

	<p>Fee Rs.25,000/ through slip no.24153498074 , dated 02.03,2023</p>	<p>Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>ISO 13485 validity: 21-08-2025</p> <p>CE FQA validity: 27.5.2024</p> <p>DOC 24.10.2022</p> <p>Shelf life: 03 years</p> <p>Storage conditions: 15°C and 30°C</p>	
526.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.25,000/ through slip no.0151000994 , dated 02.03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Angiographic Syringes & Accessories</p> <p>Class B FSC (Netherlands) Validity: 26-05-2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity: 21-08-2025</p> <p>CE FQA validity: 27-05-2024</p> <p>DOC 24.10.2022</p> <p>Shelf life: 03 years</p> <p>Storage conditions: 15°C and 30°C</p>	Approved
527.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.25,000/ through slip no.6525041949 , dated 02. 03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Introducer Needles</p> <p>Class B FSC (Netherlands) Validity: 26-05-2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity: 21-08-2025</p> <p>CE FQA validity: 27.5.2024</p> <p>DOC 24.10.2022</p> <p>Shelf life: 03 years</p> <p>Storage conditions: 15°C and 30°C</p>	Approved

528.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.25,000/ through slip no. ,9345678537 dated 02.03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Non-Vascular Guide Wires</p> <p>Class B FSC (Netherlands) Validity: 26.5.2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity: 21-08-2025</p> <p>CE FQA validity: 27.5.2024</p> <p>Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved
529.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.5,000/ through slip no.77298139430 , dated 02.03.2023</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>Manifolds</p> <p>Class A FSC (Netherlands) Validity: 26.5.2024 FSC (China) Validity: 31-12-2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity: 21.8.2025</p> <p>CE FQA validity: 27.5.2024</p> <p>Shelf life: 03 years Storage conditions: 15°C and 30°C</p>	Approved
530.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China.</p> <p>Manufacturing Site: Brun Medical Co., Ltd.</p>	<p>Balloon Inflation Devices</p> <p>Class A FSC (Netherlands) Validity: 26.5.2024 FSC (China) Validity: 31.12.2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity:</p>	Approved

	Rs.5,000/ through slip no.567137301290 , dated 02.03.2023	Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China	21.8.2025 CE FQA validity: 27.5.2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	
531.	M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi Date of R& I 06.3.2023 Fee Rs.5,000/ through slip no.17252812718 , dated 02.03.2023	Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China	Radial Artery Tourniquets Class A FSC (Netherlands) Validity: 26.5.2024 FSC (China) Validity: 31.12.2027 LOA Validity Date: 21/12/2027 ISO 13485 validity: 21.8.2025 CE FQA validity: 27.5.2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved
532.	M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi Date of R& I 06.3.2023 Fee Rs.5,000/ through slip no.909224641174 , dated 02.03.2023	Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China	Y-Connector Sets Class A FSC (Netherlands) Validity: 26-05-2024 FSC (China) Validity: 31-12-2027 LOA Validity Date: 21/12/2027 ISO 13485 validity: 21-08-2025 CE FQA validity: 27.5.2024 Shelf life: 03 years Storage conditions: 15°C and 30°C	Approved
533.	M/s Advance Cardiology System, 316-317, 3rd Floor,	Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture	Dose-Control Syringes Class A	Approved

	<p>Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p> <p>Date of R& I 06.3.2023</p> <p>Fee Rs.5,000/ through slip no.232633347 , dated 02.03.2023</p>	<p>Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China</p> <p>Manufacturing Site: Brun Medical Co., Ltd. Building 8, Phase I, Entrepreneurship and Innovation Industrial Park, Intersection of Yunlong Avenue, Changtang Road and Panlong Road, Yunlong Demonstration Zone, Zhuzhou, 412000, Hunan, P.R.China</p>	<p>FSC (Netherlands) Validity: 26.5.2024</p> <p>FSC (China) Validity: 31.12.2027</p> <p>LOA Validity Date: 21/12/2027</p> <p>ISO 13485 validity: 21.8.2025</p> <p>CE FQA Validity: 27.5.2024</p> <p>Shelf life: 03 years</p> <p>Storage conditions: 15°C and 30°C</p>	
534.	<p>M/s Benchmark Corporation</p> <p>Address: A-706 7th floor Saima Trade Tower, I.I. Chundrigar Road, Karachi.</p> <p>(ELI-00420)</p> <p>Date of submission of application: 11-10-2023</p> <p>Fee Challan: 1036056142</p> <p>Amount: PKR 5000/-</p> <p>Dated: 21-08-2023</p>	<p>Wuhan Huawei Technology Co. Ltd. Room 808-810 8th floor, unit 2, C1 Building, the eastern shopping park, spaceflight star town, two seven road, Jiang'an district, 430012, Wuhan, hubei, China</p> <p>Manufacturing Site: B-F11-13, Huazhong International industrial park, Yangluo port, 430415, Wuhan, Hubei, China 430415</p> <p>FSC (China) Validity: 21-09-2025</p> <p>FDA Certified device</p> <p>LOA Validity: 28-05-2025</p> <p>ISO 13485 Validity: 13-04-2025</p> <p>EC Certificate: Valid</p> <p>Shelf Life: 2 years</p> <p>Storage: 15°C – 30°C</p>	<p>Surgical Incise Drape</p> <p>Class: A</p> <p>Specifications: 7×4、 7×5、 7×6、 8×6、 8×7、 9×6、 10×6、 9×10、 9×15、 9×25、 10×10、 10×15、 10×20、 10×25、 11×7、 12×10、 20×14、 20×15、 30×20、 30×25、 35×14、 40×30、 45×30、 45×40、 45×45、 50×30、 50×40、 55×40、 60×40、 60×45、 60×50、 65×40、 80×40。</p> <p>Pocket shape: 20×15、 35×14、 40×30、 45×30、 45×40、 45×45、 20×14、 35×30、 55×40、 65×40、 65×45、 20×20、 20×30。</p> <p>Oval Shape: 8.5×10.5、 5×5.7、 4×5。</p> <p>Round Shape: φ2.8、 φ3、 φ3.5、 φ5、 φ6、 φ8、 φ10、 φ12。 (unit:cm)</p>	Approved
535.	<p>M/S SonoScape Medical Corporation.</p> <p>Office No. FF-21, 1st Floor, Hayat Arsallah Heights, Commercial Block, CBR Town Phase -1. Islamabad</p>	<p>Legal Manufacturer: Name: M/S SonoScape Medical Corporation.</p> <p>Address: Room No. 201, 202 ,12th Building Shenzhen software park Phase 2, Keji Middle 2nd Road, Nanshan, Shenzhen,</p>	<p>HD-550 Video Endoscope System</p> <p>Model: HD-550s, HD-550, HD-550Pro, HD-510 and Below mention details.</p> <p>Class: B</p> <p>MD group: System</p>	Approved subject to submission of differential fee.

	(ELI-01301) D.O.I: 25-10-2024 Dy. No.: Dated: 09-01-2024 Fee Challan No.: 68273405730 PKR: 31000/- Dated: 30-10-2024	Guangdong, China.	LOA Validity: 29-11-2027 FSC Validity: 07-05-2025 CE certificate validity: 29-07-2027 ISO 13485 validity: 22-04-2025 Shelf life N/A Storage Conditions: 10c – 35 degrees	
536.	M/S SonoScape Medical Corporation. Office No. FF-21, 1st Floor, Hayat Arsallah Heights, Commercial Block, CBR Town Phase -1. Islamabad (ELI-01301) D.O.I: 25-10-2024 Dy. No.: Dated: 09-01-2024 Fee Challan No.: 2400950583 PKR: 31000/- Dated: 30-10-2024	Legal Manufacturer: Name: M/S SonoScape Medical Corporation. Address: Room No. 201, 202 ,12 th Building Shenzhen software park Phase 2, Keji Middle 2nd Road, Nanshan, Shenzhen, Guangdong, China.	Digital Color Doppler Ultrasound System Product Model: S90 Exp/S80/S80T/S80 Pro/S80 Exp/S80 Plus/S80 Elite/S80 Senior/S80 Super/S70i/S100 Exp/ I80-Endo/I80-Surg/I75-Endo/I70-Endo Class: B MD group: System LOA Validity: 29-11-2027 FSC Validity: 07-05-2025 CE certificate validity: 29-07-2027 ISO 13485 validity: 22-04-2025 Shelf life: N/A Storage Conditions: 10c – 35 degrees	Approved subject to submission of differential fee.
537.	M/S SonoScape Medical Corporation. Office No. FF-21, 1st Floor, Hayat Arsallah Heights, Commercial Block, CBR Town Phase -1. Islamabad (ELI-01301)	Legal Manufacturer: Name: M/S SonoScape Medical Corporation. Address: Room No. 201, 202 ,12 th Building Shenzhen software park Phase 2, Keji Middle 2nd Road, Nanshan, Shenzhen, Guangdong, China.	Intravascular Ultrasound Diagnostic System with Accessories Intravascular Ultrasound Imaging Catheter code TJ001 Model: V10 Class: B MD group: System	Approved subject to submission of differential fee.

	<p>D.O.I: 25-10-2024 Dy. No.: Dated: 09-01-2024 Fee Challan No.: 364194330031 PKR: 31000/- Dated:30-10-2024</p>		<p>LOA Validity: 29-11-2027</p> <p>FSC Validity: 17-04-2026</p> <p>CE certificate validity: 29-07-2027</p> <p>ISO 13485 validity: 22-04-2025</p> <p>Shelf life N/A</p> <p>Storage Conditions: 10c – 35 degrees</p>	
538.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9154 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 307989733701 PKR: 5000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p> <p>LOA Validity: 30-12-2027 FSC Validity: valid EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025</p>	<p>Integrated System (Model: Biolumi CX8) Ref: 010108000901, 010108001101, 01010800301, 010108001501, 010108001701, 010108001901, 010108002101, 010108002301, Accessories: Bioassays ISE Cleaner Ref: 1305990004 Bioassays Ion Selective Electrode, REF: K+ 073101003201, Na+ 073101002601, Cl- 073101002401, Ca2+ 073101002701, pH 073101002801</p> <p>Class: A MD group: System Shelf life & storage conditions: For instrument: 10 years at room temperature For ISE cleaner: 12 months at 2-8°C For ion selective electrodes: 06 months after installed properly</p>	Approved
539.	<p>M/s. Mehran International</p> <p>498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21511-DRAP (R&I)</p>	<p>Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd.</p> <p>Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China.</p>	<p>Brand Name: M.I. Device: IV Flow regulator with Extension Tube</p> <p>Extension Tube: 100mm, 300mm, 600mm, 900mm, 1200 mm, 1500 mm, 2000 mm. Class: B MD group: SET Shelf life: 05 years</p>	Approved

	Dated: 16-12-2024 Fee Challan No.: 8010650512 PKR: 31,000/- Dated: 06-12-2024	FSC Validity (CHINA) <i>(country of origin)</i> 30-06-2025 EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026	Storage condition: stored at room temperature less than 30°C LOA Validity: 17-11-2027	
540.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21510-DRAP (R&I) Dated: 16-12-2024 Fee Challan No.: 451194665121 PKR: 31,000/- Dated: 06-12-2024	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd. Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China. Ec Certificate Validity: 08-07-2026 Iso 13485:2016 Certificate Validity: 25-05-2026	Brand Name: M.I. Device: Heparin Cap Model: GSM-01, GSM-02 Class: B MD Group: Single Loa Validity: 17-11-2027 Fsc Validity <i>(Country of Origin): CHINA</i> 30-06-2025 Shelf Life: Five Years Storage Condition: Stored at Room Temperature Less than 30°C	Approved
541.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21513-DRAP (R&I) Dated: 16-12-2024 Fee Challan No.: 91678131946 PKR: 31,000/- Dated: 06-12-2024	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd. Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China. EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026 LOA Validity: 17-11-2027	Brand Name: M.I. Device: I.V. Cannula for single use Model: 26G 0.6 x 19, 24G 0.7 x 19, 22G 0.9 x 25, 20G 1.1 x 32, 18G 1.3 x 32, 18G 1.3 x 45, 16G 1.7 x 51, 14G 2.1 x 51 Class: B MD group: SET Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C	Approved
542.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21514-DRAP (R&I) Dated: 16-12-2024	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd. Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China. EC Certificate validity:	Brand Name: M.I. Device: I.V. Cannula with Stopper Heparin Cap IV Cannula: 26G 0.6 x 19, 24G 0.7 x 19, 22G 0.9 x 25, 20G 1.1 x 32, 18G 1.3 x 32, 18G 1.3 x 45,	Approved

	Fee Challan No.: 6253805882 PKR: 31,000/- Dated: 06-12-2024	08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026 FSC Validity (<i>country of origin</i>): CHINA 30-06-2025	16G 1.7 x 51, 14G 2.1 x 51 Class: B MD group: SET LOA Validity: 17-11-2027 Shelf life: 05 years Storage condition: stored at room temperature less than 30°C	
543.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21515-DRAP (R&I) Dated: 16-12-2024 Fee Challan No.: 4601292722 PKR: 31,000/- Dated: 06-12-2024	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd. Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China. EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026	Brand Name: M.I. Device: Three-way Stopcock with Tube Extension Tube: 100mm, 300mm, 600mm, 900mm, 1200 mm, 1500 mm, 2000 mm. Class: B MD group: SET LOA Validity: 17-11-2027 FSC Validity (<i>country of origin</i>): CHINA 30-06-2025 Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C	Approved
544.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21515-DRAP (R&I) Dated: 16-12-2024 Fee Challan No.: 384243770 PKR: 31,000/- Dated: 06-12-2024	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd. Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China. EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026	Brand Name: M.I. Device: Three-way Stopcock for single use Model: 3SC-P-I, 3SC-P-II Class: B MD group: SET LOA Validity: 17-11-2027 FSC Validity (<i>country of origin</i>): CHINA 30-06-2025 EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026 Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C	Approved
545.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi.	Legal Manufacturer: Name: M/S. Jiangsu Webest Medical Products Co., Ltd.	Brand Name: M.I. Device: I.V. Cannula with Stopper with Cover IV Cannula:	Approved

	<p>(ELI-00351) D.O.I: 09-12-2024 Dy. No.: 21512-DRAP (R&I) Dated: 16-12-2024 Fee Challan No.: 829527277209 PKR: 31,000/- Dated: 06-12-2024</p>	<p>Manufacturer Address: No.5 Yingchun Rd. Industrial Park, Xuyi, Jiangsu, P.R. OF China.</p> <p>EC Certificate validity: 08-07-2026 ISO 13485:2016 Certificate validity: 25-05-2026 LOA Validity: 17-11-2027 FSC Validity (<i>country of origin</i>): CHINA 30-06-2025</p>	<p>26G 0.6 x 19, 24G 0.7 x 19, 22G 0.9 x 25, 20G 1.1 x 32, 18G 1.3 x 32, 18G 1.3 x 45, 16G 1.7 x 51, 14G 2.1 x 51</p> <p>Class: B MD group: SET</p> <p>Shelf life: FIVE YEARS</p> <p>Storage condition: stored at room temperature less than 30°C</p>	
546.	<p>M/S POPULAR INTERNATIONAL PVT. LTD. HOUSE # 141 JUSTICE INAMULLAH ROAD, BLOCK 7&8 K.M.C.H.S., NEAR HILL PARK KARACHI.</p> <p>(ELI-00091) Diary Dated: 13-02-2020 Fee Challan No.: 1904049 PKR: 25,000/-</p>	<p>Legal Manufacturer: Covidien LLC a MEDTRONIC Company, Located at 15 Hampshire Street Mansfield, Ma USA 02048 Product Owner: Medtronic, Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA Supply branch for Pakistan: Covidien AGDictor von Bruns-Strasse 190212 Neuhausen am Rheinfall Switzerland Other Plants: Covidien a MEDTRONIC Company, Building 911-67 Sabanetas Industrial Park Ponce, Puerto Rico 00731, U.S.A. Covidien Zona Franca de San Isidro Carretera San Isidro Km 17 Santo Domingo, Dominican Republic Covidien 19030 Libramiento Boulevard Insurgentes 22225 Tijuana, B.C., Mexico</p>	<p>Brand Name: APPOSE™ (Skin Stapler) Device: Slim Body Skin Stapler</p> <p>Product code: 8886803512 Appose ULC Auto Suture Slim Body Skin Stapler 35 Product code: 8886803712 Appose ULC Auto Suture Slim Body Skin Stapler 35W</p> <p>Class: B MD group: SET</p> <p>LOA Validity: N/A Issued on 09-05-2018.</p> <p>FSC Validity: USFDA (<i>country of origin</i>): 16-08-2025</p> <p>FQA validity: 26-05-2024 ISO 13485:2016 Certificate validity: 19-05-2025</p> <p>Shelf life: 05 years Storage condition: Store at below 54°C or 130°F (Ambient Temperature)</p> <p>QMS - EC Certificate validity: 24-02-2025</p>	Approved

547.	<p>M/S POPULAR INTERNATIONAL PVT. LTD.</p> <p>HOUSE # 141 JUSTICE INAMULLAH ROAD, BLOCK 7&8 K.M.C.H.S., NEAR HILL PARK KARACHI.</p> <p>(ELI-00091) Diary Dated: 05-10-2020 Fee Challan No.: 1993741 PKR: 25,000/-</p>	<p>Marketed by: Covidien LLC a MEDTRONIC Company, Located at 15 Hampshire Street Mansfield, Ma USA 02048</p> <p>Manufactured by: Covidien a MEDTRONIC Company, located at 12 Gill Street, Suite 3500 Woburn, MA USA 01801</p> <p>Other Plants:</p> <p>HENKE-SASS WOLF, GMBH located at KELTENSTRASSE 1 TUTTLINGEN, Baden-Wurttemberg Germany.</p> <p>Viant AS&O Holding LLC located at 45 Lexington Dr LACONIA, NH USA</p> <p>NPA de Mexico S. de C.V. Sor Juana Ines de la Cruz # 20150 Interior 5 Cd. Industrial TIJUANA, Baja California Mexico 22444.</p>	<p>Brand Name: TRUCLEAR™ Operative Hysteroscope</p> <p>Device: Hysteroscopic Tissue Removal System.</p> <p>Model: mentioned in table below</p> <p>Class: B MD group: System</p> <p>LOA Validity: N/A Issued on 09-05-2018.</p> <p>FSC Validity: USFDA <i>(country of origin):</i> 28-03-2026</p> <p>FQA validity: 18-07-2027</p> <p>ISO Certificate validity: 16-11-2026</p> <p>Shelf life: 05 years Storage condition: Store at below 55°C (Ambient Temperature)</p> <p>QMS - EC Certificate validity: 18-07-2027</p>	Approved
548.	<p>M/S POPULAR INTERNATIONAL PVT. LTD.</p> <p>HOUSE # 141 JUSTICE INAMULLAH ROAD, BLOCK 7&8 K.M.C.H.S., NEAR HILL PARK KARACHI.</p> <p>(ELI-00091) Diary Dated: 15-01-2023 Fee Challan No.: 2111924221 PKR: 25,000/-</p>	<p>Marketed by Adeor Medical AG Martinshof 5 83626 valley Germany</p> <p>Manufactured by 83626 valley Germany</p>	<p>HICUT Instruments</p> <p>Model: mentioned below</p> <p>Class: B MD group: Family</p> <p>LOA Validity: 31-12-2023.</p> <p>FSC Validity: Germany <i>(country of origin): N/A</i> Issued on 26-08-2022</p> <p>FQA validity: 26-05-2024</p> <p>ISO 13485 validity: 30-12-2022</p> <p>Shelf life: 10 years Storage condition: Store at below 48°C or 120°F (Ambient Temperature)</p>	Approved

			DOC: 23-08-2022	
549.	<p>M/s Al Hamd Enterprises. House # FL-11/1/1, Block 6, Gulshan e Iqbal, Karachi.</p> <p>(ELI-00285) D.O.I: 22-10-2018 (Renewal Submitted) Dy. No.: Dated: 09-01-2024 Fee Challan No.: 75532380 PKR: 5000/- Dated:09-01-2024</p>	<p>Legal Manufacturer: Name: M/s Shandong Qinkai Medical Industry Co. Ltd. Address: (South section of Quancheng road in industrial park), Medical Equipment Industrial park, Chengwu County, Heze, 274200, Shangdong, China.</p>	<p>CIKINA+ URINE BAGS (500ml, 1000ml, 1500ml, 2000ml) Class: A MD group: single LOA Validity: 29-11-2027 FSC Validity: 10-11-2024 CE certificate validity: 26-05-2024</p> <p>Shelf life: 5 years</p> <p>Storage Conditions: 10c – 35 degrees</p>	<p>Approved. The firm will submit valid free sale certificate.</p>
550.	<p>M/s Al Hamd Enterprises. House # FL-11/1/1, Block 6, Gulshan e Iqbal, Karachi.</p> <p>(ELI-00285) D.O.I: 22-10-2018 (Renewal Submitted) Dy. No.: Dated: 09-01-2024 Fee Challan No.: 70395194016 PKR: 25000/- Dated:19-12-2023</p>	<p>Legal Manufacturer: Name: M/s Shandong Qinkai Medical Industry Co. Ltd. Address: (South section of Quancheng road in industrial park), Medical Equipment Industrial park, Chengwu County, Heze, 274200, Shangdong, China.</p>	<p>CIKINA+ DISPOSABLE INFUSION SET Specifications & model: (A-1, A-2, A-3, A-4)</p> <p>Class: B MD group: single LOA Validity: 29-11-2027 FSC Validity: 10-11-2024 CE certificate validity: 26-05-2024</p> <p>Shelf life: 5 years</p> <p>Storage Conditions: 10c – 35 degrees</p>	<p>Approved. The firm will submit valid free sale certificate.</p>
551.	<p>M/s Al Hamd Enterprises. House # FL-11/1/1, Block 6, Gulshan e Iqbal, Karachi.</p> <p>(ELI-00285) D.O.I: 22-10-2018</p>	<p>Legal Manufacturer: Name: M/s Shandong Qinkai Medical Industry Co. Ltd. Address: (South section of Quancheng road in industrial park), Medical Equipment Industrial park, Chengwu County, Heze,</p>	<p>CIKINA+ DISPOSABLE BURETTE INFUSION SET 100, 120 & 150 ml</p> <p>Class: B MD group: single LOA Validity: 29-11-2027 FSC Validity:</p>	<p>Approved. The firm will submit valid free sale certificate.</p>

	(Renewal Submitted) Dy. No.: Dated: 09-01-2024 Fee Challan No.: 37112253695 PKR: 25000/- Dated: 19-12-2023	274200, Shangdong, China.	10-11-2024 CE certificate validity: 26-05-2024 Shelf life: 5 years Storage Conditions: 10c – 35 degrees	
552.	M/s MSB Medical. F2 1 st floor 51-1/C, P.E.C.H.S Block 6, Karachi. (ELI-00035) Dy. No.: 1044 R&I DRAP Dated: 15-01-2025 Fee Challan No.: 2811395663 PKR: 31000/- Dated: 08-01-2025	Legal Manufacturer: Name: M/s Dukwoo Medical Co. Ltd. Address: 35, Hwaseong-ro 1616 Beongil, Bibong-Myeon, Hwaseong-Si, Gyeonggil- DO, Korea.	3S Cath I.V Cannula Model: 16G 51, 18G 51, 22G25, 16G 51, 18G 51, 22G 25, 18G 32, 20 G 32, 24G 19, 18G 32, 20G 32, 24G 19. Class: B MD group: single LOA Validity: FSC Validity: CE certificate: ISO 13485: expired Shelf life: 03 years Storage Conditions: Store at room temperature.	Approved.
553.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 8362 DRAP (R&I) Dated: 27-05-2024 Fee Challan No.: 02173814384 PKR: 25000/- Dated: 22-04-2024	Legal Manufacturer: Name: M/s Bonree Medical Co. Ltd. Manufacturer Address: 1 st floor of Building No. 02, Building No. 04, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China. ISO 13485 validity: 31-07- 2025 LOA Validity: 21-02-2029	Brand Name: Vcare Device: Nasal Oxygen Cannula Model: Neonates, infant, Pediatric, Adult. Class: B MD group: Single FSC Validity: China (country of origin): 24-10-2025 Free sale certificate from MHRA-UK dated 22-03-2023 Shelf life: 05 years Storage condition: Store in a clean, cool and dry place which should be well ventilated without humidity and corrosive gas. EC Certificate validity: 26-05-2024	Approved
554.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 8361 DRAP (R&I) Dated: 27-05-2024 Fee Challan No.:	Legal Manufacturer: Name: M/s Bonree Medical Co. Ltd. Manufacturer Address: 1 st floor of Building No. 02, Building No. 04, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China. ISO 13485 validity: 31-07- 2025 LOA Validity: 21-02-2029	Brand Name: Vcare Device: Nebulizer mask Model: S, M, L, XL Class: B MD group: Single FSC Validity: China (country of origin): 24-10-2025 Free sale certificate from MHRA-UK dated 22-03-2023 Shelf life: 05 years Storage condition: Store in a clean, cool and dry	Approved

	56467582397 PKR: 25000/- Dated: 22-04-2024		place which should be well ventilated without humidity and corrosive gas. EC Certificate validity: 26-05-2024	
555.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 8360 DRAP (R&I) Dated: 27-05-2024 Fee Challan No.: 874341101 PKR: 25000/- Dated: 08-05-2024	Legal Manufacturer: Name: M/s Shangdong Wuzhou Medical Equipment Co. Ltd. Manufacturer Address: Dingtao (Yantai) Industrial Area, Heze City, Shangdong, China. ISO 13485 validity: 04-09- 2025 LOA Validity: 21-04-2029	Brand Name: Vcare Device: Sterile Infusion Set with needle Model: W-IS-GA, W-IS-GB, W-IS-GC, W-IS-GD. Class: B MD group: Single FSC Validity: China <i>(country of origin):</i> 07-01-2026 Free sale certificate from MHRA-UK dated 21-06-2022 Shelf life: 05 years Storage condition: Store in a clean, cool and dry place which should be well ventilated with humidity less than 80%. EC Certificate validity: 26-05-2024	Approved
556.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 8359 DRAP (R&I) Dated: 27-05-2024 Fee Challan No.: 4153057422 PKR: 25000/- Dated: 22-04-2024	Legal Manufacturer: Name: M/s Bonree Medical Co. Ltd. Manufacturer Address: 1 st floor of Building No. 02, Building No. 04, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China. ISO 13485 validity: 31-07- 2025 LOA Validity: 21-02-2029	Brand Name: Vcare Device: Oxygen mask Model: S, M, L, XL Class: B MD group: Single FSC Validity: China <i>(country of origin):</i> 24-10-2025 Free sale certificate from MHRA-UK dated 22-03-2023 Shelf life: 05 years Storage condition: Store in a clean, cool and dry place which should be well ventilated without humidity and corrosive gas. EC Certificate validity: 26-05-2024	Approved
557.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	Nucleic acid detection kit (Magnetic Bead Method) B-200, T-200 Models: B200- 8T/KIT, 16T/KIT, 20T/KIT, 32T/KIT T200- 20T/KIT, 32T/KIT, 96T/KIT Class: B MD group: single LOA Validity:	Approved.

	(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 12-08-2022 Fee Challan No.: 033362502 PKR: 25000/- Dated: 04-08-2022		31-01-2025 FSC Validity: 20-12-2023 ISO 13485 validity: 24-02-2025 FSC Germany also submitted dated 21-10-2021 Shelf life: 15 months Storage Conditions: 2 to 8 °C	
558.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 50394483 PKR: 25000/- Dated: 05-01-2023	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	DILUENT Z5 DN, LYSE Z5 LD, LYSE Z5 LB Models: DILUENT Z5 DN (1L*1, 5L*1, 10L*1, 20L*1) LYSE Z5 LD (100ml*1, 250ml*1, 500ml*1, 500ml*4) LYSE Z5 LB (50ml*1, 100ml*1, 100ml*4, 200ml*1) Class: A MD group: Cluster LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 01-05-2023 FSC Netherland also submitted dated 28-03-2022 Shelf life: 24 months Storage Conditions: 4°C-30°C	Approved.
559.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 10226547 PKR: 5000/- Dated: 05-01-2023	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	DILUENT, LYSE Blood cell dilution solution IVD, Blood cell lysis reagent IVD Models: DILUENT-(1L*1, 5L*1, 10L*1, 20L*1) LYSE-(75ml/Bottle, 150ml/Bottle, 250ml/Bottle, 500ml/Bottle, 1000ml/Bottle) Class: A MD group: Cluster LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 01-05-2023 FSC Germany also submitted	Approved.

			dated 28-03-2022 Shelf life: 24 months Storage Conditions: 4°C-30°C																			
560.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 583200398441 PKR: 25000/- Dated:05-01-2023</p>	<p>Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>C- REACTIVE protien kit (immunoturbidimetric method)</p> <p>Models: CRP Kit (CRP R1, CRP R2, CRP Calibrator, CRP Control)</p> <p>Class: B</p> <p>MD group: Single</p> <p>LOA Validity: 31-01-2025</p> <p>ISO 13485 validity: 24-02-2025</p> <p>FSC Validity: 01-05-2023</p> <p>FSC Germany also submitted dated 28-03-2022</p> <p>Shelf life: 12 months</p> <p>Storage Conditions: 2-8c</p> <table border="1"> <thead> <tr> <th>Constituent</th> <th>Packaging</th> <th>Spec</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Reagent</td> <td>25 T</td> <td>R1: 0.4 mL×25, R2: 1.5 mL×1</td> </tr> <tr> <td>100 T</td> <td>R1: 0.4 mL×100, R2: 3.0 mL×2</td> </tr> <tr> <td>200 T</td> <td>R1: 0.4 mL×200, R2: 4.0 mL×3</td> </tr> <tr> <td>400 T</td> <td>R1: 0.4 mL×400, R2: 4.0 mL×6</td> </tr> <tr> <td colspan="3">Calibrator (Optional): 6 Level×1×0.5 mL; 6 Level×1×1.0 mL</td> </tr> <tr> <td colspan="3">Control(Optional): 2 Level×1×0.5 mL; 2 Level×1×1.0 mL; 2 Level×1×2.0 mL; 2 Level×1×5.0 mL</td> </tr> </tbody> </table>	Constituent	Packaging	Spec	Reagent	25 T	R1: 0.4 mL×25, R2: 1.5 mL×1	100 T	R1: 0.4 mL×100, R2: 3.0 mL×2	200 T	R1: 0.4 mL×200, R2: 4.0 mL×3	400 T	R1: 0.4 mL×400, R2: 4.0 mL×6	Calibrator (Optional): 6 Level×1×0.5 mL; 6 Level×1×1.0 mL			Control(Optional): 2 Level×1×0.5 mL; 2 Level×1×1.0 mL; 2 Level×1×2.0 mL; 2 Level×1×5.0 mL			Approved.
Constituent	Packaging	Spec																				
Reagent	25 T	R1: 0.4 mL×25, R2: 1.5 mL×1																				
	100 T	R1: 0.4 mL×100, R2: 3.0 mL×2																				
	200 T	R1: 0.4 mL×200, R2: 4.0 mL×3																				
	400 T	R1: 0.4 mL×400, R2: 4.0 mL×6																				
Calibrator (Optional): 6 Level×1×0.5 mL; 6 Level×1×1.0 mL																						
Control(Optional): 2 Level×1×0.5 mL; 2 Level×1×1.0 mL; 2 Level×1×2.0 mL; 2 Level×1×5.0 mL																						
561.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 6802971031 PKR: 5000/- Dated:05-01-2023</p>	<p>Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>HEMATOLOGY ANALYZER (Z3), (Z3 CRP)</p> <p>Models: Z3, Z3 CRP</p> <p>Class: A</p> <p>MD group: Cluster</p> <p>LOA Validity: 31-01-2025</p> <p>ISO 13485 validity: 24-02-2025</p> <p>FSC Validity: 01-05-2023</p> <p>FSC Germany also submitted dated 28-03-2022</p> <p>Shelf life: N/A (software validation report submitted)</p> <p>Storage Conditions: 15-30°C</p>	Approved.																		
562.	<p>M/s Ayyan Molecular Products.</p>	<p>Legal Manufacturer: Name: Zybio Inc.</p>	<p>PROBE CLEANSER</p> <p>Class: A</p> <p>MD group: Single</p>	Approved.																		

	<p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 3527149385 PKR: 5000/- Dated:05-01-2023</p>	<p>Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: FSC Germany submitted dated 28-03-2022 Shelf life: 12 months Storage Conditions: 4-30°C</p>	
563.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 939239181 PKR: 5000/- Dated:10-04-2023</p>	<p>Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>Chemistry analyzer (EXC200) Class: A MD group: Single LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 06-01-2024 FSC Germany submitted dated 06-09-2021 Shelf life: N/A Storage Conditions: -20°C to 55°C</p>	Approved.
564.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023</p>	<p>Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>Cluster for Liver function TBIL= Total bilirubin kit ALP=Alanine aminotransferase kit AST= Aspartate aminotransferase kit DBIL= Direct bilirubin kit Class: B MD group: Cluster LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022 Shelf life: 12 months</p>	Approved.

	Fee Challan No.: 45065431 PKR: 25000/- Dated: 10-04-2023		Storage Conditions: +2°C to +8°C	
565.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 796884663 PKR: 25000/- Dated: 10-04-2023	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	Cluster for Substrate UREA= Urea kit GLU= Glucose kit TG= Triglyceride kit UA= Uric acid Class: B MD group: Cluster LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022 Shelf life: GLU= 18 months TG, UA, UREA= 12 months Storage Conditions: +2°C to +8°C Model: GLU (R130 mL x 1, R2 7.5 mL x 1) (R1 30 mL x 3, R2 7.5 mL x 3) TG (R1 30 mL x 3, R2 7.5 mL x 3) UA (R1 30 mL x 3, R2 7.5 mL x 3) UREA (R1 30 mL x 3, R2 7.5 mL x 3)	Approved.
566.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 22392604014	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	Cluster for LipoProtien CHOL= Total Cholesterol HDL-C= High Density Lipoprotein cholesterol LDL-C = Low Density Lipoprotein Cholesterol Class: B MD group: Cluster LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022 Shelf life: 18 months Storage Conditions: +2°C to +8°C	Approved.

	PKR: 25000/- Dated: 10-04-2023			
567.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 436676209 PKR: 25000/- Dated:10-04-2023</p>	<p>Legal Manufacturer:</p> <p>Name: Zybio Inc.</p> <p>Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>Cluster for Enzyme</p> <p>LPS – lipase kit, ALP- Alkaline phosphatase</p> <p>LDH- lactate Dehydrogenase kit</p> <p>GGT-gamma glutamyl transferase kit</p> <p>Class: B</p> <p>MD group: Cluster</p> <p>LOA Validity: 31-01-2025</p> <p>ISO 13485 validity: 24-02-2025</p> <p>FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022</p> <p>Shelf life: LDH, GGT,ALP- 12 Months LPS- 18 months</p> <p>Storage Conditions: +2°C to +8°C</p> <p>Model:</p> <p>LDH (R1 30 mL x 3, R2 7.5 ml x 3)</p> <p>GGT (R1 30 mL x 3, R2 7.5 mL x 3)</p> <p>LPS (Calibrator 1 Level x 1.0 mL x 1, Control 2 Levels x 1.0 mL x 1 RI 30 mL x 3, R2 10 mL x 3)</p> <p>ALP (R1 30 mL x 3, R2 7.5 mL x 3)</p>	Approved.
568.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023</p>	<p>Legal Manufacturer:</p> <p>Name: Zybio Inc.</p> <p>Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.</p>	<p>Cluster for Transport protein</p> <p>ALB= Albumin kit</p> <p>HBA1= Glycated hemoglobin kit</p> <p>TP= Total protein</p> <p>Class: B</p> <p>MD group: Cluster</p> <p>LOA Validity: 31-01-2025</p> <p>ISO 13485 validity: 24-02-2025</p> <p>FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022</p> <p>Shelf life: 12 months</p> <p>Storage Conditions:</p>	Approved.

	Fee Challan No.: 6678815708 PKR: 25000/- Dated: 10-04-2023		+2°C to +8°C Model: ALB (R 30 mL × 6) HBA1 (R1 15 mL x 2, R2 10 mL × 1) (Lyse 50 mL x 2) (Calibrator 5 Levels × 1.0 mL × 1) (Control 2 Levels × 1.0 mL × 1) TP (R 30 mL × 6)	
569.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 PKR: 25000/-	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	MG (Magnesium kit) Class: B MD group: kit LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 06-01-2024 FSC Netherland submitted dated 08-03-2022 Shelf life: 12 months Storage Conditions: +2°C to +8°C	Approved.
570.	M/s Ayyan Molecular Products. Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town Warehouse: Suit No. 16-B, 1 st Floor Chauburji Center Multan Road, Lahore (ELI-00721) D.O.I: 05-07-2021 Dy. No.: Dated: 10-01-2023 Fee Challan No.: 050808216 PKR: 5000/- Dated: 05-01-2023	Legal Manufacturer: Name: Zybio Inc. Address: Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, People's Republic of China.	HEMATOLOGY ANALYZER (Z50) Class: A MD group: SINGLE LOA Validity: 31-01-2025 ISO 13485 validity: 24-02-2025 FSC Validity: 01-05-2023 FSC Netherland submitted dated 08-03-2022 Shelf life: N/A Storage Conditions: 10 TO 40 °C	Approved.
571.	M/s Ayyan Molecular Products.	Legal Manufacturer: Name:	iSed ESR Analyzer	Approved.

	<p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: 22913 Dated: 12-08-2022 Fee Challan No.: 6104022744 PKR: 5000/- Dated:04-08-2022</p>	<p>Alcor Scientific Address: 20 Thurber Boulevard Smithfield R1 02917 USA.</p>	<p>Class: A MD group: Cluster LOA Validity: 31-12-2022 ISO 13485 validity: 24-02-2023 CFG USFDA validity: 08-10-2022 Shelf life: 05 years Storage Conditions: 18 to 30°C</p> <p>Model: Iwash-112-12-001 Iwaste-112-12-002 Test Cards-112-00250, 112-00500, 112-01000</p>	
572.	<p>M/s Ayyan Molecular Products.</p> <p>Head office: 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town</p> <p>Warehouse: Suit No. 16-B, 1st Floor Chauburji Center Multan Road, Lahore</p> <p>(ELI-00721) D.O.I: 05-07-2021 Dy. No.: 22912 Dated: 12-08-2022 Fee Challan No.: 6457585346 PKR: 5000/- Dated:04-08-2022</p>	<p>Legal Manufacturer: Name: Alcor Scientific Address: 20 Thurber Boulevard Smithfield R1 02917 USA.</p>	<p>MiniiSed ESR Analyzer</p> <p>Class: A MD group: Cluster LOA Validity: 31-12-2022 ISO 13485 validity: 24-02-2023 CFG USFDA validity: 08-10-2022 Shelf life: 05 years Storage Conditions: 18 to 30°C</p> <p>Model: Analyzer-112-01017 Miniwash-112-12-003, Miniwaste-112-12-004 test cards-112-00250, 112-00500, 112-01000</p>	Approved.
573.	<p>M/s Lab Link Enterprises.</p> <p>Head office: 221-H, Block-2, P.E.C.H.S, Karachi.</p> <p>(ELI-00007) Dy. No.: 12268 Dated: 29-07-2024 Fee Challan No.: 488459797 PKR: 25000/- Dated:27-06-2024</p>	<p>Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.</p>	<p>MEDLINE STERILE IV Catheter with BUTTERFLY</p> <p>Class: B MD group: Family LOA Validity: 17-03-2027 ISO 13485 validity: 11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028</p>	Approved

			Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	
574.	M/s Lab Link Enterprises. Head office: 221-H, Block-2, P.E.C.H.S, Karachi. (ELI-00007) Dy. No.: 12638 Dated: 29-07-2024 Fee Challan No.: 7134202648 PKR: 25000/- Dated: 15-07-2024	Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.	MEDLINE sterile disposable syringe without needle 30ml & 50 ml Class: B MD group: Family LOA Validity: 17-03-2027 ISO 13485 validity: 11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028 Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	Approved
575.	M/s Lab Link Enterprises. Head office: 221-H, Block-2, P.E.C.H.S, Karachi. (ELI-00007) Dy. No.: 12640 Dated: 02-08-2024 Fee Challan No.: 668057808770 PKR: 25000/- Dated: 15-07-2024	Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.	Medline Sterile Disposable Syringe with Needle 10 ml 20 ml Class: B MD group: Family LOA Validity: 17-03-2027 ISO 13485 validity: 11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028 Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	Approved
576.	M/s Lab Link Enterprises. Head office: 221-H, Block-2, P.E.C.H.S, Karachi. (ELI-00007) Dy. No.: 12266 Dated: 29-07-2024 Fee Challan No.:	Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.	MEDLINE STERILE IV Catheter with INJECTION PORT & Wings 14G, 16G, 18G, 20G, 22G, 24G Needle length : 19mm – 51 mm Class: B LOA Validity: 17-03-2027 ISO 13485 validity:	Disposed off as the case was addressed in 76 th MDB meeting.

	9614714082 PKR: 25000/- Dated: 27-06-2024		11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028 Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	
577.	M/s Lab Link Enterprises. Head office: 221-H, Block-2, P.E.C.H.S, Karachi. (ELI-00007) Dy. No.: 12269 Dated: 29-07-2024 Fee Challan No.: 8163075963 PKR: 25000/- Dated: 27-06-2024	Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.	MEDLINE STERILE IV Catheter pen type 14G, 16G, 18G, 20G, 22G, 24G Needle length: 19mm – 51 mm Class: B LOA Validity: 17-03-2027 ISO 13485 validity: 11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028 Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	Disposed off as the case was addressed in 76 th MDB meeting.
578.	M/s Lab Link Enterprises. Head office: 221-H, Block-2, P.E.C.H.S, Karachi. (ELI-00007) Dy. No.: 12267 Dated: 29-07-2024 Fee Challan No.: 12369178180 PKR: 25000/- Dated: 27-06-2024	Legal Manufacturer: Name: Yangzhou Medline Industry Co. Ltd. Address: 108, Jinshan Road, Economic Development Zone, Yangzhou China.	Medline Sterile Infusion Set with/Without Y Port Class: B LOA Validity: 17-03-2027 ISO 13485 validity: 11-10-2024 Fsc China validity: 10-01-2026 FQA validity: 31-12-2028 Shelf life: 05 years Storage Conditions: -5 to 60°C & RH 30%-80%	Board approved 'Medline Sterile Infusion Set without Y Port only' as the type 'Medline Sterile Infusion Set with Y Port' type has already been addressed in 76 th MDB meeting.
579.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926)	Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone,	Yuwell – Positive Airway Pressure units. Model: (YH-350) Class: B MD group: single LOA Validity: FSC Validity: 30-11-2022 (expired)	Deferred for submission of following information / documents : i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -20°C to -70°C Relative

	<p>D.O.I: 17/05/2022</p> <p>Dy. No.: 27600 DRAP (R&I)</p> <p>Dated: 29-09-2022</p> <p>Fee Challan No.: 9602965873</p> <p>PKR: 25000/-</p> <p>Dated:27-09-2022</p>	<p>Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd.</p> <p>Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>CE certificate validity: 01-11-2024</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C</p> <p>Transport Storage Conditions: -20°C to -70°C</p> <p>Operate & transport Relative Humidity: 15% - 90%</p>	<p>Humidity: 15% - 90%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Briefly explain type of Positive airway pressure unit (continuous/ Bi-level / automatic) applied for the purpose of registration, along with performance specifications (pressure range, humidification features, auto titration etc.)</p> <p>iv. Valid & legalized Free sale certificate.</p>
580.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926)</p> <p>D.O.I: 17/05/2022</p> <p>Dy. No.: 27587 DRAP (R&I)</p> <p>Dated: 29-09-2022</p> <p>Fee Challan No.: 02891858</p> <p>PKR: 25000/-</p> <p>Dated: 27-09-2022</p>	<p>Legal Manufacturer:</p> <p>Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd.</p> <p>Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd.</p> <p>Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Positive Airway Pressure units.</p> <p>Model: (YH-730)</p> <p>Class: B</p> <p>MD group: single</p> <p>LOA Validity:</p> <p>FSC Validity: 30-11-2022 (expired)</p> <p>CE certificate validity: 01-11-2024</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C</p> <p>Transport Storage Conditions: -20°C to -70°C</p> <p>Operate & transport Relative Humidity: 15% - 90%</p>	<p>Deferred for submission of following information / documents:</p> <p>i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -20°C to -70°C Relative Humidity: 15% - 90%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Briefly explain type of your Positive airway pressure unit (continuous/ Bi-level / automatic) applied for the purpose of registration, along with performance specifications (pressure range, humidification features, auto titration etc.)</p> <p>iv. Valid & legalized free sale certificate.</p>
581.	<p>M/s Moody Global Services. Office # 14, 2nd floor,</p>	<p>Legal Manufacturer:</p> <p>Name: M/s Jiangsu Yu Yue Medical</p>	<p>Yuwell – Positive Airway Pressure units.</p> <p>Model: (YH-830)</p>	<p>Deferred for submission of following information / documents:</p>

	<p>Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 27588 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 3158966456 PKR: 25000/- Dated: 27-09-2022</p>	<p>Equipment & Supply Co. Ltd.</p> <p>Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Class: B MD group: single LOA Validity: FSC Validity: 30-11-2022 (expired) CE certificate validity: 01-11-2024</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C</p> <p>Transport Storage Conditions: -20°C to -70°C</p> <p>Operate & transport Relative Humidity: 15% - 90%</p>	<p>i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -20°C to -70°C Relative Humidity: 15% - 90%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Briefly explain type of your Positive airway pressure unit (continuous/ Bi-level / automatic) applied for the purpose of registration, along with performance specifications (pressure range, humidification features, auto titration etc.)</p> <p>iv. Valid & legalized free sale certificate.</p>
582.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 275590 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 48928089394 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Positive Airway Pressure units. Model: (YH-480) Class: B MD group: single LOA Validity: FSC Validity: 30-11-2022 (expired) CE certificate validity: 01-11-2024</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C</p> <p>Transport Storage Conditions: -20°C to -70°C</p> <p>Operate & transport Relative Humidity: 15% - 90%</p>	<p>Deferred for submission of following information / documents:</p> <p>i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -20°C to -70°C Relative Humidity: 15% - 90%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Briefly explain type of your Positive airway pressure unit (continuous/ Bi-level / automatic) applied for the purpose of registration, along with performance specifications (pressure range, humidification features, auto titration etc.)</p>

				iv. Valid & legalized free sale certificate.
583.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 275593 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 7820037852 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Positive Airway Pressure units. Model: (YH-550) Class: B MD group: single LOA Validity: FSC Validity: 30-11-2022 (expired) CE certificate validity: 01-11-2024</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C</p> <p>Transport Storage Conditions: -20°C to -70°C</p> <p>Operate & transport Relative Humidity: 15% - 90%</p>	<p>Deferred for submission of following information / documents:</p> <p>i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -20°C to -70°C Relative Humidity: 15% - 90%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Briefly explain type of your Positive airway pressure unit (continuous/ Bi-level / automatic) applied for the purpose of registration, along with performance specifications (pressure range, humidification features, auto titration etc.)</p> <p>iv. Valid & legalized free sale certificate.</p>
584.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 27589 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 96309617795 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Portable Phlegm Suction Unit. Model: 7E-C Class: B MD group: single LOA Validity: FSC Validity: 21-10-2023 (expired)</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C Relative Humidity: 30% - 80%</p> <p>CE certificate validity: 26-05-2024</p>	<p>Deferred for submission of following information / documents:</p> <p>i. Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: -40°C – 55°C, Relative Humidity: 10% - 93%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.?</p> <p>ii. Submit letter of authorization with date issued and its validity.</p> <p>iii. Mention whether the device has both AC and battery power options. Valid & legalized free sale certificate.</p>

585.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 27586 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 0375132082 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Portable Phlegm Suction Unit. Model: 7E-D Class: B MD group: single LOA Validity: FSC Validity: 21-10-2023 (expired)</p> <p>Shelf life: 5 years</p> <p>Operate temperature: +5°C - +35°C Relative Humidity: 30% - 80%</p> <p>CE certificate validity: 26-05-2024</p>	<p>Deferred for submission of following information / documents:</p> <ol style="list-style-type: none"> Clarify about the storage conditions mentioned on the form submitted (Storage Conditions: - 40°C – 55°C, Relative Humidity: 10% - 93%), is it storage condition for stability studies or storage at warehouse/pharmacies etc.? Submit letter of authorization with date issued and its validity. Mention whether the device has both AC and battery power options. Valid & legalized free sale certificate.
586.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 27591 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 9045917322 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, China. Manufacturer Address: Yunyang Industrial Park, 212300, Danyang, Jiangsu, China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>Yuwell – Non-contact Infrared Thermometer Model: YT-2 Class: B MD group: single LOA Validity: FSC Validity: (expired)</p> <p>Shelf life: 5 years</p> <p>Storage condition: 10°C - 40°C Relative Humidity: 15% - 90%</p> <p>Verified from EUDAMED</p>	<p>Deferred for submission of following information / documents:</p> <ol style="list-style-type: none"> Submit letter of authorization with date issued and its validity. Valid & legalized free sale certificate.
587.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.:</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, China. Manufacturer Address: Yunyang Industrial Park,</p>	<p>Yuwell – Non-contact Infrared Ear Thermometer Model: YHT200 Class: B MD group: single LOA Validity: FSC Validity: (expired)</p> <p>Shelf life: 5 years</p> <p>Storage condition:</p>	<p>Deferred for submission of following information / documents:</p> <ol style="list-style-type: none"> Submit letter of authorization with date issued and its validity. Valid & legalized free sale certificate.

	27585 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 259716729205 PKR: 25000/- Dated: 27-09-2022	212300, Danyang, Jiangsu, China. Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.	10°C - 40°C Relative Humidity: 15% - 90% (non condensing) Verified from EUDAMED	
588.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 27599 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 7477713614 PKR: 25000/- Dated: 27-09-2022	Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, China. Manufacturer Address: Yunyang Industrial Park, 212300, Danyang, Jiangsu, China. Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.	YUWELL - Air Compressive Nebulizer Model: 407A Class: B MD group: single LOA Validity: FSC Validity: (expired) EC Certificate validity: 26-05-2024 Shelf life: 5 years Storage condition: 5°C to 40°C	Deferred for submission of following information / documents: i. Submit letter of authorization with date issued and its validity. ii. Valid & legalized free sale certificate.
589.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 27592 DRAP (R&I) Dated: 29-09-2022 Fee Challan No.: 8554498088 PKR: 25000/- Dated: 27-09-2022	Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, China. Manufacturer Address: Yunyang Industrial Park, 212300, Danyang, Jiangsu, China. Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.	YUWELL – Mesh Nebulizer Model: M-103 Class: B MD group: single LOA Validity: FSC Validity: (expired) EC Certificate validity: 26-05-2024 Shelf life: 5 years Storage condition: 5°C to 40°C	Deferred for submission of following information / documents: i. Letter of authorization with date issued and its validity. ii. Legalized and valid free sale certificate & EC Certificate required which should be valid till date.

590.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 27595 DRAP (R&I) Dated: 29-09-2022</p> <p>Fee Challan No.: 4850768929 PKR: 25000/- Dated: 27-09-2022</p>	<p>Legal Manufacturer: Name: M/s Jiangsu Yu Yue Medical Equipment & Supply Co. Ltd. Address: No. 01, Baisheng Road, Development Zone, Danyang, Jiangsu, China. Manufacturer Address: Yunyang Industrial Park, 212300, Danyang, Jiangsu, China.</p> <p>Name: M/s Suzhou Yuyue Medical Technology Co. Ltd. Address: No. 09, Jinfeng Road, Suzhou Science & Technology Town Suzhou, Jiangsu, China.</p>	<p>YUWELL – Nasal Pillow mask Model: YP-01 Class: B MD group: single LOA Validity: FSC Validity: (expired) EC Certificate validity: 26-05-2024</p> <p>Shelf life: 5 years</p> <p>Storage condition: 5°C to 40°C</p>	<p>Deferred for submission of following information / documents: Letter of authorization with date issued and its validity, Free sale certificate, ISO 13485 certificate & EC Certificate required which should be valid till date and legalised.</p>
591.	<p>M/s Hospital Solutions. 174-e, Block-2, PECHS, Karachi.</p> <p>(ELI-00250) D.O.I:19/10/2018 <i>Renewal submitted</i></p> <p>Dy. No.: 780 DRAP (R&I) Dated: 12-01-2024</p> <p>Fee Challan No.: 972339238 PKR: 25000/- Dated: 14-12-2023</p>	<p>Legal Manufacturer: Name: M/s Jiangxi ZhouRuiHua Medical Instruments Co. Ltd. Address: At 14th industrial building, Xiajiang industrial Zone, Xiajiang Ji, Aan, Jiangxi Province, China.</p>	<p>Single Use - Disposable Stone Retrieval Basket</p> <p>Class: B MD group: single LOA Validity: 12-06-2025 FSC Validity: 13-12-2023 (expired) EC Certificate validity: 26-05-2024(expired) ISO 13485 validity: 14-02-2026</p> <p>Shelf life: 2 years Storage condition: 15°C to 35°C</p>	<p>Approved.</p>
592.	<p>M/s BEST-MED TRADERS Banglow # B-63, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi</p> <p>Import License # - ELI-00236</p> <p>Date of Dossier Submission: 06-01-2021</p> <p>Fee PKR 25,000/- (04-01-202) Challan No #: 1982048</p>	<p>(Legal Manufacturer) HANGZHOU FUSHAN MEDICAL APPLIANCES CO., LTD., Address: No.1288 South Jinxi Road, Linglong Industry Park, Lin'an District Hangzhou City,Zhejiang Province 311301 China.</p> <p>ISO 13485 Validity: 03-07-2026</p> <p>LOA Validity: 19-05-2026</p>	<p>Silicone Stomach Tube</p> <p>Model No: 5FR, 6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR & 20FR</p> <p>Class- B Shelf Life: 3 years Storage conditions: Room Temperature</p> <p>Packing: Single packing each tube.</p> <p>FSC (China) validity:09-01-2024</p> <p>EC Certificate Validity: 31-12-2028</p>	<p>Approved.</p>

593.	M/s BEST-MED TRADERS Banglow # 63-B, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission: 10-11-2022 PKR 25,000/- deposit slip no: 233483306	(Legal Manufacturer) Dongguan Tondaus Meditech Co. ltd 3rd Floor, No.27, Rd.Guantai, Chiling Community, Houjie Town, Dongguan, Guangdong, China. ISO 13485 Validity: 10-11-2025 LOA Validity: 10-01-2024	Surgical Skin Marker Class – A Size & Model: TD01 Shelf Life: 3 years Storage conditions: Keep in cool & dry place. Keep away from sunlight. Single Packing. FSC – China Validity: 15-11-2024 EC Certificate Validity: 26-05-2024	Approved. Registration letter shall be issued after provision of valid & legalized free sale certificate, EC certificate and LoA
594.	M/s BEST-MED TRADERS Banglow # 63-B, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission: 22-12-2022 PKR 5,000/- Deposit Slip No: 8717401547	(Legal Manufacturer) Vitaimed Instrument Co.,Ltd, located at Factory No.101 Nanmatou Rd., Pudong, Shanghai 200125, China. ISO 13485 Validity: 27-07-2026 LOA Validity: 30-12-2024	Urine Meter Class - A Shelf Life: 3 years Size & Model: KYD04 Storage conditions: Keep in cool & dry place. Keep away from sunlight. FSC – China Validity: 01-02-2025 EC Certificate Validity: 26-05-2024	Approved. Registration letter shall be issued after provision of valid & legalized EC certificate and LoA
595.	M/s BEST-MED TRADERS Banglow # B-63, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission: 30-07-2022 PKR 25,000/- Deposit Slip No: 09966364	Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd. Floor2, Building 102, NO.198 East Wuzhou Road, Development Zone, Yangzhou City ISO 13485 Validity: 20-10-2025 EC Certificate Validity: 26-05-2024 LOA Validity: 19-05-2026	Chest Drainage Catheter with trocar Class - B Shelf Life: 3 years Size & Model: 8FR/10FR/12FR/14FR 16FR/18FR/20FR/22FR/24FR /28 FR/30FR/32FR/34FR/36FR Storage conditions: Keep in cool & dry place. Keep away from sunlight. FSC – China Validity:09-01-2024	Approved.
596.	M/s BEST-MED TRADERS Banglow # 63-B, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission:	Vitaimed Instrument Co. Ltd, located at Factory No.101 Nanmatou Rd., Pudong, Shanghai 200125, China. ISO 13485 Validity: 27-07-2026 LOA Validity: 30-12-2024	Urine Bag Class - A Shelf Life: 3 years Size & Model: KYB13 Storage conditions: Keep in cool & dry place. Keep away from sunlight.	Approved. Registration letter shall be issued after provision of valid & legalized free sale certificate, EC certificate, and valid letter of authorization.

	22-12-2022 PKR 5,000/- Deposit Slip No: 72320197660		EC Certificate Validity: 26-05-2024 FSC – China Validity: 01-02-2025	
597.	M/s BEST-MED TRADERS Banglow # 63-B, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission: DATE: 05-03-2021 PKR 25,000/- (05-03-2021) Deposit Slip No: 1994365	(Legal Manufacturer) Vitaimed Instrument Co.,Ltd, located at Factory No.101 Nanmatou Rd., Pudong, Shanghai 200125, China. FSC – China Validity: 01-02-2025 ISO 1385 Validity: 27-07-2026	Feeding Set Class - B Shelf Life: 3 years Size & Model: 1000 mL Storage conditions: Keep in cool & dry place. Keep away from sunlight. LOA Validity: 30-12-2024 EC Certificate Validity: 26-05-2024,	Approved. Registration letter shall be issued after provision of valid & legalized EC certificate, and valid letter of authorization.
598.	M/s BEST-MED TRADERS Banglow # B-63, Block 13-D/2 Gulshan-E-Iqbal, Near Abrar Masjid Karachi Import License # - ELI-00236 Date of Dossier Submission: 30-07-2022 PKR 25,000/- Deposit Slip No: 09966364	Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd. Floor2, Building 102, NO.198 East Wuzhou Road, Development Zone, Yangzhou City FSC – China Validity: 09-01-2024 ISO 13485 Validity: 20-10-2025 EC Certificate Validity: 26-05-2024 LOA Validity: 19-05-2026	Chest Drainage Catheter without Trocar Class - B Shelf Life: 3 years Size & Model: 8FR/10FR/12FR/14FR/ 16F/18FR/20FR/22FR/24FR/28 FR/30FR/32FR/36FR Storage conditions: Keep in cool & dry place. Keep away from sunlight.	Approved.
599.	M/s Hospital Solutions. 174-e, Block-2, PECHS, Karachi. (ELI-00250) D.O.I:19/10/2018 <i>Renewal submitted</i> Dy. No.: 779 DRAP (R&I) Dated: 12-01-2024 Fee Challan No.: 6435031419 PKR: 50000/- Dated: 14-12-2023	Legal Manufacturer: Name: M/s Jiangxi ZhouRuiHua Medical Instruments Co. Ltd. Address: At 14 th industrial building, Xiajiang industrial Zone, Xiajiang Ji, Aan, Jiangxi Province, China.	Disposable Biopsy Forceps Class: B MD group: single LOA Validity: 12-06-2025 FSC Validity: 13-12-2023 (expired) EC Certificate validity: 26-05-2024 (expired) ISO 13485 validity: 14-02-2026 Shelf life: 2 years Storage condition:	Approved. Registration letter shall be issued after provision of valid & legalized free sale certificate, EC certificate.

			15°C to 35°C	
600.	<p>M/s. Mana & Co Office # 401, 4th floor, Masood Chamber, Shahrah-e-Liaquat, Karachi.</p> <p>(ELI-00098)</p> <p>Fee challan No 800366133 PKR.50000/- Date:26/07/2024</p>	<p>Legal Manufacturer: Name: M/s Assure Tech. (Hangzhou) Co., Ltd. Manufacturer Address: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou 310011, Zhejiang, China</p>	<p>Brand Name: Medicare Generic Name: HCV Rapid Test (Single –Use) MD Group: Kit Class: D Codes / Sizes: HCV-W23, HCV-P23 HCV-W11 & HCV-P11 FSC: China Validity: 03-01-2026 LOA Validity: 25-01-2029 ISO 13485 certificate validity: 25-11-2025 Shelf Life: 5 years Storage condition: 2-30°C</p>	Approved
601.	<p>M/s. Mana & Co Office # 401, 4th floor, Masood Chamber, Shahrah-e-Liaquat, Karachi.</p> <p>(ELI-00098)</p> <p>Fee challan No 370266976302 PKR.50000/- Dated:26/07/2024</p>	<p>Legal Manufacturer: Name: M/s Assure Tech. (Hangzhou) Co., Ltd.</p> <p>Manufacturer Address: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou 310011, Zhejiang, China</p>	<p>Brand Name: Medicare Generic Name: HIV ½ Rapid Test MD Group: Kit Class: D Codes / Sizes: HIV-W23M, HIV-P23M HIV- P11M & HIV-W11M FSC: China Validity: 03-01-2026 LOA Validity: 25-01-2029 ISO 13485 certificate validity: 25-11-2025 Shelf Life: 5 years Storage condition: 2-30°C</p>	Approved
602.	<p>M/s. IWANT Office # 01, 3rd floor, Parkland city Centre, I- 8 Markaz, Islamabad.</p> <p>(ELI-01119)</p> <p>Date of Submission of application: 24-01-2025 PKR.62000/-</p>	<p>Legal Manufacturer: Matex Lab SpA Via Carlo Urbani 2, angolo via Enrico Fermi, 72100 Brindisi Italy.</p> <p>Product Owner: Name: QVENTIS GmbH Address: Neuendofstrasse 18 A, 16761 Hennigsdorf, Germany.</p> <p>FSC (Italy) Issuance date: 10-07-2024 Validity date: Not mentioned LOA Validity: 06-11-2027 ISO 13485 certificate validity: 03-04-2026</p>	<p>Brand Name: RENÉE SMILE Generic Name: Dermal fillers MD Group: Single Class: D Description: A pre-filled syringe containing a smooth, hydro-balanced gel containing 22 mg/mL of hyaluronic acid (HA), which helps provide natural-looking volume and hydration to the lips. Pakcing: 2x1.0ml, 1 x1.0 ml Codes: DE22P1/M, DE22P2/M</p> <p>Shelf Life: 24 months Storage condition: 2°C and 25°C</p>	Approved

			FQA QMS validity: 26-01-2028	
603.	<p>M/s. IWANT Office # 01, 3rd floor, Parkland city Centre, I- 8 Markaz, Islamabad.</p> <p>(ELI-01119)</p> <p>Date of Submission of application: 24-01-2025 PKR.62000/-</p>	<p>Legal Manufacturer: Matex Lab SpA Via Carlo Urbani 2, angolo via Enrico Fermi, 72100 Brindisi Italy.</p> <p>Product Owner: Name: QVENTIS GmbH Address: Neuendofstrasse 18 A, 16761 Hennigsdorf, Germany.</p> <p>FSC (Italy) Issuance date: 10-07-2024 Validity date: Not mentioned LOA Validity: 06-11-2027 ISO 13485 certificate validity: 03-04-2026</p>	<p>Brand Name: RENÉE LIFT Generic Name: Dermal fillers MD Group: Single Class: D Description: A pre-filled syringe containing a smooth, hydro-balanced gel containing 26 mg/mL of hyaluronic acid (HA), which helps provide natural-looking volume and hydration to the lips. Packing: 2x1.0ml, 1 x1.0 ml Codes: DE26P1/Y, DE26P2/Y</p> <p>Shelf Life: 24 months Storage condition: 2°C and 25°C</p> <p>FQA QMS validity: 26-01-2028</p>	Approved
604.	<p>M/s. IWANT Office # 01, 3rd floor, Parkland city Centre, I- 8 Markaz, Islamabad.</p> <p>(ELI-01119)</p> <p>Date of Submission of application: 24-01-2025 PKR.62000/-</p>	<p>Legal Manufacturer: Matex Lab SpA Via Carlo Urbani 2, angolo via Enrico Fermi, 72100 Brindisi Italy.</p> <p>Product Owner: Name: QVENTIS GmbH Address: Neuendofstrasse 18 A, 16761 Hennigsdorf, Germany.</p> <p>FSC (Italy) Issuance date: 10-07-2024 Validity date: Not mentioned LOA Validity: 06-11-2027 ISO 13485 certificate validity: 03-04-2026</p>	<p>Brand Name: RENÉE TOUCH Generic Name: Dermal fillers MD Group: Single Class: D Description: A pre-filled syringe containing a smooth, hydro-balanced gel containing 24 mg/mL of hyaluronic acid (HA), which helps provide natural-looking volume and hydration to the lips. Packing: 2x1.0ml, 1 x1.0 ml Codes: DE24P1/S, DE24P2/S</p> <p>Shelf Life: 24 months Storage condition: 2°C and 25°C</p> <p>FQA QMS validity: 26-01-2028</p>	Approved
605.	<p>M/s. IWANT Office # 01, 3rd floor,</p>	<p>Legal Manufacturer: Matex Lab SpA</p>	<p>Brand Name: RENÉE VOLUME</p>	Approved

	<p>Parkland city Centre, I-8 Markaz, Islamabad.</p> <p>(ELI-01119)</p> <p>Date of Submission of application: 24-01-2025 PKR.62000/-</p>	<p>Via Carlo Urbani 2, angolo via Enrico Fermi, 72100 Brindisi Italy.</p> <p>Product Owner: Name: QVENTIS GmbH Address: Neuendofstrasse 18 A, 16761 Hennigsdorf, Germany.</p> <p>FSC (Italy) Issuance date: 10-07-2024 Validity date: Not mentioned LOA Validity: 06-11-2027 ISO 13485 certificate validity: 03-04-2026</p>	<p>Generic Name: Dermal fillers MD Group: Single Class: D Description: A pre-filled syringe containing a smooth, hydro-balanced gel containing 28 mg/mL of hyaluronic acid (HA), which helps provide natural-looking volume and hydration to the lips. Pakcing: 2x1.0ml, 1 x1.0 ml Codes: DE28P1/AE, DE28P2/AE</p> <p>Shelf Life: 24 months Storage condition: 2°C and 25°C</p> <p>FQA QMS validity: 26-01-2028</p>	
606.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12925 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 466959715 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products Reproductive Endocrinology Controls (Control x 03 set) Model: 1009406 Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: 104 weeks Storage Conditions: 2 - 8°C</p>	Approved, subject to submission of differential fee.
607.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12938 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 578283072785 PKR: 50000/-</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products HIV Combo Controls (HIV p24 Antigen) (Control x 03 vials) HS Code: 3822190090 GMDN Code: 52846 Class: D MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p>	Approved, subject to submission of differential fee.

	Dated: 01-08-2024		Shelf life: 104 weeks Storage Conditions: 2 - 8°C	
608.	M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12934 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 546604421600 PKR: 50000/- Dated: 01-08-2024	Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom	VITROS Immunodiagnostic Products Toxoplasma IgM Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 52442 • Calibrator – 52442 Class: C MD group: Kit LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life: • Reagent: 30 weeks • Calibrator: 30 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C	Approved, subject to submission of differential fee.
609.	M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12933 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 3425366632 PKR: 50000/- Dated: 01-08-2024	Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom	VITROS Immunodiagnostic Products HBsAg ES Confirmatory Kit (CLIA) (Control x 03 set) HS Code: 3502907000 GMDN Code: 48321 Class: D MD group: Kit LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life: 52 weeks Storage Conditions: 2 - 8°C	Approved, subject to submission of differential fee.
610.	M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160)	Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed	VITROS Immunodiagnostic Products CMV IgG Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 49713	Approved, subject to submission of differential fee.

	<p>Dy. No.: 12935 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 10105334792 PKR: 50000/- Dated:01-08-2024</p>	Bridgend, CF35 5PZ, United Kingdom	<ul style="list-style-type: none"> • Calibrator – 49713 <p>Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life:</p> <ul style="list-style-type: none"> • Reagent: 52 weeks • Calibrator: 26 weeks <p>Storage Conditions:</p> <ul style="list-style-type: none"> • Reagent: 2 - 8°C • Calibrator: 2 - 8°C 	
611.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12923 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 1016519209 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products HIV Combo Controls (Anti-HIV-1 group O) (Control x 03 vials) HS Code: 3822190090 GMDN Code: 48485 Class: D MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: 104 weeks Storage Conditions: 2 - 8°C</p>	Approved, subject to submission of differential fee.
612.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12937 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 2671686889 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products CK-MB Reagent & Calibrator (Reagent x 01 set) (Calibrator x 03 set) HS Code:</p> <ul style="list-style-type: none"> • Reagent – 3002120000 • Calibrator – 3822190090 <p>GMDN Code:</p> <ul style="list-style-type: none"> • Reagent – 61000 • Calibrator – 61000 <p>Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life:</p>	Approved, subject to submission of differential fee.

			<ul style="list-style-type: none"> • Reagent: 72 weeks • Calibrator: 104 weeks Storage Conditions: <ul style="list-style-type: none"> • Reagent: 2 - 8°C • Calibrator: ≤ -20°C 	
613.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12941 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 750804614187 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products Free PSA Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3822190090 • Calibrator – 3822190090 GMDN Code: • Reagent – 54669 • Calibrator – 54669 Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: • Reagent: 52 weeks • Calibrator: 52 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C</p>	Approved, subject to submission of differential fee.
614.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12948 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 35547221 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products Anti-HIV 1+2 Reagent & Calibrators (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 48452 • Calibrator – 48452 Class: D MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: • Reagent: 52 weeks • Calibrator: 44 weeks Storage Conditions:</p>	Approved, subject to submission of differential fee.

			<ul style="list-style-type: none"> • Reagent: 2 - 8°C • Calibrator: 2 - 8°C 	
615.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12946 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 6578304145 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products Intact PTH Reagent & Calibrator (Reagent x 01 set) (Calibrator x 03 set) HS Code: 3822190090 GMDN Code: • Reagent – 54277 • Calibrator – 54277 Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: • Reagent: 48 weeks • Calibrator: 41 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C</p>	Approved, subject to submission of differential fee.
616.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12947 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 94592839 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products Myoglobin Reagent & Calibrator (Reagent x 01 set) (Calibrator x 03 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 53952 • Calibrator – 53952 Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025</p> <p>Shelf life: • Reagent: 52 weeks • Calibrator: 52 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C</p>	Approved, subject to submission of differential fee.
617.	<p>M/s Martin Dow Specialties (Pvt) Limited.</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics</p>	<p>VITROS Immunodiagnostic Products BRAHMS PCT Reagent, Calibrator &</p>	Approved, subject to submission of differential fee.

	<p>7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12927 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 704109308 PKR: 50000/- Dated:01-08-2024</p>	<p>Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>Control (Reagent x 01 set) (Calibrator x 03 set) (Control x 03 set) HS Code: 3822190090 GMDN Code: • Reagent – 58731 • Calibrator – 54314 • Control - 54315 Class: C MD group: Kit LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life: • Reagent: 52 weeks • Calibrator: 104 weeks • Control: 52 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: ≤ -20°C • Control: ≤ -20°C</p>	
618.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12942 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 7361236941 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic Products CMV IgM Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 49724 • Calibrator – 49724 Class: C MD group: Kit LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life: • Reagent: 22 weeks • Calibrator: 22 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C</p>	<p>Approved, subject to submission of differential fee.</p>

619.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 12940 DRAP (R&I) Dated: 07-08-2024 Fee Challan No.: 563061105272 PKR: 50000/- Dated:01-08-2024</p>	<p>Legal Manufacturer: M/s Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom</p>	<p>VITROS Immunodiagnostic +Products Toxoplasma IgG Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: • Reagent – 3002120000 • Calibrator – 3822190090 GMDN Code: • Reagent – 52438 • Calibrator – 52438 Class: C MD group: Kit</p> <p>LOA Validity: 13-Jun-25 Free Sale Certificate: MHRA - UK Validity: 26-May-2025 ISO 13485 Certificate validity: 07-04-2025 Shelf life: • Reagent: 52 weeks • Calibrator: 52 weeks Storage Conditions: • Reagent: 2 - 8°C • Calibrator: 2 - 8°C</p>	Approved, subject to submission of differential fee.
620.	<p>M/s Martin Dow Specialties (Pvt) Limited. 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy. No.: 21795 DRAP (R&I) Dated: 18-12-2024 Fee Challan No.: 688903506824 PKR: 62000/- Dated:27-11-2024</p>	<p>Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA</p> <p>ISO Certificate: Validity: 18-Oct-2026</p>	<p>iFlash – HE4 (CLIA) (2 x 50 Tests/Kit) HS Code: 38220000 GMDN Code: 56656</p> <p>MD group: Kit Class: C Shelf Life: 18 Months. Storage Conditions: 2-8°C</p> <p>Free Sale Certificate (CHINA) Valid till: 29-Mar-2025 Free Sale Certificate (RRA Country -Australia) Issue date: 27-Aug-2024 Letter of Authorization: Validity: 31-Dec-2025</p>	Approved
621.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 21799 DRAP (R&I) Dated: 18-12-2024</p>	<p>Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA</p> <p>ISO Certificate: Validity: 18-Oct-2026</p>	<p>iFlash – SCC (CLIA) (2 x 50 Tests/Kit) HS Code: 38220000 GMDN Code: 61418 MD group: Kit Class: C</p> <p>Shelf Life: 18 Months. Storage Conditions: 2-8°C</p> <p>Free Sale Certificate CHINA</p>	Approved

	Fee Challan No.: 87480071 PKR: 62000/- Dated: 27-11-2024		Valid till: 29-Mar-2025 Free Sale Certificate (RRA Country -Australia) Issue date: 27-Aug-2024 <u>Letter of Authorization:</u> Validity: 31-Dec-2025	
622.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 21800 DRAP (R&I) Dated: 18-12-2024 Fee Challan No.: 3313996957 PKR: 62000/- Dated: 27-11-2024	Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2 nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA <u>ISO Certificate:</u> Validity: 18-Oct-2026	iFlash – CA72-4 (CLIA) (2 x 50 Tests/Kit) HS Code: 38220000 GMDN Code: 65193 MD group: Kit Class: C Shelf Life: 18 Months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CHINA Valid till: 29-Mar-2025 Free Sale Certificate (RRA Country -Australia) Issue date: 27-Aug-2024 <u>Letter of Authorization:</u> Validity: 31-Dec-2025	Approved
623.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 21801 DRAP (R&I) Dated: 18-12-2024 PKR: 50000/- Dated: 15-11-2022	Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2 nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA <u>ISO Certificate:</u> Validity: 18-Oct-2026	iFlash- Myoglobin (CLIA) (2 x 50 test/kit) HS Code: 3822.9000 GMDN Code: 53952 MD group: Kit Class: C Shelf Life: Before opening: 12 months After opening: 28 days. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CHINA Valid till: 30-Nov-2024 Free Sale Certificate (RRA Country -Australia) Issue date: 25-May-2023 <u>Letter of Authorization:</u> 31-Dec-2024	Approved
624.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.:	Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2 nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF	iFlash- CK-MB (CLIA) HS Code: 3822.9000 GMDN Code: 61000 MD group: Kit Class: C Shelf Life: Before opening: 12 months After opening: 28 days. Storage Conditions: 2-8°C	Approved

	21801 DRAP (R&I) Dated: 18-12-2024 PKR: 50000/- Dated: 15-11-2022	CHINA ISO Certificate: Validity: 18-Oct-2026	Free Sale Certificate CHINA Valid till: 30-Nov-2024 Free Sale Certificate (RRA Country -Australia) Issue date: 25-May-2023 Letter of Authorization: 31-Dec-2024	
625.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 21801 DRAP (R&I) Dated: 18-12-2024 PKR: 50000/- Dated: 15-11-2022	Legal Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD. Manufacturing Site: Building 1 YHLO Biopark, Baolong 2 nd road, Baolong Subdistrict Longgang District, 518116 Shenzhen, PEOPLE'S REPUBLIC OF CHINA ISO Certificate: Validity: 18-Oct-2026	iFlash- BNP (CLIA) (2 x 50 test/kit) HS Code: 3822.9000 GMDN Code: 47351 MD group: Kit Class: C Shelf Life: Before opening: 12 months After opening: 28 days. Storage Conditions: 2-8°C. Free Sale Certificate CHINA Valid till: 30-Nov-2024 Free Sale Certificate (RRA Country -Australia) Issue date: 25-May-2023 Letter of Authorization: 31-Dec-2024	Approved
626.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 5166 DRAP (R&I) Dated: 02-04-2024 Challan No. 78516669712 PKR: 50000/- Dated: 07-12-2023	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic ISO Certificate: Validity: 01-Dec-2027	ERBA NORM (ERBA NORM 4x5) (ERBA NORM 10x5) HS Code: 3822.9000 GMDN Code: 47351 MD group: Kit Class: C Shelf Life: 36 months. Storage Conditions: 2-8°C Free Sale Certificate CZECH Republic Valid till: 17-Mar-2025 Letter of Authorization: 31-Dec-2025	Approved
627.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic ISO Certificate:	ERBA PATH (ERBA PATH 4x5) (ERBA PATH 10x5) HS Code: 30029010 GMDN Code: 47869 MD group: Kit Class: C	Approved

	Dy. No.: 5167 DRAP (R&I) Dated: 02-04-2024 Challan No. 047788658345 PKR: 50000/- Dated: 18-05-2023	Validity: 01-Dec-2027	Shelf Life: 36 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 17-Mar-2025 <u>Letter of Authorization:</u> 31-Dec-2025	
628.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 19796 DRAP (R&I) Dated: 02-04-2024 Challan No. 1225700943 PKR: 62000/- Dated: 18-05-2023	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic <u>ISO Certificate:</u> Validity: 01-Dec-2027	ERBA Control N Multiple Coagulation Factor IVD Control (10 x 1ml) HS Code: 38220000 GMDN Code: 30590 MD group: Kit Class: C Shelf Life: 36 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 18-01-2026 <u>Letter of Authorization:</u> 31-Dec-2025	Approved
629.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 19795 DRAP (R&I) Dated: 02-04-2024 Challan No. 902154419 PKR: 62000/- Dated: 15-11-2024	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic <u>ISO Certificate:</u> Validity: 01-Dec-2027	ERBA Control P Multiple Coagulation Factor IVD Control (10 x 1ml) HS Code: 38220000 GMDN Code: 30590 MD group: Kit Class: C Shelf Life: 36 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 18-01-2026 <u>Letter of Authorization:</u> 31-Dec-2025	Approved
630.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.:	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic <u>ISO Certificate:</u> Validity: 01-Dec-2027	ERBA Prottime Prothrombin time (PT) IVD Kit (Erba Prottime 20 - 4 x 5ml) (Erba Prottime 40 - 8 x 5ml) HS Code: 38220000 MD group: Kit Class: C	Approved

	19793 DRAP (R&I) Dated: 02-04-2024 Challan No. 617497983274 PKR: 62000/- Dated: 15-11-2024		Shelf Life: 24 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 18-01-2026 <u>Letter of Authorization:</u> 31-Dec-2025	
631.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 19797 DRAP (R&I) Dated: 20-11-2024 Challan No. 014797388990 PKR: 62000/- Dated: 15-11-2024	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic <u>ISO Certificate:</u> Validity: 01-Dec-2027	ERBA Protime LS Prothrombin time (PT) IVD Kit (Erba Protime LS 10 – 4 x 5ml) (Erba Protime LS 50 - 8 x5ml) HS Code: 38220000 GMDN Code: 55983 MD group: Kit Class: C Shelf Life: 18 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 18-01-2026 <u>Letter of Authorization:</u> 31-Dec-2025	Approved
632.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Dy. No.: 19798 DRAP (R&I) Dated: 20-11-2024 Challan No. 33517583174 PKR: 62000/- Dated: 15-11-2024	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic <u>ISO Certificate:</u> Validity: 01-Dec-2027	ERBA Actime Activated partial thromboplastin time (APTT) IVD Kit (6 x 5ml) HS Code: 38220000 GMDN Code: 55981 MD group: Kit Class: C Shelf Life: 30 months. Storage Conditions: 2-8°C <u>Free Sale Certificate</u> CZECH Republic Valid till: 18-01-2026 <u>Letter of Authorization:</u> 31-Dec-2025	Approved
633.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi	Legal Manufacturer: ERBA LACHEMA S.R.O. Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic	ERBA Calcium Chloride Calcium Chloride coagulation reagent IVD (10 x 10ml) HS Code: 38220000 GMDN Code: 30593 MD group: Kit	Approved

	<p>ELI-00160</p> <p>Dy. No.: 19805 DRAP (R&I) Dated: 20-11-2024 Challan No. 5426253004 PKR: 62000/- Dated: 15-11-2024</p>	<p>ISO Certificate: Validity: 01-Dec-2027</p>	<p>Class: C</p> <p>Shelf Life: 24 months. Storage Conditions: 2-8°C</p> <p>Free Sale Certificate CZECH Republic Valid till: 18-01-2026 Letter of Authorization: 31-Dec-2025</p>	
634.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Dy. No.: 19804 DRAP (R&I) Dated: 20-11-2024 Challan No. 8093200955 PKR: 62000/- Dated: 15-11-2024</p>	<p>Legal Manufacturer: ERBA LACHEMA S.R.O.</p> <p>Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic</p> <p>ISO Certificate: Validity: 01-Dec-2027</p>	<p>Erba DDimer Control N+P In-Vitro Diagnostic Reagent (R1: 5 x 1ml Control N) (R2: 5 x 1ml Control P) HS Code: 38220000 GMDN Code: 47347 Shelf Life: MD group: Kit Class: C</p> <p>Shelf Life: 24 months. Storage Conditions: 2-8°C</p> <p>Free Sale Certificate CZECH Republic Valid till: 18-01-2026 Letter of Authorization: 31-Dec-2025</p>	Approved
635.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Dy. No.: 19799 DRAP (R&I) Dated: 20-11-2024 Challan No. 16710776782 PKR: 62000/- Dated: 15-11-2024</p>	<p>Legal Manufacturer: ERBA LACHEMA S.R.O.</p> <p>Manufacturing Site: Karásek 2219/1d 62100 Brno Czech Republic</p> <p>ISO Certificate: Validity: 01-Dec-2027</p>	<p>Erba Standard Plasma Multiple coagulation factor IVD Calibrator (5 x 1ml) HS Code: 38220000 GMDN Code: 55995 MD group: Kit Class: C</p> <p>Shelf Life: 24 months. Storage Conditions: 2-8°C</p> <p>Free Sale Certificate CZECH Republic Valid till: 18-01-2026 Letter of Authorization: 31-Dec-2025</p>	Approved
636.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14751 DRAP (R&I) Dated: 02-09-2024</p>	<p>Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.</p>	<p>Getein – MAGICL NT-proBNP (CLIA)</p> <p>Specifications: F01: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity:</p>	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate.

	Fee Challan No.: 02293825646 PKR: 50000/- Dated: 26-08-2024		<i>Country of origin - China</i> 23-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	
637.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14747 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 943870312080 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL CK-MB (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
638.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14753 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 943870312080 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL CRP (CLIA) Specifications: 10 tests, 2x 10 tests, 3x10 tests, 4x10 tests, 25 tests, 2x25 tests, 3x25 tests, 4x25 tests, 50 tests, 2 x 50 tests, 3x50 tests, 4x50 tests, 75 tests, 2x75 tests, 3x75 tests, 100 tests, 2x100 tests, 150 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
639.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.:	Legal Manufacturer Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing,	Getein – MAGICL CEA (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity:	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.

	14748 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 4285218676 PKR: 50000/- Dated: 26-08-2024	China.	<i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	
640.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14750 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 43900736 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL hs-cTnl (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
641.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14752 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 59585069493 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL PCT (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
642.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14768 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 60917660 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL Cortisol (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
643.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address:	Getein – MAGICL D-Dimer (CLIA) Specifications: 50 tests, 100 tests, 200 tests	Approved subject to the submission of following information / documents:

	Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14754 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 544444921 PKR: 50000/- Dated: 26-08-2024	No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	i.Differential Fee of PKR 12000/- required. ii.Valid & legalized free sale certificate, EC Certificate.
644.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14767 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 08176876453 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL G17 (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the r submission of following information / documents: i.Differential Fee of PKR 12000/- required. ii.Valid & legalized free sale certificate, EC Certificate.
645.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14765 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 2099001739 PKR: 50000/- Dated: 26-08-2024	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL CA125 (CLIA) Specifications: 10 tests, 2x 10 tests, 3x10 tests, 4x10 tests, 25 tests, 2x25 tests, 3x25 tests, 4x25 tests, 50 tests, 2 x 50 tests, 3x50 tests, 4x50 tests, 75 tests, 2x75 tests, 3x75 tests, 100 tests, 2x100 tests, 150 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i.Differential Fee of PKR 12000/- required. ii.Valid & legalized free sale certificate, EC Certificate.
646.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.:	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing,	Getein – MAGICL HbA1c (CLIA) Specifications: 25 tests, 2x25 tests, 3x25 tests, 4x25 tests, 50 tests, 2 x 50 tests, 3x50 tests, 4x50 tests, 75 tests, 2x75 tests, 3x75 tests, 100 tests, 2x100 tests, 150 tests, 200 tests	Deferred for submission of following information / documents: i.Submit required Fee PKR 62000/- or submit Clarification regarding validity of fee challan.

	14781 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 67098659243 PKR: 50000/- (expired)	China.	Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	ii. Valid & legalized free sale certificate, EC Certificate.
647.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14762 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 13354154 PKR: 50000/-	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL AFP (CLIA) Specifications: 10 tests, 2x 10 tests, 3x10 tests, 4x10 tests, 25 tests, 2x25 tests, 3x25 tests, 4x25 tests, 50 tests, 2 x 50 tests, 3x50 tests, 4x50 tests, 75 tests, 2x75 tests, 3x75 tests, 100 tests, 2x100 tests, 150 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23--06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
648.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14763 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 0966770055 PKR: 50000/-	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL CA19-9 (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 23-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
649.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14764 DRAP (R&I)	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – MAGICL CA15-3 (CLIA) Specifications: 50 tests, 100 tests, 200 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i>	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.

	Dated: 02-09-2024 Fee Challan No.: 426761243 PKR: 50000/-		23-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 18 months Storage condition: 2-8°C	
650.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14749 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 58742394114 PKR: 50000/-	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – Cardiac Troponin I Fast Test Kit (Immunofluorescence assay) Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	Approved subject to the submission of following information / documents: i. Differential Fee of PKR 12000/- required. ii. Valid & legalized free sale certificate, EC Certificate.
651.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14774 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 14323710707 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – HbA1c Fast Test Kit (Immunofluorescence assay) Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
652.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14775 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 63185847204 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – hs-CRP+CRP Fast Test Kit (Immunofluorescence assay) Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
653.	M/s Moody Global Services.	Legal Manufacturer: Name:	Getein – PCT Fast Test Kit (Immunofluorescence assay)	Deferred for submission of following information /

	Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14776 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 196866007564 PKR: 50000/- (expired)	M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
654.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14777 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 5110386257 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – Dimmer Fast Test Kit (Immunofluorescence assay) Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
655.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 14778 DRAP (R&I) Dated: 02-09-2024 Fee Challan No.: 5184229714 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Getein Biotech Inc. Manufacturer Address: No. 09, Bofu Road, Luhe District, Nanjing, China. & No. 06, Kefeng Road, Jiangbei New Area, Nanjing, China.	Getein – NT-ProBNP Fast Test Kit (Immunofluorescence assay) Specifications: 10 tests, 25 tests Class: C MD group: kit LOA Validity: 09-05-2029 FSC Validity: <i>Country of origin - China</i> 07-06-2025 ISO 13485 Certificate validity: 25-07-2026 Shelf life: 24 months Storage condition: 4-30°C	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
656.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13847 DRAP (R&I) Dated: 21-08-2024	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China.	Tianjin Walkman -Ortho-bridge System. Type: QZX & QZX-W Specification (mm) <hr/> $\Phi 2.0 \sim \Phi 6.5 \times 40 \sim$ 480 Class: C MD group: System	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.

	Fee Challan No.: 58997362 PKR: 50000/- (expired)	Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 15-05-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	
657.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13849 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 022548510758 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Posterior Internal Spinal Fixation System. Type: as per FSC Class: C MD group: System LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 31-01-2025 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.
658.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13850 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 59350834172 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Metal Bone Plates. Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 28-04-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
659.	M/s Moody Global	Legal Manufacturer:	Tianjin Walkman –	Deferred for submission of

	<p>Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13857 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 3977599052 PKR: 50000/- (expired)</p>	<p>Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.</p>	<p>Metal Bone Plates. (Straight) Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 26-06-2023 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A <i>because non-sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</i></p>	<p>following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.</p>
660.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13853 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 82122071166 PKR: 50000/- (expired)</p>	<p>Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.</p>	<p>Tianjin Walkman – Metal Bone Plates. (Maxillofacial) Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 12-07-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A <i>because non-sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</i></p>	<p>Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.</p>
661.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13852 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 5180215926 PKR: 50000/- (expired)</p>	<p>Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.</p>	<p>Tianjin Walkman – Metal Bone Plates. (Angular) Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 31-01-2025 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A <i>because non-sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated</i></p>	<p>Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.</p>

			<i>room with relative humidity less than 80% and without corrosive gas.</i>	
662.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13842 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 132926990320 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Metal Bone Screws Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 10-07-2023 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A <i>because non-sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</i>	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
663.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13843 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 161558598136 PKR: 50000/- (expired)	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Metal Bone Screws; Metal Locking Bone Screws and Plate system – Locking Screws Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 09-06-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A <i>because non-sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</i>	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
664.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13854 DRAP (R&I) Dated: 21-08-2024	Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China.	Tianjin Walkman – Metal Bone plates; Metal Locking Bone Screws and Plate system – Locking Plate I Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity:	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate.

	Fee Challan No.: 7801574316 PKR: 50000/- (expired)	Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	<i>Country of origin - China</i> 09-06-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	iii. detail of system with accessories / components if any.
665.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13855 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 9583259304 PKR: 50000/- (expired)	Legal Manufacturer Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Metal Bone plates; Metal Locking Bone Screws and Plate system – Locking Plate II Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 09-06-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
666.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13844 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 1264098396 PKR: 50000/- (expired)	Legal Manufacturer Name: M/s Tianjin Walkman Biomaterial Co. Ltd. Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.	Tianjin Walkman – Metal Bone Screws – Metal Femoral Fixation Screw. Type: as per FSC Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 10-02-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.	Deferred for submission of following information / documents: i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
667.	M/s Moody Global	Legal Manufacturer:	Tianjin Walkman –	Deferred for submission of

	<p>Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13848 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 95851954056 PKR: 50000/- (expired)</p>	<p>Name: M/s Tianjin Walkman Biomaterial Co. Ltd.</p> <p>Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.</p>	<p>Orthopedic Internal Fixation – Anterior Spinal Fixation System.</p> <p>Type: as per FSC</p> <p>Class: C MD group: family LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 10-02-2024 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non- sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</p>	<p>following information / documents:</p> <ol style="list-style-type: none"> i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.
668.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13846 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 90805586 PKR: 50000/- (expired)</p>	<p>Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd.</p> <p>Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai Economic Development Zone, Jinghai County, Tianjin, China.</p>	<p>Tianjin Walkman – Metal Intramedullary Nailing System.</p> <p>Type: as per FSC</p> <p>Class: C MD group: system LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 06-04-2025 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non- sterile metal product. Storage condition: the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</p>	<p>Deferred for submission of following information / documents:</p> <ol style="list-style-type: none"> i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any. i.
669.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 13845 DRAP (R&I) Dated: 21-08-2024 Fee Challan No.: 4916422459 PKR: 50000/-</p>	<p>Legal Manufacturer: Name: M/s Tianjin Walkman Biomaterial Co. Ltd.</p> <p>Business Address: 401 building B, Haitai Torch Pioneer Park, 2 Wuhua Road, Huayuan Industrial Park, Tianjin New-Tech I Industrial Park. China. Manufacturer Address: No. 19, Technology Road, South District, Jinghai</p>	<p>Tianjin Walkman – Metal Bone Screws – Cranial and Maxillofacial Bone Screws</p> <p>Type: as per FSC</p> <p>Class: C MD group: system LOA Validity: 19-09-2028 FSC Validity: <i>Country of origin - China</i> 06-04-2025 ISO 13485 Certificate validity: 08-08-2024 Shelf life: N/A because non-</p>	<p>Deferred for submission of following information / documents:</p> <ol style="list-style-type: none"> i. Submit required Fee PKR 62000/- required or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate. iii. detail of system with accessories / components if any.

	(expired)	Economic Development Zone, Jinghai County, Tianjin, China.	<i>sterile metal product.</i> Storage condition: <i>the product shall be stored in the clean, dry & well-ventilated room with relative humidity less than 80% and without corrosive gas.</i>	
670.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000. (ELI-00926) D.O.I: 17/05/2022 Dy. No.: 4200 DRAP (R&I) Dated: 07-03-2024 Fee Challan No.: 6258206008 (expired) PKR: 50000/- Dated:	Legal Manufacturer: Name: M/s Chanzhou Tongchuang Medical Instrument Technology Co. Ltd. Manufacturer Address: Building A1, Hutang Science and Technology Industrial Par, Hutang Town, Wujin District, Changzhou, 213161, Jiangsu, P.R. China.	Bluesail+ Disposable Linear Cutter Staplers & Cartridges Model: Staplers: TCYQ-55 x 2.5/ 60x2.5/ 75x2.5/ 80x2.5/ 90x2.5/100x2.5 TCYQ-55 x 3.85/ 60x3.85/ 75x3.85/ 80x3.85/ 90x3.85/100x3.85 TCYQ-55 x 4.5/ 60x4.5/ 75x4.5/ 80x4.5/ 90x4.5/100x4.5 Cartridges: TCYQ-55 x 2.5/ 60x2.5/ 75x2.5/ 80x2.5/ 90x2.5/100x2.5 Reload TCYQ-55 x 3.85/ 60x3.85/ 75x3.85/ 80x3.85/ 90x3.85/100x3.85 Reload TCYQ-55 x 4.5/ 60x4.5/ 75x4.5/ 80x4.5/ 90x4.5/100x4.5 Reload Class: C MD group: family LOA Validity: 29-11-2028 FSC Validity: 29-04-2025 EC Certificate validity: 04-11-2023 ISO 13485 Certificate validity: valid Shelf life: 3 years Storage condition: room temperature with RH less than 90%	Deferred for submission of following information / documents: i. Submit required Fee PKR 100000/- or submit clarification of the validity of the fee challan. ii. Valid & legalized free sale certificate, EC Certificate, ISO 13485.
671.	M/s Moody Global Services. Office # 14, 2 nd floor, Mujahid Plaza, Jinnah	Legal Manufacturer: Name: M/s Chanzhou Tongchuang Medical Instrument	Disposable PPH Staplers Model: TCYG32, TCYG34, TCYG36 Class: C	Deferred for submission of following information / documents:

	<p>Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 4195 DRAP (R&I) Dated: 07-03-2024 Fee Challan No.: 5269325877 (expired) PKR: 50000/- Dated:</p>	<p>Technology Co. Ltd. Manufacturer Address: Buiding A1, Hutang Science and Technology Industrial Par, Hutang Town, Wujin District, Changzhou, 213161, Jiangsu, P.R. China.</p>	<p>MD group: family LOA Validity: 29-11-2028 FSC Validity: 29-04-2025 EC Certificate validity: 04-11-2023 ISO 13485 Certificate validity: valid</p> <p>Shelf life: 3 years</p> <p>Storage condition: room temperature with RH less than 90%</p>	<p>i. Submit required Fee PKR 100000/- or submit clarification of the validity of the fee challan.</p> <p>ii. Valid & legalized free sale certificate, EC Certificate, ISO 13485.</p>
672.	<p>M/s Moody Global Services. Office # 14, 2nd floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. 44000.</p> <p>(ELI-00926) D.O.I: 17/05/2022</p> <p>Dy. No.: 4194 DRAP (R&I) Dated: 07-03-2024 Fee Challan No.: 167000104506 PKR: 50000/- (expired) Dated:</p>	<p>Legal Manufacturer Name: M/s Chanzhou Tongchuang Medical Instrument Technology Co. Ltd. Manufacturer Address: Buiding A1, Hutang Science and Technology Industrial Par, Hutang Town, Wujin District, Changzhou, 213161, Jiangsu, P.R. China.</p>	<p>Bluesail+ - Disposable Endo Cutter & Cartridges</p> <p>Model: Staplers: TCNQ-L, TCNQ-M, TCNQ-S, TCNP-L, TCNP-M, TCNP-S, TCNZ-30/45/60L, TCNZ-30/45/60M, TCNZ-30/45/60S, TCNX-30/45/60L, TCNX-30/45/60M, TCNX-30/45/60S.</p> <p>Cartridges: TCZNZ-30-A/B/C/D/E/F/G/H/I/J, TCZNZO-30-A/B/C/D/E/F/G/H/I/J, TCZLNK-30-A/B/C/D/E/F/G/H/I/J, TCZLNKO-30-A/B/C/D/E/F/G/H/I/J, TCZLNZ-45-A/B/C/D/E/F/G/H/I/J, TCZLNZO-45-A/B/C/D/E/F/G/H/I/J, TCZLNK-45-A/B/C/D/E/F/G/H/I/J, TCZLNKO-45-A/B/C/D/E/F/G/H/I/J, TCZLNZ-60-A/B/C/D/E/F/G/H/I/J, TCZLNZO-60-A/B/C/D/E/F/G/H/I/J, TCZLNK-60-A/B/C/D/E/F/G/H/I/J, TCZLNKO-60-A/B/C/D/E/F/G/H/I/J, TCZLNZ-30-A/B/C/D/E/F/G/H/I/J, TCZLNZO-30-A/B/C/D/E/F/G/H/I/J, TCZLNK-30-</p>	<p>Deferred for submission of following information / documents:</p> <p>i. Submit required Fee PKR 100000/- or submit clarification of the validity of the fee challan.</p> <p>ii. Valid & legalized free sale certificate, EC Certificate, ISO 13485.</p>

			<p>A/B/C/D/E/F/G/H/I/J, TCZNXKO-30- A/B/C/D/E/F/G/H/I/J, TCZNX-45- A/B/C/D/E/F/G/H/I/J, TCZNXO-45- A/B/C/D/E/F/G/H/I/J, TCZNXK-45- A/B/C/D/E/F/G/H/I/J, TCZNXKO-45- A/B/C/D/E/F/G/H/I/J, TCZNX-60- A/B/C/D/E/F/G/H/I/J, TCZNXO-60- A/B/C/D/E/F/G/H/I/J, TCZNXK-60- A/B/C/D/E/F/G/H/I/J, TCZNXKO-60- A/B/C/D/E/F/G/H/I/J, TCZNH-45- A/B/C/D/E/F/G/H/I/J, TCZN- 30-A/B/C/D/E/F/G/H/I/J, TCZN-45- A/B/C/D/E/F/G/H/I/J, TCZN- 60-A/B/C/D/E/F/G/H/I/J Class: C MD group: family LOA Validity: 29-11-2028 FSC Validity: 29-04-2025 EC Certificate validity: 04-11-2023 ISO 13485 Certificate validity: valid</p> <p>Shelf life: 3 years</p> <p>Storage condition: room temperature with RH less than 90%</p>	
673.	<p>M/s Safemed Technologies.</p> <p>Retoon Plaza, 2nd floor, Apt No 03, Mini Market, Sector G-15/1, 44000 Islamabad.</p> <p>(ELI-00296) D.O.I: 18/10/2018 (Renewal fee challan of PKR 10000/- submitted on 24-11-2023)</p> <p>Dy. No.: 7234 DRAP (R&I) Dated: 10-05-2024</p>	<p>Legal Manufacturer Name: M/s Epic International (Thailand) Co. Ltd, Manufacturer Address: 500/73 Moo 2, Tasit, Pluakdaeng, Rayong Thailand 21140.</p>	<p>Smart eZ Pump – single use only Elastomeric Pump (soft and hard shell)</p> <p>Grouping: - Chemo - Chemo CS (continuous infusion) - Short time infusion - Long time infusion.</p> <p>Class: C MD group: family LOA Validity: 31-12-2026</p>	<p>Deferred for clarification of following information / documents:</p> <p>i. The FDA classifies elastomeric pumps as class II medical devices while firm has submitted its application as Class C.</p> <p>ii. Renewal of establishment license for import of devices has been submitted after 31 days from the due date of renewal application submission.</p>

	<p>Fee Challan No.: 85290070 + 952660585982 PKR: 50000/-</p> <p>Dated: 02-04-2024 & 06-05-2024</p>		<p>FSC Validity (country of origin): Not provided</p> <p>EC Certificate validity: 04-11-2023 ISO 13485 Certificate validity: 12-01-2026</p> <p>Shelf life: 3 years Storage condition: room temperature.</p>	iii.Free sale certificate of country of origin
674.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9162 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 72652078695 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi α2- Plasmininhibitor-plasmin Complex (CLIA) Ref:130218003M, 130618003M, 130718003M. Controls: 160201236MT</p> <p>Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (country of origin): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C</p>	Approved
675.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9160 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 6128509186 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi thrombin-antithrombin III Complex (CLIA) Ref:130218001M, 130618001M, 130718001M. Controls: 160201234MT</p> <p>Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (country of origin): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life:</p>	Approved

			For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	
676.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9152 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 4652040089 PKR: 50000/- Dated: 04-06-2024	Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.	Maglumi Tissue Plasminogen activator-inhibitor complex (CLIA) Ref: 130218004M, 130618004M, 130718004M. Controls: 160201237MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (country of origin): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	Approved
677.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9156 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 5561755562 PKR: 50000/- Dated: 04-06-2024	Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.	Maglumi Chlamydia pneumoniae IgM (CLIA) Ref: 130219012M, 130619012M, 130719012M. Controls: 160201192MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (country of origin): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	Approved
678.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st	Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd.	Maglumi Thrombomodulin (CLIA) Ref: 130218002M, 130618002M, 130718002M.	Approved

	<p>floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9153 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 1923559217 PKR: 50000/- Dated: 04-06-2024</p>	<p>(SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Controls: 160201235MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C</p>	
679.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9157 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 37266420453 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi Mycoplasma pneumoniae (CLIA) Ref:130219011M, 130619011M, 130719011M. Controls: 160201190MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C</p>	Approved
680.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9157 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 555673074618 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi Mycoplasma pneumoniae IgG (CLIA) Ref:130219009M, 130619009M, 130719009M. Controls: 160201189MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate</p>	Approved

			validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	
681.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9151 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 9249375827 PKR: 50000/- Dated: 04-06-2024	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.	Maglumi Homocysteine (CLIA) Ref: 130206024M, 130606024M, 130706024M. Controls: 160201269MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity <i>(country of origin):</i> 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	Approved
682.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9161 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 9641226122 PKR: 50000/- Dated: 04-06-2024	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.	Maglumi hs-CRP (CLIA) Ref: 130206023M, 130606023M, 130706023M. Controls: 160201494MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity <i>(country of origin):</i> 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C	Approved
683.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers,	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE)	Maglumi Chlamydia Pneumoniae IgG (CLIA) Ref: 130219010M, 130619010M, 130719010M. Controls: 160201191MT	Approved

	<p>PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9158 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 5230203212 PKR: 50000/- Dated: 04-06-2024</p>	<p>Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity <i>(country of origin):</i> 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C</p>	
684.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9155 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 628273874802 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi HSV-2 IgM (CLIA) Ref:130212014M, 130612014M, 130712014M. Controls: 160201161MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity <i>(country of origin):</i> 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 – 8°C</p>	Approved
685.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 9150 DRAP (R&I) Dated: 10-06-2024 Fee Challan No.: 021308956742 PKR: 50000/- Dated: 04-06-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China.</p>	<p>Maglumi HSV-1 IgM (CLIA) Ref:130212013M, 130612013M, 130712013M. Controls: 160201160MT Class: C MD group: Kit LOA Validity: 30-12-2027 FSC Validity <i>(country of origin):</i> 19-01-2026 EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 Shelf life: For assay: 18 months</p>	Approved

			For controls: 18 months Storage condition: 2 – 8°C			
686.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18740 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 6243236349 PKR: 62000/- Dated: 01-11-2024	Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 FSC Validity (country of origin): 11-05-2025 LOA Validity: 30-12-2027	Bioassays – Hemoglobin A1c (Latex) with Hemoglobin A1c Calibrator <table border="1"><tr><td>Class: C</td><td>MD group: Kit</td></tr></table> Hemoglobin A1c (Latex): • Catalog No.: 130505002S; 130505002SC8; 130505002A; 130505002A24 • Model: R1: 1x60 mL, R2: 1x20 mL, Hemolyzing Solution: 4x65 mL; 400 tests/kit, Hemolyzing Solution: 4x65 mL; R1: 2x30 mL, R2: 2x10 mL, Hemolyzing Solution: 3x50 mL; 320 tests/kit, Hemolyzing Solution: 3x50 mL Hemoglobin A1c Calibrator: • Catalog No.: 160202551C • Model: Calibrator 1: 1x0.5 mL(Lyophilized), Calibrator 2: 1x0.5 mL(Lyophilized), Calibrator 3: 1x0.5 mL(Lyophilized), Calibrator 4: 1x0.5 mL(Lyophilized), Calibrator 5: 1x0.5 mL(Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C	Class: C	MD group: Kit	Deferred for submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period.
Class: C	MD group: Kit					
687.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18756 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 693093231 PKR: 62000/- Dated: 01-11-2024	Legal Manufacturer Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027	Bioassays – Hemoglobin A1c Controls <table border="1"><tr><td>Class: C</td><td>MD group: Kit</td></tr></table> Catalog No.: 160202551QL; 160202551QT; 160202551Q1; 160202551Q2; 160202551Q3; 160202551Q4 Model: Level 1: 3x0.5 mL, Level 2: 3x0.5 mL; Level 1: 1x0.5 mL, Level 2: 1x0.5 mL; Level 1: 3x0.5 mL; Level 2: 3x0.5 mL; Level 1: 6x0.5 mL; 6x0.5 mL Level 2: 6x0.5ml Shelf life: 24 months Storage condition: 2 – 8°C FSC Validity (country of origin): 11-05-2025 FSc German dated 22-04-2024	Class: C	MD group: Kit	Approved
Class: C	MD group: Kit					
688.	M/s Snibe Diagnostic Pakistan (SMC-	Legal Manufacturer Name:	Bioassays – Assayed Chemistry Controls	Approved		

	<p>PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18757 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 34811090967 PKR: 62000/- Dated: 01-11-2024</p>	<p>M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p>	<p>Class: C MD group: Kit Catalog No.: 1601022001; 1601022002; 1601022004; 1601022003; 1601022005 Model: Level 2: 3x5 mL, Level 3: 3x5 mL; Level 2: 6x5 mL; Level 3: 6x5 mL; Level 2: 1x5 mL; Level 3: 1x5 mL Shelf life: 24 months Storage condition: 2 – 8^oC</p> <p>FSC Validity (country of origin): 11-05-2025 FSc German dated 22-04-2024</p>	
689.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18758 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 356705583 PKR: 62000/- Dated: 01-11-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p>	<p>Bioassays – Specific Protein controls Class: C MD group: Kit Catalog No.: 1601022021; 1601022022; 1601022023; 1601022024; 1601022025 Model: Level 1: 6x1 mL; Level 2: 6x1 mL; Level 3: 6x1 mL; Level 1: 2x1 mL, Level 2: 2x1 mL, Level 3: 2x1 mL; Level 1: 1x1 mL, Level 2: 1x1 mL, Level 3: 1x1 mL Shelf life: 24 months Storage condition: 2 – 8^oC</p> <p>FSC Validity (country of origin): 11-05-2025 FSc German dated 22-04-2024</p>	Approved
690.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p> <p>Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18745 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 1329788160 PKR: 62000/-</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p>	<p>Bioassays – Homocysteine (Enzymatic Cycling) with Homocysteine Calibrator & Controls Class: C MD group: Kit Homocysteine (Enzymatic Cycling): Catalog No.: 130551007S; 130551007SC8; 130551007A; 130551007A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit</p>	<p>Approved subject to the submission of following information / documents:</p> <p>i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator.</p> <p>ii. Submit stability data available, including the expiration date or recommended usage period.</p>

	Dated: 01-11-2024	FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	Homocysteine Calibrator: Catalog No.: 160202576C Model: Calibrator 1: 1x1 mL, Calibrator 2: 1x1 mL, Calibrator 3: 1x1 mL; Calibrator 4: 1x1 mL, Calibrator 5: 1x1 mL, Calibrator 6: 1x1 mL Homocysteine Control: Catalog No.: 160202576Q Model: Control 1: 1x1 mL, Control 2: 1x1 mL Shelf life: 12 months Storage condition: 2 – 8°C	
691.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18746 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 33660169136 PKR: 62000/- Dated: 01-11-2024	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	Biossays – Aspartate Aminotransferase (Aspartic Acid Substrate) with Aspartate Aminotransferase Calibrator and Control. Class: C MD group: Kit (Aspartic Acid Substrate) Catalog No.: 130552003S; 130552003SC8; 130552003A; 130552003A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit Aspartate Aminotransferase Calibrator: Catalog No.: 160202579C Model: Calibrator: 1x1 mL (Lyophilized) Aspartate Aminotransferase Control: Catalog No.: 160202579Q Model: Control 1: 1x1 mL (Lyophilized), Control2: 1x1 mL (Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period
692.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.:	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity:	Biossays – α-Hydroxybutyrate Dehydrogenase (α-Ketobutyrate Substrate) with α-Hydroxybutyrate Dehydrogenase Calibrator and Control. Class: C MD group: Kit	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator.

	18752 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 7034382971 PKR: 62000/- Dated: 01-11-2024	14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	α-Hydroxybutyrate Dehydrogenase (a-Ketobutyrate Substrate): Catalog No.: 130554003S; 130554003SC8; 130554003A; 130554003A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit α-Hydroxybutyrate Dehydrogenase Calibrator: Catalog No.: 160202592C Model: Calibrator: 1x1 mL α Hydroxybutyrate Dehydrogenase Control: Catalog No.: 160202592Q Model: Control 1: 1x1 mL, Control 2: 1x1 mL Shelf life: 18 months Storage condition: 2 – 8°C	ii. Submit stability data available, including the expiration date or recommended usage period
693.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18751 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 87103070795 PKR: 62000/- Dated: 01-11-2024	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	Biossays – Creatinine Kinase-MB (Immunosuppressive) with Creatinine Kinase-MB Calibrator and Control. Class: C MD group: Kit Creatine Kinase-MB (Immunosuppressive): Catalog No.: 130554002S; 130554002SC8; 130554002A; 130554002A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit Creatine Kinase-MB Control: Catalog No.: 160202591C Model: Calibrator: 1x1 mL (Lyophilized) Creatine Kinase-MB Calibrator: Catalog No.: 160202591Q Model: Control 1: 1x1 mL (Lyophilized), Control 2: 1x1 mL (Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period
694.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd.	Biossays – Creatinine Kinase (Phosphate Creatine Substrate) with Creatinine Kinase Calibrator and	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of

	<p>floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18750 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 7995126506 PKR: 62000/- Dated: 01-11-2024</p>	<p>(SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p> <p>FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024</p>	<p>Control. Class: C MD group: Kit Creatine Kinase (Phosphate Creatine Substrate): Catalog No.: 130554001S; 130554001SC8; 130554001A; 130554001A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit Creatine Kinase Calibrator: Catalog No.: 160202590C Model: Calibrator: 1x1 mL (Lyophilized) Creatine Kinase Controls: Catalog No.: 160202590Q Model: Control 1: 1x1 mL (Lyophilized), Control 2: 1x1 mL (Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C</p>	<p>the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator.</p> <p>ii. Submit stability data available, including the expiration date or recommended usage period</p>
695.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18749 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 55697327686 PKR: 62000/- Dated: 01-11-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p> <p>FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024</p>	<p>Biossays – Direct Bilirubin (Vanadate oxidation) with Direct Bilirubin Calibrator & Control. Class: C MD group: Kit Direct Bilirubin (Vanadate Oxidation): Catalog No.: 130552007; 130552007SC8; 130552007A; 130552007A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit Direct Bilirubin Calibrator: Catalog No.: 160202586C Model: Calibrator: 1x1 mL (Lyophilized) Direct Bilirubin Controls Catalog No.: 160202586Q Model: Control 1: 1x1 mL (Lyophilized), Control2: 1x1 mL (Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C</p>	<p>Approved subject to the submission of following information / documents:</p> <p>i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator.</p> <p>ii. Submit stability data available, including the expiration date or recommended usage period</p>
696.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited.</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical</p>	<p>Biossays – Glucose (Hexokinase) with Glucose Calibrator & Control.</p>	<p>Approved subject to the submission of following information / documents:</p>

	Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18747 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 09893227 PKR: 62000/- Dated: 01-11-2024	Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	Class: C MD group: Kit Glucose (Hexokinase): Catalog No.: 130555001S; 130555001SC8; 130555001A; 130555001A24 Model: R1: 1x60 mL, R2: 1x15 mL;415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 290 tests/kit Glucose Calibrator: Catalog No.: 160202582C Model: Calibrator: 1x1 MI Glucose Control: Catalog No.: 160202582Q Model: Control 1: 1x1 mL, Control2: 1x1 MI Shelf life: 18 months Storage condition: 2 – 8°C	i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period
697.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18748 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 51029800119 PKR: 62000/- Dated: 01-11-2024	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027 FSC Validity (<i>country of origin</i>): 11-05-2025 FSc German dated 22-04-2024	Biossays – Total Bilirubin (Vanadate Oxidation) with Total Bilirubin Calibrator and Control. Class: C MD group: Kit Total Bilirubin (Vanadate Oxidation): Catalog No.: 130552006S; 130552006SC8; 130552006A; 130552006A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 300 tests/kit Total Bilirubin Calibrator: Catalog No.: 160202585C Model: Calibrator: 1x1 mL (Lyophilized) Total Bilirubin Controls: Catalog No.: 160202585Q Model: Control 1: 1x1 mL (Lyophilized), Control2: 1x1 mL (Lyophilized) Shelf life: 18 months Storage condition: 2 – 8°C	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period
698.	M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1 st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036)	Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen,	Biossays – Haptoglobin (Immunoturbidimetric) with Haptoglobin Calibrator. Class: C MD group: Kit Total Bilirubin (Vanadate Haptoglobin (Immunoturbidimetric):	Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this

	<p>D.O.I: 13-02-2023 Dy. No.: 18741 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 647742934531 PKR: 62000/- Dated: 01-11-2024</p>	<p>China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p>	<p>Catalog No.: 130502014S; 130502014SC8; 130502014A; 130502014A24 Model: R1: 1x60 mL, R2: 1x15 mL; 340 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 190 tests/kit Haptoglobin Calibrator: Catalog No.: 160202555C Model: Calibrator: 1x1 mL Shelf life: 18 months Storage condition: 2 – 8°C FSC Validity <i>(country of origin):</i> 11-05-2025 FSc German dated 22-04- 2024</p>	<p>applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period</p>
699.	<p>M/s Snibe Diagnostic Pakistan (SMC-PRIVATE) Limited. Office No. A107, 1st floor, Fortune Towers, PECHS, Shahrah-e-Faisal, Karachi. (ELI-01036) D.O.I: 13-02-2023 Dy. No.: 18753 DRAP (R&I) Dated: 06-11-2024 Fee Challan No.: 053243954036 PKR: 62000/- Dated: 01-11-2024</p>	<p>Legal Manufacturer: Name: M/s Shenzhen New Industries Biomedical Engineering Co. Ltd. (SNIBE) Manufacturer Address: No. 23, Jinxiu Est Road, Pingshan District, Shenzhen, China. EC Certificate validity: 14-12-2025 ISO 13485 Certificate validity: 31-12-2025 LOA Validity: 30-12-2027</p>	<p>Biossays – (Lactic Acid Substrate) with Lactate Dehydrogenase Calibrator & Control. Class: C MD group: Kit Lactate Dehydrogenase (Lactic Acid Substrate): Catalog No.: 130554004S; 130554004SC8; 130554004A; 130554004A24 Model: R1: 1x60 mL, R2: 1x15 mL; 415 tests/kit; R1: 2x28 mL, R2: 2x7 mL; 190 tests/kit Lactate Dehydrogenase Calibrator: Catalog No.: 160202593C Model: Calibrator: 1x1 MI Lactate Dehydrogenase Control: Catalog No. : 160202593Q Model: Control 1:1x1ml, Control 2: 1x1 ml. Shelf life: 18 months Storage condition: 2 – 8°C FSC Validity <i>(country of origin):</i> 11-05-2025 FSc German dated 22-04- 2024</p>	<p>Approved subject to the submission of following information / documents: i. Clarification is needed regarding the shelf life of the reagents and calibrator, as the firm has stated 18 months, but it is unclear whether this applies to the reagent or the calibrator. ii. Submit stability data available, including the expiration date or recommended usage period</p>
700.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153)</p>	<p>Legal Manufacturer: Name: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County,</p>	<p>Brand Name: Suigly Suicon Surgical Sutures Device: Polyglycolic Acid Surgical Suture with Needle (PGA) USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-</p>	<p>Deferred for submission Design examination certificate which should be valid and legalized.</p>

	<p>D.O.I: 07-09-2023 Dy. No.: 15745 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 070482265107 PKR: 50000/- Dated: 30-07-2024</p>	<p>274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027</p>	<p>0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper Cutting, Non cutting. Needle Curvature: ½ Circle, 3/8 circle, straight & double spatulated. Class: D MD group: Single FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019 Shelf life: 05 years Storage condition: - Store in a cool and dry place. Keep away from direct sunlight.</p>	
701.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15744 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 838593134 PKR: 50000/- Dated: 30-07-2024</p>	<p>Legal Manufacturer: Name: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027</p>	<p>Brand Name: Suicon Surgical Sutures Device: Silk Braided Surgical Suture with needle USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D MD group: Single FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019 Shelf life: 05 years Storage condition: - Store in a cool and dry place. Keep away from direct sunlight.</p>	<p>Deferred for submission Design examination certificate which should be valid and legalized.</p>
702.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15747 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 7798811089</p>	<p>Legal Manufacturer: Name: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024</p>	<p>Brand Name: Suicon Surgical Sutures Suilene Device: Polypropylene Monofilament Surgical Suture with Needle USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting and non-cutting. Needle Curvature: ½ Circle,</p>	<p>Deferred for submission Design examination certificate which should be valid and legalized.</p>

	<p>PKR: 50000/- Dated: 09-08-2024</p>	<p>LOA Validity: 30-12-2027</p>	<p>3/8 circle, straight, Double Needle. Class: D MD group: Single FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019 Shelf life: 05 years Storage condition: - Store in a cool and dry place. Keep away from direct sunlight.</p>	
703.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15746 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 06434554213 PKR: 50000/- Dated: 09-08-2024</p>	<p>Legal Manufacturer: Name: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027</p>	<p>Brand Name: Suicon Surgical Sutures Suicryl Device: Polyglactin 910 (PGLA) Surgical Suture with Needle USP Suture Size: 8-0, 7-0, 6- 0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D MD group: Single FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019 Shelf life: 05 years Storage condition: - Store in a cool and dry place. Keep away from direct sunlight.</p>	<p>Deferred for submission Design examination certificate which should be valid and legalized.</p>
704.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 16222 DRAP (R&I) Dated: 25-09-2024 Fee Challan No.: 657320693649 PKR: 50000/- Dated: 14-03-2024</p>	<p>Legal Manufacturer: Name: M/s Shangai Transfusion Technology Co. Ltd. Manufacturer Address: No. 500, Youdong Road, Minhang, 201100 Shanghai, China. ISO 13485 Certificate validity: 26-10-2024 EC Certificate validity: 26-05-2024 LOA Validity: 20-12-2028</p>	<p>Brand Name: Vcare Device: Disposable Plastic Blood Collecting Bag CPDA-1 (Single) Size: 250ml, 500 ml Class: D MD group: Single FSC Validity: China <i>(country of origin):</i> 01-02-2025 FSC (MHRA-UK) Dated 22-01-2022 Shelf life: 02 years Storage condition: - Store in a cool and dry place. Keep away from direct sunlight.</p>	<p>Deferred for submission Design examination certificate which should be valid and legalized.</p>

705.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 15488 R & I DRAP Dated:02-10-2023 Fee Challan No: 72428178 PKR: 50,000/- Dated: 14-02-2022</p>	<p>Legal Manufacturer: VitalScientific (Formerly known as ELITech Group Clinical Systems SAS), Zone Industrielle, 61500 series France</p> <p>Manufacturing Site: VitalScientific (Formerly known as ELITech Group Clinical Systems SAS), Zone Industrielle, 61500 series France</p>	<p>Selectra Mach 5 Reagent (Heart Profile) HS Code: 38220000 GMDN Code: CK NAC: 53003 CK-MB: 52994 LDH IFCC: 53072</p> <p>Class: C MD Group: Kit LOA Validity: 29-July-2027 Free Sale Certificate: Date of issue: 06-June-2024 ISO Certificate: Validity: 27-July-2026 Shelf Life: CK NAC: 14 Months CK-MB: 14 Months LDH IFCC: 18 Months Storage Conditions: 2-8°C</p>	Approved
706.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 15031 R & I DRAP Dated:02-10-2023 Fee Challan No: 2026457 PKR: 25,000/- 1044568595 (Additional Fees) – PKR: 25,000/- PKR: 50,000/-</p> <p>Dated: 2026457: 28-12-2020 1044568595: 15-09-2023</p>	<p>Legal Manufacturer: VitalScientific (Formerly known as ELITech Group Clinical Systems SAS), Zone Industrielle, 61500 series France</p> <p>Manufacturing Site: VitalScientific (Formerly known as ELITech Group Clinical Systems SAS), Zone Industrielle, 61500 series France</p>	<p>Heart Profile-CK NAC SL HS Code: 3822.0000 GMDN Code: CK NAC SL 4X25 ML: 53303 CK NAC SL 2X62.5 ML:53003 CK NAC SL 4X62.5 ML:53003</p> <p>Class: C MD Group: Kit</p> <p>LOA Validity: 29-July-2027</p> <p>Free Sale Certificate: Date of issue: 06-June-2024</p> <p>ISO Certificate: Validity: 27-July-2026</p> <p>Shelf Life: CK NAC SL: 14 Months</p> <p>Storage Conditions: 2-8°C</p>	Approved
707.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6,</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p>	<p>VITROS Immunodiagnostic Product Anti-HBc Reagent HS Code: 38229000 GMDN Code:</p>	Approved

	<p>PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12345 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 40416725955 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Phone: +44 1656 778031 Fax: +44 1656 778350 www.orthoclinicaldiagnostics.com ISO Certificate: Validity:07-April-2025</p>	<p>VITROS Immunodiagnostic Product Anti-HBc Reagent Pack : 48304</p> <p>Class: D MD Group: Kit LOA Validity: 12-June-2025 Free Sale Certificate: MHRA-UK Validity:26-May-2025 Shelf life: 52 weeks Storage Conditions: 2-8°C</p>	
708.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12351 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 1490177857 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p>	<p>VITROS Immunodiagnostic Product Anti-HCV Reagent HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Anti-HCV Reagent: 48366</p> <p>Class: D MD Group: Kit LOA Validity: 12-June-2025</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025 ISO Certificate: Validity:07-April-2025</p> <p>Shelf life: 52 weeks Storage Conditions: 2-8°C</p>	Approved
709.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12350 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 87913709 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025</p> <p>ISO Certificate: Validity:07-April-2025</p>	<p>VITROS Immunodiagnostic Product Anti-HCV Calibrator & Control:</p> <p>HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Anti-HCV Calibrator: 48366 VITROS Immunodiagnostic Product Anti-HCV Control: 41973</p> <p>Class: D MD Group: Kit</p> <p>Shelf life: VITROS Immunodiagnostic Product Anti-HCV Calibrator: 35 weeks</p>	Approved

			VITROS Immunodiagnostic Product Anti-HCV Control: 52 weeks Storage Conditions: 2-8°C	
710.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 12359 R & I DRAP Dated: 02-10-2023 Fee Challan No: 8353334351 PKR: 50,000/- Dated: 15-11-2022	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom ISO Certificate: Validity:07-April-2025 LOA Validity: 12-June-2025	VITROS Immunodiagnostic Product Anti-HIV 1+2 Reagent: HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Anti-HIV 1+2 Reagents : 48446 Class: D MD Group: Kit Free Sale Certificate: MHRA-UK Validity:26-May-2025 Shelf life: 52 weeks Storage Conditions: 2-8°C	Approved
711.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 12358 R & I DRAP Dated: 02-10-2023 Fee Challan No: 573852858896 PKR: 50,000/- Dated: 15-11-2022	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom ISO Certificate: Validity:07-April-2025 LOA Validity: 12-June-2025 Free Sale Certificate: MHRA-UK Validity:26-May-2025	VITROS Immunodiagnostic Product Anti-HIV 1+2 Calibrator & Control: HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Anti-HIV 1+2 Calibrator: 48446 VITROS Immunodiagnostic Product Anti-HIV 1+2 Control: 48456 Class: D MD Group: Kit Shelf life: VITROS Immunodiagnostic Product Anti-HIV 1+2 Calibrator: 52 weeks VITROS Immunodiagnostic Product Anti-HIV 1+2 Contols: 104 weeks Storage Conditions: 2-8°C	Approved
712.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building,	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA	VITROS Immunodiagnostic Product Total PSA II Reagent HS Code: 38229000	Approved

	<p>44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12353 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 13175130</p> <p>PKR: 50,000/- Dated: 15-11-2022</p>	<p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p> <p>ISO Certificate: Validity:07-April-2025</p>	<p>GMDN Code: VITROS Immunodiagnostic Product Total PSA II Reagent: 54665</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025</p> <p>Shelf Life: 52 weeks Storage Conditions: 2-8°C</p>	
713.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12353 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 2709664099 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p> <p>ISO Certificate: Validity:07-April-2025</p>	<p>VITROS Immunodiagnostic Product Total PSA II Calibrator</p> <p>HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Total PSA II Calibrator: 54665</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025</p> <p>Shelf Life: 52 weeks Storage Conditions: 2-8°C</p>	Approved
714.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12343 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 1342888740 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>ISO Certificate: Validity:07-April-2025</p> <p>LOA Validity: 12-June-2025</p>	<p>VITROS Immunodiagnostic Product Total B HCG II Reagent</p> <p>HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Total B HCG II Reagent: 54211</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025</p> <p>Shelf life: 48 weeks Storage Conditions: 2-8°C</p>	Approved

715.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12344 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 2331862855</p> <p>PKR: 50,000/-</p> <p>Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p> <p>ISO Certificate: Validity:07-April-2025</p> <p>Free Sale Certificate: MHRA-UK Validity:26-May-2025</p>	<p>VITROS Immunodiagnostic Product Anti-HBc Calibrator & Control</p> <p>HS Code: 38229000 GMDN Code: VITROS Immunodiagnostic Product Anti-HBc Calibrator: 48304</p> <p>VITROS Immunodiagnostic Product Anti-HBc Control: 41984</p> <p>Class: D MD Group: Kit.</p> <p>Shelf life: VITROS Immunodiagnostic Product Anti-HBc Calibrator: 52 WEEKS</p> <p>VITROS Immunodiagnostic Product Anti-HBc Control: 52 weeks</p> <p>Storage Conditions: 2-8°C</p>	Approved
716.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12356 R & I DRAP Dated:02-10-2023 Fee Challan No: 37487453876 PKR: 50,000/- Dated: 15-11-2022</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p> <p>ISO Certificate: Validity:07-April-2025</p>	<p>VITROS Immunodiagnostic Product Total B HCG II Calibrator</p> <p>HS Code: 38229000 GMDN Code: 54211</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: MHRA-UK Validity: 26-May-2025</p> <p>Shelf life: 32 weeks Storage Conditions: 2-8°C</p>	Approved
717.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 12356 R & I DRAP</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>LOA Validity: 12-June-2025</p>	<p>VITROS Immunodiagnostic Product Anti HIV -1/2 Combo Control Reagent & Calibrator</p> <p>HS Code: 38229000 GMDN Code: 691225</p> <p>Class: D MD Group: Kit</p> <p>Free Sale Certificate: MHRA-UK</p>	Approved

	Dated: 02-10-2023 Fee Challan No: 296043045 PKR: 50,000/- Dated: 15-09-2023	ISO Certificate: 07-April-2025	Validity: 26-May-2025 Shelf life: 104 weeks Storage Conditions: 2-8°C	
718.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 12949 R & I DRAP Dated: 02-10-2023 Fee Challan No: 8246267820 PKR: 50,000/- Dated: 01-08-2024	Legal Manufacturer: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom LOA Validity: 12-June-2025 ISO Certificate: 07-April-2025 Free Sale Certificate: MHRA-UK 26-May-2025	VITROS Immunodiagnostic Products Troponin I ES Reagent & Calibrator (Reagent x 01 set) (Calibrator x 01 set) HS Code: Reagent: 3002120000 Calibrator: 3822190090 GMDN Code: Reagent: 60780 Calibrator: 60780 Class: C MD Group: Kit Shelf life Reagent: 52 weeks Calibrator: 60 weeks Storage Conditions: Reagent: 2-8°C Calibrator: 2-8°C:	Approved
719.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 18128 R & I DRAP Dated: 02-10-2023 Fee Challan No: 8567940835 PKR: 62,000/- Dated: 25-10-2024	Legal Manufacturer: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows, Pencoed Bridgend, CF35 5PZ, United Kingdom LOA Validity: 12-June-2025 ISO Certificate: 07-April-2025	VITROS Immunodiagnostic Products hs Troponin I Low Control (Control x 03 set) HS Code: 3822190090 GMDN Code: 54012 Class: C MD Group: Kit Free Sale Certificate: MHRA-UK 26-May-2025 Shelf life Reagent: 52 weeks Calibrator: 60 weeks Storage Conditions: ≤20°C	Approved
720.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road,	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site:	C.K. Prest 5 (Vials of Reagent 1 (6 x 5ml) – (C.K. Prest) Vials of Reagent 2 (6 x 5ml) - Activator)	Approved

	<p>Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17448 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 336909051 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverny – France</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>LOA Validity: 31-Dec-2025</p>	<p>HS Code: 3822190090 GMDN Code: 55981</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	
721.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17460 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 896677221 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverny – France</p> <p>LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p>	<p>STA – Apixaban Calibrator & Control (STA – Apixaban Calibrator 0 (3x1 ml) STA – Apixaban Calibrator 1 (3x1 ml) STA – Apixaban Calibrator 2 (3x1 ml) STA – Apixaban Calibrator 3 (3x1 ml) STA – Apixaban Control 1 (3x1 ml) STA – Apixaban Control 2 (3x1 ml)</p> <p>HS Code: 3822190090 GMDN Code: • Calibrator - 56272 • Control – 56181</p> <p>Class: C MD Group: Kit Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
722.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17448 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 98688521269 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverny – France</p> <p>MD Group: Kit LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p>	<p>STA - C.K. Prest 5 (Vials of Reagent 1 (6 x 5ml) – (STA - C.K. Prest) Vials of Reagent 2 (6 x 5ml) - Activator)</p> <p>HS Code: 3822190090 GMDN Code: Vials of Reagent 1 – 55981 Vials of Reagent 2- 55987 Class: C</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved

723.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17448 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 83495318239 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverny – France</p> <p>LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p>	<p>STA – Coag Control N+P (STA – Coag Control N (12 x 1ml) (STA – Coag Control P (12 x 1ml)</p> <p>HS Code: 3822190090</p> <p>GMDN Code: 30590</p> <p>Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
724.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17458 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 7627633623 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverny – France</p> <p>LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p>	<p>STA – Dabigatran Calibrator & Control (STA – Dabigatran Calibrator 0 (2 x 1 ml) STA – Dabigatran Calibrator 1 (2 x 1 ml) STA – Dabigatran Calibrator 2 (2 x 1 ml) STA – Dabigatran Calibrator 3 (2 x 1 ml) STA – Dabigatran Calibrator 4 (2 x 1 ml) STA – Dabigatran Control 1 (3 x 1 ml) STA – Dabigatran Control 2 (3 x 1 ml)</p> <p>HS Code: 3822190090 GMDN Code: • Calibrator - 60687 • Control – 60688 Class: C MD Group: Kit</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
725.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin</p>	<p>STA – D-Di Control (STA – D-Di Control 1 (6 x 2ml) STA – D-Di Control 2 (6 x 2ml))</p> <p>HS Code: 3822190090</p> <p>GMDN Code: 47347</p>	Approved

	Dy.No.: 17451 R & I DRAP Dated: 02-10-2023 Fee Challan No: 32917172021 PKR: 62,000/- Dated: 01-10-2024	Pecqueur – 95150 Taverny – France ISO Certificate Validity: 23-May-2025 LOA Validity: 31-Dec-2025	Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 18 Months Storage Conditions: 2-8°C	
726.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17451 R & I DRAP Dated: 02-10-2023 Fee Challan No: 6187542916 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France ISO Certificate Validity: 23-May-2025 LOA Validity: 31-Dec-2025	STA – D-Di Plus (Buffer - 6 x 2ml) (Latex - 6 x 2ml) HS Code: 3822190090 GMDN Code: 47346 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 15 Months Storage Conditions: 2-8°C	Approved
727.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17451 R & I DRAP Dated: 02-10-2023 Fee Challan No: 686144583 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025	STA – ECA (Prothrombin (2 x 3.5ml – Reagent 1)) (Substrate (2 x 2ml – Reagent 2)) (Ecarin (2 x 2ml – Reagent 3)) HS Code: 3822190090 GMDN Code: 60686 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
728.	M/s Martin Dow Specialties (Pvt)	Legal Manufacturer:	STA – Edoxaban Calibrator & Control	Approved

	<p>Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17465 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 0129050332 PKR: 62,000/- Dated:01-10-2024</p>	<p>Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p> <p>LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p>	<p>(STA – Edoxaban Calibrator 0 (3 x 1 ml) STA – Edoxaban Calibrator 1 (3 x 1 ml) STA – Edoxaban Calibrator 2 (3 x 1 ml) STA – Edoxaban Calibrator 3 (3 x 1 ml) STA – Edoxaban Calibrator 4 (3 x 1 ml) STA – Edoxaban Control 1 (3 x 1 ml) STA – Edoxaban Control 2 (3 x 1 ml) HS Code: 3822190090 GMDN Code: • Calibrator - 56272 • Control – 56181 Class: C MD Group: Kit Shelf life: 24 Months Storage Conditions: 2-8°C</p>	
729.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17463 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 6531841891 PKR: 62,000/- Dated:01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p> <p>LOA Validity: 31-Dec-2025</p> <p>ISO Certificate Validity: 23-May-2025</p>	<p>STA – Liatest Control N+P (STA – Liatest Control N (12 x 1ml) (STA – Liatest Control P (12 x 1ml)</p> <p>HS Code: 3822190090 GMDN Code: 30590</p> <p>Class: C MD Group: Kit</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
730.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17449 R & I DRAP Dated:02-10-2023</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p> <p>ISO Certificate Validity: 23-May-2025</p>	<p>STA – Liquid Anti - Xa (Substrate - 6 x 4ml) (F.Xa - 6 x 4ml)</p> <p>HS Code: 3822190090 GMDN Code: 56195 Class: C MD Group: Kit</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p>	Approved

	Fee Challan No: 8041184332 PKR: 62,000/- Dated: 01-10-2024		Shelf life: 24 Months Storage Conditions: 2-8°C	
731.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17466 R & I DRAP Dated: 02-10-2023 Fee Challan No: 9204365037 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025 Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024	STA – Multi Hep Calibrator (STA – Multi Hep Calibrator 0 (4 x 1ml) STA – Multi Hep Calibrator 4 (4 x 1ml) STA – Multi Hep Calibrator 7 (4 x 1ml) STA – Multi Hep Calibrator 10 (4 x 1ml) STA – Multi Hep Calibrator 18 (4 x 1ml)) HS Code: 3822190090 GMDN Code: 56196 Class: C MD Group: Kit Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
732.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17466 R & I DRAP Dated: 02-10-2023 Fee Challan No: 3062822810 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025	STA – NeoPTimal (STA – NeoPTimal 5 (6 x 5ml) Solvent (6 x 5ml) STA – NeoPTimal 10 (12 x 10ml) Solvent (12 x 10ml) STA – NeoPTimal 20 (12 x 20ml) Solvent (12 x 20ml)) HS Code: 3822190090 GMDN Code: 55983 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 24 Months Storage Conditions: 2-8°C	Approved

733.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17464 R & I DRAP Dated: 02-10-2023 Fee Challan No: 7975454179 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025	STA – PTTA 5 (12x5ml) HS Code: 3822190090 GMDN Code: 55981 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
734.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17445 R & I DRAP Dated: 02-10-2023 Fee Challan No: 3691617883 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025	STA – Quality HBPM/LMWH (STA – Quality HBPM/LMWH 8 (6 x 1ml) STA – Quality HBPM/LMWH 14 (6 x 1ml)) HS Code: 3822190090 GMDN Code: 56273 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
735.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17445 R & I DRAP Dated: 02-10-2023	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity:	STA – Quality HNF/UFH (STA – Quality HNF/UFH 2 - (6 x 1ml) STA – Quality HNF/UFH 7 - (6 x 1ml)) HS Code: 3822190090 GMDN Code: 56273 Class: C MD Group: Kit Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024	Approved

	Fee Challan No: 190142156 PKR: 62,000/- Dated: 01-10-2024	23-May-2025	Shelf life: 24 Months Storage Conditions: 2-8°C	
736.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17469 R & I DRAP Dated: 02-10-2023 Fee Challan No: 626801643 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France LOA Validity: 31-Dec-2025 ISO Certificate Validity: 23-May-2025 Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024	STA – Rivaroxaban Calibrator & Control (3 x STA – Rivaroxaban Calibrator 0 3 x STA – Rivaroxaban Calibrator 1 3 x STA – Rivaroxaban Calibrator 2 3 x STA – Rivaroxaban Calibrator 3 3 x STA – Rivaroxaban Control 1 3 x STA – Rivaroxaban Control 2) HS Code: 3822190090 GMDN Code: • Calibrator - 56272 • Control – 56181 Class: C MD Group: Kit Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
737.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17476 R & I DRAP Dated: 02-10-2023 Fee Challan No: 09136088937 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France	STA – Routine QC 2ml (STA – Routine QC 2ml N (12 x 2ml) STA – Routine QC 2ml P (12 x 2ml)) Class: C MD Group: Kit LOA Validity: 31-Dec-2025 Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024 ISO Certificate Validity: 23-May-2025 Shelf life: 24 Months Storage Conditions: 2-8°C	Approved
738.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6,	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France	STA – Unicalibrator (6 x 1ml) Class: C MD Group: Kit	Approved

	<p>PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17454 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 657751953 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	
739.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17450 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 17639620 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>STA – System Control N+P (STA – System Control Control N (12 x 1ml) (STA – System Control Control P (12 x 1ml))</p> <p>Class: C MD Group: Kit</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 24-May-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
740.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17447 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 1516259898 PKR: 62,000/- Dated:01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>sthemO – CK Prest (sthemO CK Prest (6 x 5ml) Activator (6 x 5ml))</p> <p>Class: C MD Group: Kit</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved

741.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17446 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 98208165 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>sthemO – Complete QC 1 & 2 (Level 1 (12 x 2ml)) (Level 2 (12 x 2ml))</p> <p>MD Group: Kit Class: C</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
742.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17443 R & I DRAP Dated:02-10-2023</p> <p>Fee Challan No: 9635819128 PKR: 62,000/- Dated: 01-10-2024</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>sthemO – Daily QC 1 & 2 (Level 1 (12 x 2ml)) (Level 2 (12 x 2ml))</p> <p>MD Group: Kit Class: C</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	Approved
743.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>Dy.No.: 17457 R & I DRAP Dated:02-10-2023</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France</p>	<p>sthemO – D-Di M (Buffer (6 x 5ml)) (Latex (6 x 6ml))</p> <p>MD Group: Kit Class: C</p> <p>LOA Validity: 31-Dec-2025</p> <p>Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024</p>	Approved

	Fee Challan No: 79338330420 PKR: 62,000/- Dated: 01-10-2024		Shelf life: 15 Months Storage Conditions: 2-8°C ISO Certificate Validity: 23-May-2025	
744.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17444 R & I DRAP Dated: 02-10-2023 Fee Challan No: 9884834604 PKR: 62,000/- Dated: 01-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France ISO Certificate Validity: 23-May-2025	sthemO – D-Di QC 1 & 2 (Buffer (6 x 5ml)) (Latex (6 x 6ml)) MD Group: Kit Class: C LOA Validity: 31-Dec-2025 Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024 Shelf life: 18 Months Storage Conditions: 2-8°C	Approved
745.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) Dy.No.: 17455 R & I DRAP Dated: 02-10-2023 Fee Challan No: 73141989933 PKR: 62,000/- Dated: 10-10-2024	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France	sthemO – PTTA (12 x 5ml) MD Group: Kit Class: C LOA Validity: 31-Dec-2025 Free Sale Certificate: <u>Date of Issue:</u> 08-Feb-2024 ISO Certificate Validity: 23-May-2025 Shelf life: 18 Months Storage Conditions: 2-8°C	Approved
746.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160)	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing site: Taverny: ZAC des Chataigniers – 23/29 rue Constantin Pecqueur – 95150 Taverns – France	Unicalibrator (6 x Unicalibrator) MD Group: Kit Class: C LOA Validity: 31-Dec-2025 Free Sale Certificate: <u>Date of Issue:</u>	Approved

	<p>Dy.No.: 17455 R & I DRAP Dated:02-10-2023 Fee Challan No.: 95539069452 PKR: 62,000/- Dated: 10-10-2024</p>		<p>24-May-2024</p> <p>ISO Certificate Validity: 23-May-2025</p> <p>Shelf life: 24 Months Storage Conditions: 2-8°C</p>	
747.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273)</p> <p>Dy.No.: 8161 R & I DRAP Dated:24-05-2024 Fee Challan No.: 516945047 PKR: 50,000/- Dated: 24-05-2024</p>	<p>Name of Manufacturer: Micro Therapeutics, INC, DBA EV3 NEUROVASCULAR, 9775 Toledo Way, Irvine, CA, USA 92618 ISO 13485 Validity: 30-11-2026</p> <p>FQA Validity Date: 26-05-2024</p> <p>EC Design Examination Certificate Validity: 26-05-2024</p> <p>LOA Date: 16-11-2022</p>	<p>Artisse Intrascular Device Class: D</p> <p>Size & Model: ISF-045-030, ISF-045-040, ISF-050-030, ISF-050-040, ISF-055-030, ISF-055-040, ISF-055-050, ISF-060-030, ISF-060-040, ISF-060-050, ISF-065-030, ISF-065-040, ISF-065-050, ISF-070-030, ISF-070-040, ISF-070-050, ISF-075-040, ISF-075-050, ISF-080-040, ISF-080-050.</p> <p>Shelf life: 3 years Storage conditions: in a dry place, away from sunlight. FSC: Netherlands Validity: 31-12-2027 <i>(Original attached with Artisse Detachment Device dated 22-May-2024.)</i></p>	Approved
748.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273)</p> <p>Dy.No.: 8162 R & I DRAP Dated:24-05-2024 Fee Challan No.: 123554901 PKR: 50,000/- Dated: 24-05-2024</p>	<p>Name of Manufacturer: Micro Therapeutics, INC, DBA EV3 NEUROVASCULAR, 9775 Toledo Way, Irvine, CA, USA 92618 ISO 13485 Validity: 30-11-2026</p> <p>FQA Validity Date: 26-05-2024</p> <p>EC Design Examination Certificate Validity: 26-05-2024</p> <p>LOA Date: 16-11-2022</p> <p>FSC: USA Validity: 08-02-2025</p>	<p>Pipeline™ Vantage Embolization Device with Shield Technology</p> <p>Class: D Shelf life: 3 years Storage conditions: This device should be stored in a dry place, away from sunlight.</p> <p>Size & Model: PED3-021-250-10, PED3-021-250-12 PED3-021-250-14, PED3-021-250-16 PED3-021-250-18, PED3-021-250-20 PED3-021-275-10, PED3-021-275-12 PED3-021-275-14, PED3-021-275-16 PED3-021-275-18, PED3-021-275-20 PED3-021-300-10, PED3-021-300-12 PED3-021-300-14, PED3-021-300-16 PED3-021-300-18, PED3-021-300-20</p>	Approved subject to submission of valid letter of authorization.

			<p> PED3-021-325-10, PED3-021-325-12 PED3-021-325-14, PED3-021-325-16 PED3-021-325-18, PED3-021-325-20 PED3-021-350-10, PED3-021-350-12 PED3-021-350-14, PED3-021-350-16 PED3-021-350-18, PED3-021-350-20 PED3-021-350-25, PED3-027-350-10 PED3-027-350-12, PED3-027-350-14 PED3-027-350-16, PED3-027-350-18 PED3-027-350-20, PED3-027-350-25 PED3-027-350-30, PED3-027-350-35 PED3-027-400-10, PED3-027-400-12 PED3-027-400-14, PED3-027-400-16 PED3-027-400-18, PED3-027-400-20 PED3-027-400-25, PED3-027-400-30 PED3-027-400-35, PED3-027-400-40 PED3-027-450-10, PED3-027-450-12 PED3-027-450-14, PED3-027-450-16 PED3-027-450-18, PED3-027-450-20 PED3-027-450-25, PED3-027-450-30 PED3-027-450-35, PED3-027-450-40 PED3-027-500-10, PED3-027-500-12 PED3-027-500-14, PED3-027-500-16 PED3-027-500-18, PED3-027-500-20 PED3-027-500-25, PED3-027-500-30 PED3-027-500-35, PED3-027-500-40 PED3-027-550-10, PED3-027-550-12 PED3-027-550-14, PED3-027-550-16 PED3-027-550-18, PED3-027-550-20 </p>	
--	--	--	---	--

			<p>PED3-027-550-25, PED3-027-550-30 PED3-027-550-35, PED3-027-550-40 PED3-027-550-45, PED3-027-550-50 PED3-027-600-10, PED3-027-600-12 PED3-027-600-14, PED3-027-600-16 PED3-027-600-18, PED3-027-600-20 PED3-027-600-25, PED3-027-600-30 PED3-027-600-35, PED3-027-600-40 PED3-027-600-45, PED3-027-600-50</p>	
749.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273)</p> <p>Dated:06-03-2024 Fee Challan No.: 28517201278 PKR: 50,000/- Dated: 07-12-2023</p>	<p>Name of Manufacturer: Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432 Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432 Manufacturing facilities: i. Medtronic Inc. 8200 Carol Sea Street NE Mounds View, Mn USA 55112 ii. Medtronic Inc. 7000 Central Ave., N.E. USA 55432 Minneapolis, MN iii. Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II Bayan Lepas, Pulau Pinang Malaysia 11900 iv. Medtronic Operations Puerto Co., Rico Villalba located at RD. 149, KM.56.3 Call Box 6001 Villalbba, PR USA 00766 V. Medtronic Singapore Operations Pte Ltd located at 49 Changi South Avenue 2 Nasaco Tech Centre Singapore, Central Singapore Singapore 486057</p>	<p>Sprint Quattro Secure MRI SureScan</p> <p>Class: D Shelf life: 2 years Size & Model: 6947-65 6947-58 Storage conditions: No specific storage conditions</p> <p>ISO 13485 Validity: 31-03-2025 (Singapore) 12-02-2025 (Malaysia) 31-03-2025 (USA) 21-03-2025 (Puerto Rico)</p> <p>FQA Validity Date: 01-12-2025</p> <p>EC Design Examination Certificate Validity: 01-07-2027</p> <p>LOA Date: 21-10-2022</p> <p>FSC: USFDA Validity: 21-08-2024</p>	<p>Deferred for submission of valid letter of authorization.</p>
750.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p>	<p>Name of Manufacturer: Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432 Medtronic Inc, 710 Medtronic Parkway</p>	<p>CareLink SmartSync Device Manager Base</p> <p>Class: D Size & Model: 24970A</p>	<p>Deferred for submission of valid letter of authorization.</p>

	<p>(ELI-00273)</p> <p>Dated:06-03-2024 Fee Challan No.: 750299622757 PKR: 50,000/- Dated: 08-12-2023</p>	<p>Minneapolis, MN, USA 55432</p> <p>Manufacturing facilities:</p> <p>i. Medtronic Inc. 8200 Carol Sea Street NE Mounds View, Mn USA 55112</p> <p>ii. Medtronic Inc. 7000 Central Ave., N.E. USA 55432 Minneapolis, MN</p> <p>iii. Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II Bayan Lepas, Pulau Pinang Malaysia 11900</p> <p>iv. Medtronic Operations Puerto Co., Rico Villalba located at RD. 149, KM.56.3 Call Box 6001 Villalbba, PR USA 00766</p> <p>v. Medtronic Singapore Operations Pte Ltd located at 49 Changi South Avenue 2 Nasaco Tech Centre Singapore, Central Singapore Singapore 486057</p>	<p>Storage and Temperature conditions: No specific storage conditions Shelf life: N/A</p> <p>ISO 13485 Validity: 31-03-2025 (Singapore) 12-02-2025 (Malaysia) 31-03-2025 (USA) 21-03-2025 (Puerto Rico)</p> <p>FQA Validity Date: 01-12-2025</p> <p>EC Design Examination Certificate Validity: 01-07-2027</p> <p>LOA Date: 21-10-2022</p> <p>FSC: USFDA Validity: 21-08-2024</p>	
751.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273) 16461 DRAP (R&I) Dated:30-09-2024 Fee Challan No.: 830223488055 PKR: 50,000/- Dated: 09-09-2024</p>	<p>Name of Manufacturer: Medtronic Sofamor Danek USA, Inc, 1800 Pyramid Place Memphis, USA</p> <p>Medtronic Trading NL BC Earl Bakkenstraat 10 6422 PJ Herlen Netherlands</p> <p>Manufacturing facilities:</p> <p>i. Medtronic Medical Costa Rica S.R.L Coyol free, Zone Bldg B7 Multitenant 7-8, Module F Coyol, Alajuela Costa Rica.</p> <p>ii. Medtronic Sofamor Danek USA, INC 4340 Swinnea Road Memphis, TN USA 38118</p> <p>iii. Warsaw ortho Inc, also known as M/s Medtronic Sofamor Danek manufacturing located at 2500 Silveus Crossing Warsaw, IN USA 46582</p>	<p>Rialto™ SI Fusion System</p> <p>Class: C Size & Model: -74200001240 12mm x 40mm threaded device. -74200001245 12mm x 45mm threaded device. -74200001250 12mm x 50mm threaded device. -74200001250 12mm x 55mm threaded device. -74200001260 12mm x 60mm threaded device.</p> <p>Storage conditions: Corrosion free environment. Shelf life: 08 years</p> <p>ISO 13485 Validity: 20-09-2025</p> <p>FQA Validity Date: 26-05-2024</p> <p>Design Examination Certificate: N/A</p> <p>LOA Date: 21-10-2022 FSC: USFDA Validity: 20-09-2025</p>	<p>Deferred for submission of valid letter of authorization.</p>

			EC Certificate validity: 20-09-2025	
752.	<p>Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN.</p> <p>(ELI-00240) Date of R& I 30 May 2024 Fee: -Rs. 50,000/</p>	<p>(Legal Manufacturer) GUILIN FUKANGSEN MEDICAL INSTRUMENT CO., LTD (Manufacturing site) NO.397 XINGXIAN ROAD, QINGSHAN STREET, QINGSHAN TOWN, LIPU CITY, GUILIN, GUANGXI, CHINA</p> <p>ISO 13485 Validity: 30-11-2026</p> <p>FQA Validity Date: 230-11-2026 Design Examination Certificate: 30-11-2026</p> <p>LOA validity: 08-03-2034</p> <p>FSC: China Validity: 11-12-2024</p>	<p>CARESPONGE ABSORBABLE GELATIN SPONGE HAEMOSTATIC (ABSORBABLE GELATIN SPONGE)</p> <p>Class: D Model/Specifications FKS-A (80X50X10MM), 70X50X10MM, 15X15X15MM, 10X10X10MM, 80X125MM, 20X20MM, 60X20MM, 80X30ØMM, FKS-B, FKS-C</p> <p>FKS-A (80X50X10MM, 70X50X10MM, 15X15X15MM, 10X10X10MM, 80X125MM, 20X20MM, 60X20MM, 80X30ØMM, FKS-B, FKS-C</p> <p>Storage conditions: Corrosion free environment. Shelf life: 03 years</p>	Approved
753.	<p>Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN.</p> <p>(ELI-00240) Date of R& I 30 May 2024 Fee: Rs. 50,000/- Slip no.: 98588323112 Dated: 22-05-2024</p>	<p>(Legal Manufacturer) GUANGDONG BAIHE MEDICAL TECHNOLOGY CO., LTD (Manufacturing site) NO.89, TAOYUAN EAST ROAD, NANHAI FOSHAN 528225 GUANGDONG P.R. CHINA</p> <p>ISO 13485 Validity: 06-08-2024</p> <p>FQA Validity Date: 26-05-2024</p>	<p>HOSPITAL & HOMECARE HAEMODIALYSER</p> <p>Class: C Model: -LOW FLUX (POLYETHERSULFONE) with sizes: A40/ A60/ A80/A200 -HIGH FLUX (POLYETHERSULFONE) with sizes: H-40/ H-60/ H-80/ H-200</p> <p>Storage conditions: Corrosion free environment. Shelf life: 03 years FSC: China Validity: 16-07-2024 LOA validity: 28-03-2026</p>	Approved
754.	<p>Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN.</p>	<p>(Legal Manufacturer) GUANGDONG BAIHE MEDICAL TECHNOLOGY CO., LTD (Manufacturing site) NO.89, TAOYUAN EAST ROAD, NANHAI FOSHAN 528225 GUANGDONG P.R. CHINA</p>	<p>HOSPITAL & HOMECARE HAEMODIALYSER</p> <p>Class: C Model: -LOW FLUX (POLYETHERSULFONE) with sizes: A40/ A60/ A80/A200</p>	Approved

	<p>(ELI-00240) Date of R& I 30 May 2024 Fee: Rs. 50,000/- Slip no.: 98588323112 Dated: 22-05-2024</p>	<p>ISO 13485 Validity: 06-08-2024</p> <p>FQA Validity Date: 26-05-2024</p>	<p>-HIGH FLUX (POLYETHERSULFONE) with sizes: H-40/ H-60/ H-80/ H-200</p> <p>Storage conditions: Corrosion free environment. Shelf life: 03 years FSC: China Validity: 16-07-2024 LOA validity: 28-03-2026</p>	
755.	<p>M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi</p> <p>(ELI-00154) Date of R&I: 30-Sep- 2024 Fee Challan No: 380474252 PKR 62,000/-</p>	<p>Legal Manufacturer: Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, USA 00969</p> <p>Physical Manufacturer: Nypro Healthcare Baja Inc. Address: Avenida De Las Torres No. 7125 Colonia Salvarcar 118 Ciudad Juarez, Chihuahua, 32580, Mexico</p>	<p>ECHELON Linear Cutter Reloads</p> <p>Class C Shelf-life: 3 Years</p> <p>Codes: GLCR60B GLCR60G GLCR80B GLCR80G GLCR100B GLCR100G</p> <p>FSC (USFDA) Validity: 19-Jun-2026 FQA Validity: 14-01-2026 LOA: Valid ISO 13485 validity: 31 Mar 2026</p>	Approved
756.	<p>M/s Melamine Emporium. 814, Star City Mall, Saddar, Karachi.</p> <p>(ELI-00414)</p> <p>Submission date: 06-02-2024 Fee Challan No: 9104953624 PKR 50,000/- Dated: 15-01-2024</p>	<p>Legal Manufacturer: Lepu Medical Technology (Beijing) Co.</p> <p>Address: No. 37, Chaoqian Road, Changping District, Beijing 102200, China.</p> <p>FSC (China) Validity: 28-09-2024</p> <p>FSC (Netherlands) Validity: 27-05-2024</p> <p>FQA Validity: 27-05-2024</p> <p>Design Examination Certificate Validity: 27-05-2024 (UDEM)</p> <p>LOA: 31-12-2026 ISO 13485 validity: 06-03-2026</p>	<p>Brand: GuReater™ CoCr Sirolimus-eluting Coronary Stent System</p> <p>Device: Sirolimus-eluting Coronary Stent System.</p> <p>MD Group: System Class D Shelf-life: 3 Years Storage Conditions: 10°C – 30°C</p> <p>Codes: LPRPC2208, LPRPC2508, LPRPC2708, LPRPC3008, LPRPC3508, LPRPC4008, LPRPC4512, LPRPC2212, LPRPC2512, LPRPC2712, LPRPC3012, LPRPC3512, LPRPC4012, LPRPC4515, LPRPC2215, LPRPC2515, LPRPC2715, LPRPC3015, LPRPC3515, LPRPC4015, LPRPC4518, LPRPC2218, LPRPC2518, LPRPC2718, LPRPC3018, LPRPC3518, LPRPC4018, LPRPC4521, LPRPC2221, LPRPC2521,</p>	Approved. Registration letter shall be issued after provision of valid & legalized free sale certificate, ISO 13485 certificate, Letter of authorization & EC Certificate.

			LPRPC2721, LPRPC3021, LPRPC3521, LPRPC4021, LPRPC4524, LPRPC2224, LPRPC2524, LPRPC2724, LPRPC3024, LPRPC3524, LPRPC4024, LPRPC4529, LPRPC2229, LPRPC2529, LPRPC2729, LPRPC3029, LPRPC3529, LPRPC4029, LPRPC4533, LPRPC2233, LPRPC2533, LPRPC2733, LPRPC3033, LPRPC3533, LPRPC4033, LPRPC4536, LPRPC2236, LPRPC2536, LPRPC2736, LPRPC3036, LPRPC3536, LPRPC4036	
757.	<p>M/s Microport Scientific Pakistan Pvt. Ltd.</p> <p>Office No. 02 / 3,2,2nd floor Hive Gizri Road, Block – 9, Clifton, Karachi.</p> <p>(ELI-01182)</p> <p>Submission date: 06-12-2024</p> <p>Fee Challan No: 43852176312 PKR 180000/- Dated: 03-12-2024</p>	<p>Legal Manufacturer: Shanghai Microport MedBot (Group) Co. Ltd.</p> <p>Address: Room No 101, Zone B, Building 1, No. 1601, Zhangdong Road China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China.</p> <p>Site # 01: For Design and development, Production, manufacture and distribution:</p> <p>Name: Shanghai MicroPort MedBot (Group) Co., Ltd.</p> <p>Address: Room 01, Zone A, 3rd basement, Building 11, No. 2585, Zuchongzhi Road, No. 1661, Zhangdong Road, China (Shanghai) Pilot Free Trade Zone Shanghai 201203 China.</p> <p>Name: Shanghai MicroPort MedBot (Group) Co., Ltd.</p> <p>Address: Room 01, 2nd Floor, Building 4, No. 128, Dieqiao Road, Pudong New district Shanghai 201315 China.</p>	<p>Toumai ® - Endoscopic Surgical System (MT1000) with system components.</p> <p>MD Group: System Class C</p> <p>Shelf-life: 10 Years service life.</p> <p>Storage Conditions: -20°C – 55°C</p> <p>Models: MT-1000 mentioned in table below.</p> <p>FSC (China) Validity: 16-03-2026</p> <p>DOC (Netherlands) submitted</p> <p>QMS - FQA Validity: 18-06-2028</p> <p>Design Examination Certificate Validity: ISO 13485 certification including on design and development.</p>	Approved
758.	<p>M/s Microport Scientific Pakistan Pvt. Ltd.</p> <p>Office No. 02 / 3,2,2nd floor Hive Gizri Road, Block – 9, Clifton, Karachi.</p> <p>(ELI-01182)</p>	<p>Legal Manufacturer: Shanghai Microport CardioFlow Medtech Co. Ltd.</p> <p>Address: Room No. 1002, Area A and Area B of G floor (Nominal Floor G Floor, Actual Floor 1 Floor), Area A of Second floor (Nominal floor 2 Floor, Actual Floor 3</p>	<p>VitaFlow Liberty™ – Transcatheter Aortic Valve System</p> <p>MD Group: System Class D</p> <p>Shelf-life: 02 years.</p> <p>Storage Conditions: 10°C – 25°C</p>	Approved

	<p>Submission date: 06-12-2024</p> <p>Fee Challan No: 25329860 PKR 100000/- Dated: 03-12-2024</p>	<p>Floor), Building 1, 1601 Zhangdong Road, Shanghai Free Trade Pilot Area, China.</p> <p>Site # 01: For Design, manufacturing & sales Aortic Valve Bioprosthesis, Delivery System and Loading tool: 8 floor and 9 floor, Building 3, 1661 Zhangdong Road, 2585 Zuchongzhi Road, Pudong District, Shanghai City, China.</p>	<p>FSC (China) Validity: 16-03-2026</p> <p>DOC (Netherlands) submitted</p> <p>QMS - FQA Validity: (Netherlands) 01-04-2029</p> <p>Design Examination Certificate Validity: ISO 13485 certification including on design and development.</p>	
759.	<p>M/s B. Braun Pakistan Pvt. Ltd. The Forum Suite 216, Khayaban-e-Jami, Block # 9, Clifton, Karachi. (ELI-00006) 9855 DRAP R& I: Dated: 02-07-2024</p> <p>Fee Challan No. 86803864640 PKR 50,000/- Dated: 13-06-2024</p>	<p>(Legal Manufacturer)</p> <p>Name: Aesculap AG. Address: Am Aesculap-Platz, 78532 Tuttlingen, Germany.</p> <p>LOA Validity: 06-07-2025</p> <p>ISO 13485 Validity: 12-12-2027</p> <p>FSC Validity: (Germany) <i>Country of Origin</i> – 26-06-2019</p> <p>EC Certificare validity: 26-05-2024</p> <p>EU QMS Certificate validity: 09-07-2025</p>	<p>Brand name: Aesculap® NeuroEndoscopy (Suction Tubes / Cannula Family)</p> <p>Device name: Device for NeuroEndoscopy</p> <p>MD Group: Family Class: D</p> <p>Shelf life: N/A</p> <p>Storage Conditions: No specific storage conditions</p> <p>Model / Specifications: GF408R, GF398R, GF418R, GF428R, GF409R, GF399R, GF419R, GF429R, GF401R, GF391R, GF411R, GF421R, GF402R, GF392R, GF412R, GF422R, GF403R, GF393R, GF413R, GF423R, GF404R, GF394R, GF414R, GF424R, GF405R, GF395R, GF415R, GF425R, GF406R, GF396R, GF416R, GF426R, GF407R, GF397R, GF417R, GF427R, GF431R, GF432R, GF470R, GF471R, GF472R, GF473R, GF474R, GF475R, GF476R, GF477R, GF478R, GF479R, GF480R, GF481R, FH605SU, FH605SU, FH606SU, FH607SU, FH610R, FH610R, FH611R, FH615</p>	<p>Approved Registration letter shall be issued after provision of valid free sale certificate.</p>
760.	<p>M/s INVACOR. Office # 304, 3rd floor Al-Sehat Center Rafiqui</p>	<p>(Legal Manufacturer)</p> <p>Name: Shunmei Medical Co. Ltd.</p>	<p>Brand name: Shunmei NORa</p> <p>Device name: Micro Guide wire</p>	<p>Approved subject to the submission of following information / documents:</p>

<p>(H.J) Shaheed Road Karachi. (ELI-01203) 7162 DRAP R& I: Dated: 09-05-2024 Fee Challan No. 407322302511 PKR 50,000/- Dated: 09-04-2024</p>	<p>Address: R401 of Building B, No. 08 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China.</p> <p>For the activities of Design, manufacture and packs, sterilization and store.</p> <p>Name: Huizhou Branch, Shunmei Medical Co. Ltd. Address: Yifa 3rd Road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China. LOA Validity: 28-11-2026</p> <p>ISO 13485 Validity: 12-12-2027</p> <p>FSC Validity: (China) <i>Country of Origin</i> – 13-07-2024 EC Certificare validity: 06-02-2024 Design examination certificate validity: 06-02-2024</p>	<p>MD Group: System Class: D</p> <p>Shelf life: 36 months Storage Conditions: Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature.</p> <p>Model / Specifications: For MGWN series: the guide wire is composed of proximal core wire, distal core wire, proximal coil wire, distal core wire.</p> <p>For MGWNA, MGWNB, MGWNC series: the guide wire is composed of proximal core wire, distal core wire, core wire, polymer jacket and hydrophilic coating.</p> <p>For MGWND series: the guide wire is composed of core wire, core wire, polymer jacket and hydrophilic coating.</p> <p>MGWN200-14S MGWN200-14SX MGWN115-14E MGWN300-14S MGWN300-14SX MGWNA200-14SX MGWNA200-14SS MGWNA200-14PS MGWNA200-14P MGWNA300-14SS MGWNA300-14PS MGWNA300-14S MGWNA300-14P MGWNB200-14S MGWNB200-14Sa MGWNB200-14SX MGWNB300-14S MGWNB300-14Sa MGWNC200-10-12 MGWNC300-10-12 MGWND200-14S MGWND200-14SS MGWND200-14SF MGWND200-14Sa MGWND300-14SX MGWND300-14SS MGWND300-14SF</p>	<ul style="list-style-type: none"> - FSc expired on 31-07-2024 (was valid at the time of submission of file). - Clarification regarding the configurations/models specifically, the models MGWN200-14S, MGWN200-14SX, and MGWN300-14SX only. - Valid design examination certificate
--	---	---	---

			MGWND200-10S	
761.	<p>M/s INVACOR. Office # 304, 3rd floor Al-Sehat Center Rafiqui (H.J) Shaheed Road Karachi. (ELI-01203) 7161 DRAP R& I: Dated: 09-05-2024 Fee Challan No. 9279821324 PKR 50,000/- Dated: 09-04-2024</p>	<p>(Legal Manufacturer) Name: Shunmei Medical Co. Ltd. Address: R401 of Building B, No. 08 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China. For the activities of Design, manufacture and packs, sterilization and store. Name: Huizhou Branch, Shunmei Medical Co. Ltd. Address: Yifa 3rd Road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China. LOA Validity: 28-11-2026 ISO 13485 Validity: 12-12-2027 FSC Validity: (China) <i>Country of Origin –</i> 13-07-2024 EC Certificare validity: 06-02-2024 Design examination certificate validity: 06-02-2024</p>	<p>Brand name: Shunmei NORa Device name: Micro Catheter MD Group: System Class: D Shelf life: 36 months Storage Conditions: Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature. Model / Specifications: Micro Catheter is composed of catheter hub, strain relief, main body, hydrophilic coating and radiopaque marker. MCS150-17S MCS150-17A45 MCS150-17A90 MCS150-17J MCS150-22SX MCS150-17SA MCS150-17A45A MCS150-17A90A MCS150-17JA MCS156-17SA MCS156-17S MCS165-17SA MCS150-22SAX MCS150-20S MCS156-20S MCS150-20SA MCS156-20SA MCS150-26SY MCS156-26S MCS150-26SAY MCS156-26SA</p>	<p>Approved subject to submission of following information / documents: - Free sale certificate expired on 31-07-2024 (was valid at the time of submission of file). - Valid CE marking certificate (design examination certificate)</p>
762.	<p>M/S POPULAR INTERNATIONAL PVT. LTD. HOUSE # 141 JUSTICE INAMULLAH ROAD, BLOCK 7&8 K.M.C.H.S., NEAR HILL PARK KARACHI. (ELI-00091) Diary Dated: 08-10-2020 Fee Challan No.: 1993742 PKR: 50,000/-</p>	<p>Legal Manufacturer: W.O.M. WORLD OF MEDICINE GmbH located at ALTE POST STR. 11 LUDWIGSST ADT, Bayern GERMANY. Covidien LLC a MEDTRONIC Company, Located at 15 Hampshire Street Mansfield, Ma USA 02048 Product Owner: Medtronic, Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA Supply branch for Pakistan:</p>	<p>Brand Name: HYSTEROLUX™ Fluid Management System Device: Hysteroscopic Tissue Removal System. Model: Control Unit, System Scale, Vacuum tube set, Y-Adaptor Inflow Tube set, Outflow tube set with models mentioned in table below. Class: C MD group: System LOA Validity: N/A Issued on 09-05-2018. FSC (Germany)</p>	<p>Approved</p>

		<p>Covidien AG Dictor von Bruns-Strasse 190212 Neuhausen am Rheinfall Switzerland</p> <p>Other Plants: INFUS MEDICAL (THAILAND) CO. LTD. Located at 706 MOO 4, Bangpoo Industrial Estate, I-EA-T Free Zone, Tambon Preaksa, Amphoe Muang Samutprakarn, Samutprakarn Province, Samut Prakan Thailand.</p>	<p>(<i>country of origin</i>): Issuance date: 31-03-2022</p> <p>FQA validity: 24-02-2022 (Covidien)</p> <p>ISO 13485 validity: 31-01-2022 (INFUS) 31-08-2019 (W.O.M)</p> <p>Shelf life: 05 years Storage condition: Store at below 54°C</p>	
763.	<p>DIAG.M (PRIVATE) LIMITED B-270, Sector 6-F.EBM Causeway, Mehran Town, Korangi - KARACHI (ELI-00184)</p> <p>Diary Dated: 19-11-2024 Fee Challan No.: 03084598575 PKR: 62,000/-</p>	<p>Biosystems S.A. Costa Brava 30, Barcelona, Spain</p>	<p>Biosystems Fecal Occult Blood (FOB) Reagent</p> <p>Class C</p> <p>Shelf life: 15 Months</p> <p>Storage Condition: 2-8° C Codes & Sizes N/A</p> <p>MD group: Kit LOA Validity: 30-04-2029. FSC (Spain) (<i>country of origin</i>): Issuance date: 24-09-2021</p> <p>FQA validity: Not provided ISO 13485 validity: 12-12-2025 (DAKks)</p>	<p>Approved subject to provision of valid Free sale certificate, EC Certificate, ISO 13485 certification, FQA,</p>
764.	<p>DIAG.M (PRIVATE) LIMITED B-270, Sector 6-F.EBM Causeway, Mehran Town, Korangi - KARACHI (ELI-00184)</p> <p>Diary Dated: 19-11-2024 Fee Challan No.: 5398425697 PKR: 62,000/-</p>	<p>Biosystems S.A. Costa Brava 30, Barcelona, Spain</p>	<p>Biosystems Fecal Occult Blood (FOB) Standards</p> <p>Class C</p> <p>Shelf life: 15 Months</p> <p>Storage Condition: 2-8° C Codes & Sizes N/A</p> <p>MD group: Kit LOA Validity: 30-04-2029.</p>	<p>Approved subject to provision of original & legalized documents (Free sale certificate, EC Certificate, ISO 13485 certification, FQA, Letter of authorization).</p>

			<p>FSC (Spain) (country of origin): Issuance date: 24-09-2021</p> <p>FQA validity: Not provided</p> <p>ISO 13485 validity: 12-12-2025 (DAKks)</p>	
765.	<p>DIAG.M (PRIVATE) LIMITED B-270, Sector 6-F.EBM Causeway, Mehran Town, Korangi - KARACHI (ELI-00184)</p> <p>Diary Dated: 19-11-2024 Fee Challan No.: 273712256 PKR: 62,000/-</p>	Biosystems S.A. Costa Brava 30, Barcelona, Spain	<p>Biosystems Fecal Occult Blood (FOB) Controls</p> <p>Class C</p> <p>Shelf life: 15 Months</p> <p>Storage Condition: 2-8° C Codes & Sizes N/A</p> <p>MD group: Kit</p> <p>LOA Validity: 30-04-2029.</p> <p>FSC (Spain) (country of origin): Issuance date: 24-09-2021</p> <p>FQA validity: Not provided</p> <p>ISO 13485 validity: 12-12-2025 (DAKks)</p>	Approved subject to provision of original & legalized documents (Free sale certificate, EC Certificate, ISO 13485 certification, FQA, Letter of authorization).
766.	<p>DIAG.M (PRIVATE) LIMITED B-270, Sector 6-F.EBM Causeway, Mehran Town, Korangi - KARACHI (ELI-00184)</p> <p>Diary Dated: 19-11-2024 Fee Challan No.: 16455738486 PKR: 62,000/-</p>	Biosystems S.A. Costa Brava 30, Barcelona, Spain	<p>Biosystems Haptoglobin Calibrator</p> <p>Class C</p> <p>Shelf life: Not provided</p> <p>Storage Condition: 2-8° C Codes & Sizes N/A</p> <p>MD group: Kit</p> <p>LOA Validity: 30-04-2029.</p> <p>FSC (Spain) (country of origin):</p>	Approved subject to provision of original & legalized documents (Free sale certificate, EC Certificate, ISO 13485 certification, FQA, Letter of authorization).

			<p>Issuance date: 24-09-2021</p> <p>FQA validity: Not provided</p> <p>ISO 13485 validity: 12-12-2025 (DAkks)</p>	
767.	<p>DIAG.M (PRIVATE) LIMITED B-270, Sector 6-F.EBM Causeway, Mehran Town, Korangi - KARACHI (ELI-00184)</p> <p>Diary Dated: 19-11-2024 Fee Challan No.: 3995574424 PKR: 31,000/-</p>	<p>Biosystems S.A. Costa Brava 30, Barcelona, Spain</p>	<p>Biosystems 17-Ketosteroids</p> <p>Class B</p> <p>Shelf life: 36 Months</p> <p>Storage Condition: 2-8° C Codes & Sizes N/A</p> <p>MD group: Kit</p> <p>LOA Validity: 30-04-2029.</p> <p>FSC (Spain) (country of origin): Issuance date: 24-09-2021</p> <p>FQA validity: Not provided</p> <p>ISO 13485 validity: 12-12-2025 (DAkks)</p>	<p>Approved subject to provision of original & legalized documents (Free sale certificate, EC Certificate, ISO 13485 certification, FQA, Letter of authorization).</p>
768.	<p>Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 16209284496 PKR: 50,000/-</p>	<p>Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan</p>	<p>LightLas 577 (Ophthalmic Yellow Laser)</p> <p>Class C</p> <p>Shelf life: 01 Year</p> <p>Storage Condition: -10 to 55° C Codes & Sizes As per FSC</p> <p>MD group: Family</p> <p>LOA Validity: 31-01-2027.</p> <p>FSC (Taiwan) (country of origin): validity: 05-10-2025</p> <p>FQA validity: Extension Letter provided</p>	<p>Approved</p>

			ISO 13485 validity: 27-02-2025 (DNV)	
769.	Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi. (ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 5933170265 PKR: 50,000/-	Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan	LightLas 532 (Ophthalmic Frequency Doubled Yag Laser) Class C Shelf life: 01 Year Storage Condition: -10 to 55° C Codes & Sizes As per FSC MD group: Family LOA Validity: 31-01-2027. FSC (Taiwan) (<i>country of origin</i>): validity: 30-10-2026 FQA validity: Extension Letter provided ISO 13485 validity: 27-02-2025 (DNV)	Approved
770.	Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi. (ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 3412432298 PKR: 50,000/-	Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan	LightLas SeLec Tor Deux Lightlas SLT DEUX (SLT and SLT/YAG Combination Laser) Class C Shelf life: 01 Year Storage Condition: -10 to 55° C Codes & Sizes As per FSC MD group: Family LOA Validity: 31-01-2027. FSC (Taiwan) (<i>country of origin</i>): validity: 24-03-2025 FQA validity: Extension Letter provided	Approved

			ISO 13485 validity: 27-02-2025 (DNV)	
771.	Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi. (ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 6596801633 PKR: 50,000/-	Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan	LightLas Yaq Lpalsa SYL- 9000 (Ophthalmic YAG Laser) Class C Shelf life: 01 Year Storage Condition: -10 to 55° C Codes & Sizes As per FSC MD group: Family LOA Validity: 31-01-2027. FSC (Taiwan) (<i>country of origin</i>): validity: 24-03-2025 FQA validity: Extension Letter provided ISO 13485 validity: 27-02-2025 (DNV)	Approved
772.	Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi. (ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 6526299990 PKR: 50,000/-	Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan	TruScan Pro (LightLas Pattern Scanning Laser System) Class C Shelf life: 01 Year Storage Condition: -10 to 55° C Codes & Sizes As per FSC MD group: Family LOA Validity: 31-01-2027. FSC (Taiwan) (<i>country of origin</i>): validity: 13-01-2026 FQA validity: Extension Letter provided ISO 13485 validity: 27-02-2025 (DNV)	Approved

773.	<p>Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416) Diary Dated: 13-06-2024 Fee Challan No.: 6526299990 PKR: 50,000/-</p>	<p>Lightmed Corporation, No. 1-1, Lane I Pao An St, Sec 3 Shulin District, New Taipei City 23861, Taiwan</p>	<p>LightLas 810 (Ophthalmic Diode Laser)</p> <p>Class C</p> <p>Shelf life: 01 Year</p> <p>Storage Condition: -10 to 55° C Codes & Sizes As per FSC</p> <p>MD group: Family</p> <p>LOA Validity: 31-01-2027.</p> <p>FSC (Taiwan) (country of origin): validity: 05-10-2026</p> <p>FQA validity: Extension Letter provided</p> <p>ISO 13485 validity: 27-02-2025 (DNV)</p>	Approved
774.	<p>M/s Global Biotech Medical Devices (Private) Limited.</p> <p>1st floor of Plot # 35- N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.</p> <p>(ELI-01292)</p> <p>Submission date: 10-12-2024 Fee Challan No: 4644004208 PKR 100,000/- Dated: 05-12-2024</p>	<p>Legal Manufacturer: Vascular Innovations Co. Ltd. Address: 88/38 Moo 1, 345 Road, Bangtanai Sup- District, Pakkret District, Nonthaburi 11120, Thailand.</p> <p>For Sterilization: Name: Siam Steri Service Co. Ltd (SIS) Address: 700/644, Amata City Chonburi, Moo 3, Tambol Bankao, Amphur Pantong, Chonburi 20160, Thailand.</p> <p>LOA: 29-08-2026 ISO 13485 certificate validity: 27-02-2026</p> <p>FSC (Thailand) Validity: 13-11-2026</p> <p>QMS - FQA Validity: 27-05-2024</p> <p>Design Examination Certificate Validity: 27-05-2024. (Poland)</p>	<p>Brand: Hydra Aortic Valve, Delivery & loading System. Generic:</p> <ul style="list-style-type: none"> • Transcatheter Aortic Valve (Bioprosthesis) • Aortic valve Delivery Catheter • Aortic valve Loading system. <p>MD Group: System Class D</p> <p>Shelf-life of: Hydra Aortic valve: 01 year Hydra Aortic Valve Delivery catether: 02 years Aortic valve loading system: 02 years</p> <p>Storage Conditions: Hydra Aortic valve: 15 – 25°C, do not freeze.</p> <p>Hydra Aortic Valve Delivery Catether (Model: HYDRA 18F) and Hydra Aortic Valve Loading system (Model: HYDRA18VLS-HL) and (Model: HYDRA18VLS-HN)</p>	Approved

			Store at cool, and dry environment.	
775.	<p>M/s Global Biotech Medical Devices (Private) Limited.</p> <p>1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.</p> <p>(ELI-01292)</p> <p>Submission date: 24-10-2024</p> <p>Fee Challan No: 35540778931 PKR 62000/- Dated: 22-10-2024</p>	<p>Legal Manufacturer: Sahajanand Medical Technologies Ireland Ltd.</p> <p>Address: Ground floor, Block 5, Galway Technology Park, Pakmore, Galway H91R9yr, Ireland.</p> <p>Original equipment manufacturer:</p> <p>Name: Sahajanand Medical Technologies Ireland Ltd.</p> <p>Address: Plot # 33,34,35,52,53,54 Surat Special Economic Zone, Sachin, Surat, Gujarat, India.</p> <p>FSC (Ireland) Validity: 12-10-2026</p>	<p>Brand: Supraflex Cruz Sirolimus Eluting Stent.</p> <p>Generic:</p> <ul style="list-style-type: none"> • Sirolimus Eluting Cobalt Chromium Coronary Stent System. <p>Diameter: 3.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50</p> <p>Length: 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48.</p> <p>Class D Shelf-life: 24 months Storage Conditions: 20 – 30°C</p> <p>QMS - FQA Validity: 27-05-2024</p> <p>Design Examination Certificate Validity: EUDAMED verified</p> <p>LOA: 29-08-2026 ISO 13485 certificate validity: 25-04-2025</p>	Approved
776.	<p>M/s Global Biotech Medical Devices (Private) Limited.</p> <p>1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.</p> <p>(ELI-01292)</p> <p>Submission date: 03-12-2024</p> <p>Fee Challan No: 02386055134 PKR 62000/- Dated: 26-11-2024</p>	<p>Legal Manufacturer: Curatia Medical Limited</p> <p>Address: No. 198, Xiangjiang Road, New District Suzhou, China.</p> <p>Sterilization process:</p> <p>Name: Goals sterilization Co. Ltd.</p> <p>Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.</p> <p>FSC (China) Validity: 03-07-2026</p> <p>CFG USA Dated 14-12-2018.</p>	<p>Brand: Xcess Guiding Catheter</p> <p>Generic:</p> <ul style="list-style-type: none"> • Guiding Catheter <p>Model: as per FSC</p> <p>Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place.</p> <p>QMS - FQA Validity: 07-01-2029</p> <p>Design Examination Certificate Validity: 31-12-2027</p> <p>LOA: 04-07-2026 ISO 13485 certificate validity: 31-07-2026</p>	Approved
777.	<p>M/s Global Biotech Medical Devices (Private) Limited.</p>	<p>Legal Manufacturer: Curatia Medical Limited</p>	<p>Brand: URSA Angiographic Catheter</p> <p>Generic:</p> <ul style="list-style-type: none"> • Angiographic Catheter 	Approved

	<p>1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.</p> <p>(ELI-01292)</p> <p>Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/- Dated: 26-11-2024</p>	<p>Address: No. 198, Xiangjiang Road, New District Suzhou, China.</p> <p>Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.</p> <p>FSC (China) Validity: 03-07-2026</p> <p>CFG USA Dated 14-12-2018.</p>	<p>Model: as per FSC</p> <p>Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place.</p> <p>QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027</p> <p>LOA: 04-07-2026 ISO 13485 certificate validity: 31-07-2026</p>	
778.	<p>M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi.</p> <p>(ELI-00006) R&I Dated: 20-02-2024. Fee Challan No. 35528295 PKR: 50,000/-</p>	<p>Legal Manufacturer: Name: M/s. B. Braun Surgical S.A. Carretera. de Terrassa, 121 08191 Rubi (Barcelona), Spain.</p>	<p>Histoacryl</p> <p>Class: D MD group: Family LOA Validity: 20.12.2028 FSC Validity: 20.09.2028 Shelf life: 2 Years</p> <p>Codes: 1050044, 1050052, 1050060, 1050071, 9381104.</p>	Approved
779.	<p>M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006)</p> <p>R&I Dated: 24-06-2024. Fee Challan No.: 0057219566 PKR: 50,000/-</p>	<p>Legal Manufacturer: Name:</p> <p>Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.</p>	<p>Aesculap® NeuroEndoscopy (Forcep Family)</p> <p>Class: D MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A</p> <p>Codes: FF387R, FF388R, FF389R, FH621R, FH622R, FH623R, FH624R, FH629R, FH630R, FH631R, FH632R, FH633R, FH634R, FH637R, FH638R, FH639R, FH604SU, GK362R, GK363R, GK364R, GK365R, GK366R, OK081R, OK082R, OK083R, OK084R, OK090R, OK091R, OK092R, OK093R, OK094R, OK680R, OK681R, OK682R, OK683R, OK684R, FD224R, FD222R, FD824B, FD825B, FD827B, FD826B, FD828B, FD835B, FD836B, FD821B, FD822B, FD823B,</p>	Approved

			<p>FD819B, FD818B, FD812B, FD811B, FD849B, FD848B, FD808B, FD809B, FD805B, FD713B, FD761B, FD711B, FD741B, FD763B, FD743B, FD719B, FD717B, FD718B, FD798B, FD799B, FD797B, FD831B, FD832B, FD833B, FD814B, FD815B, FD816B, FD787B, FD767B, FD788B, FD768B, FD786B, FD766B, FD789B, FD769B, FD839B, FD840B, FD841B, BN175R, FF378R, FH603SU, FF374R, FF590R, FM156R, FM157R, FM158R, OF601R, OK525R, FA034R, FA062R, FA036R, FA035R, FA038R, FA037R, FA045R, FA046R, FA047R, FA060R, FA063R, FA064R, FA065R, FA066R, FA061R, FA042R, FA041R, FA031R, FA030R, FA040R, FA068R, FA032R, FA033R, FA043R, FA044R, FA067R, FA039R, OK505R, OK506R, OK507R, OK508R, OK509R, OK520R, OK521R, OK522R, FD467R, FE491K, FE490K, FT491T, FT490T, FE496K, FE495K, FT496T, FT495T, FM711R, FM712R, FM710R, GK361R, OK608R, OK609R, OK607R, OK606R, OK603R, OK602R, OK105R, OK106R, OK107R, OK108R, FF456B, FF457B, FF458B, FF459B, FM720R, FM721R, FM722R, FA069R, FA070R, FA071R, FA076R, FF345R, FF432R, FF436R, FF437R, FF438R, FF439R.</p>	
780.	<p>M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 24-06-2024. Fee Challan No.: 43498759956 PKR: 50,000/-</p>	<p>Legal Manufacturer Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.</p>	<p>Aesculap® NeuroEndoscopy (Scissor Family) Class: D MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: FF385R, FF386R, FH625R, FH626R, FH627R, FH628R, FH635R, FH636R, FD731B, FD776B,</p>	Approved

			FD706B, FD736B, FD775B, FD705B, FD735B, FD774B, FD704B, FD734B, FD773B, FD703B, FD733B, FD702B, FD772B, FD732B, FD771B, FD701B, FF373R, FA075R, FA073R, FA074R, FA072R, FD226R, FM701R, FM702R, FM700R, FM681R, FM682R, FM680R, FM691R, FM692R, FM690R, FM671R, FM672R, FM670R, FD220R, OK561R, OK562R, OK560R, FD228R, FF432R, FF433R, FF435R.	
781.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 24-06-2024. Fee Challan No.: 56720788990 PKR: 50,000/-	Legal Manufacturer: Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® NeuroEndoscopy (Scope Family) Class: D MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: PE204A, PE486A, PE487A, PE507A, PE506A, PF011A, PF010A, PE184A.	Approved
782.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 24-06-2024. Fee Challan No.: 73885682158 PKR: 50,000/-	Legal Manufacturer: Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® NeuroEndoscopy (Trocar Family) Class: D MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: FF397R, FF398R, FF399R, FF357R, FF358R, FF359R, FH358R, FH359R, FH620R.	Approved
783.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 24-06-2024. Fee Challan No.: 26820773	Legal Manufacturer: Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® NeuroEndoscopy (Bipolar Forcep Family) Class: D MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: GK800R, GK822R, GK823R, GK824R, GK825R, GK826R,	Approved

	PKR: 50,000/-		GK827R, GK828R, GK829R, GK343R, GK344R, GK345R, GK360R, GK777R, GK780R, GK781R, GK785R.	
784.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 14-06-2024. Fee Challan No.: 5173227551 PKR: 50,000/-	Legal Manufacturer Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® AdTec® bipolar (Forceps Family) Class: C MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: PM401R, PM402R, PM403R, PM405R, PM406R, PM408R, PM410R, PM412R, PM413R, PM415R, PM431R, PM432R, PM433R, PM435R, PM436R, PM438R, PM440R, PM442R, PM443R, PM445R, GN130, GN131, GN132, GN133, GN134, GN145, GN146, GN088, PM450R, PM970R, PM973R, PM981R.	Approved
785.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006) R&I Dated: 14-06-2024. Fee Challan No.: 24601923030 PKR: 50,000/-	Legal Manufacturer Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® AdTec® Mini (Forceps Family) Class: C MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A Codes: PO302R, PO303R, PO304R, PO305R, PO306R, PO307R, PO308R, PO309R, PO322R, PO323R, PO324R, PO325R, PO326R, PO327R, PO328R, PO329R, PO342R, PO343R, PO344R, PO345R, PO346R, PO347R, PO348R, PO349R, PO362R, PO363R, PO364R, PO365R, PO380R, PO381R, PO366R, PO367R, PO368R, PO369R.	Approved
786.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006)	Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	AESCULAP® AdTec® MONOPOLAR (Diathermy Electrode with Accessories) Class: C MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A	Approved

	<p>R&I Dated: 14-06-2024. Fee Challan No.: 13982798593 PKR: 50,000/-</p>		<p>Codes: GK383R, GK384R, GK385R, GK386R, GK389R, GK390R, GK393R, GK394R, GK395R, GK372R, GK373R, GK374R, GK217, GK239, GK245, GK246, GN202, GK375R, GK397R, GK398R, GN230, GK376P, GK370P, GK371P.</p>	
787.	<p>M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi. (ELI-00006)</p> <p>R&I Dated: 14-06-2024. Fee Challan No.: 49163092 PKR: 50,000/-</p>	<p>Legal Manufacturer Name: Legal Manufacturer M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.</p> <p>Class: C MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 Shelf life: N/A</p>	<p>AESULAP® AdTec® MONOPOLAR (Forceps Family) Codes: PO100R, PO101R, PO102R, PO103R, PO104R, PO105R, PO107R, PO109R, PO111R, PO112R, PO113R, PO114R, PO117R, PO118R, PO127R, PO128R, PO129R, PO130R, PO132R, PO134R, PO137R, PO141R, PO147R, PO149R, PO151R, PO152R, PO182R, PO183R, PO185R, PO186R, PO187R, PO188R, PO189R, PO190R, PO191R, PO194R, PO195R, PO196R, PO197R, PO199R, PO200R, PO201R, PO202R, PO203R, PO204R, PO205R, PO206R, PO207R, PO208R, PO209R, PO210R, PO211R, PO212R, PO213R, PO214R, PO215R, PO216R, PO217R, PO218R, PO219R, PO220R, PO221R, PO222R, PO223R, PO224R, PO225R, PO228R, PO229R, PO230R, PO231R, PO232R, PO233R, PO234R, PO235R, PO236R, PO237R, PO238R, PO500R, PO501R, PO502R, PO505R, PO509R, PO510R, PO511R, PO512R, PO550R, PO559R, PM171R, PM173R, PM175R, PM176R, PM177R, PM178R, PM609R, PM612R, PM614R, PM616R, PM618R, PM621R, PM635R, PM640R, PM643R, PM647R, PM649R, PM651R, PM653R, PM654R, PM657R, PM658R, PM670R, PM671R, PM679R, PM681R, PM687R, PM688R, PM689R, PM690R, PM693R, PM696R, PM699R, PM700R, PM701R, PM711R, PM712R, PM713R, PM719R, PO605R, PO606R, PO607R, PO608R, PO610R, PO611R, PO613R, PO615R, PO617R,</p>	Approved

			PO618R, PO619R, PO620R, PO623R, PO624R, PO626R, PO627R, PO628R, PO632R, PO633R, PO634R, PO638R, PO641R, PO642R, PO644R, PO645R, PO646R, PO647R, PO648R, PO650R, PO652R, PO657R, PO661R, PO667R, PO668R, PO669R, PO678R, PO680R, PO684R, PO705R, PO717R, PO718R, PO726R, PO728R, PO729R, PO730R, PO731R, PO734R, PO735R, PO736R, PO739R, PO740R, PO741R, PO742R, PO747R, PO748R, PO749R, PO750R, PO751R, PO752R, PO753R, PO755R, PO756R, PO757R, PO758R, PO759R, PO761R, PO762R, PO763R, PO764R, PO765R, PO766R, PO767R, PO768R, PO769R, PO770R, PO771R, PO772R, PO773R, PO774R, PO775R, PO776R, PO777R, PO778R, PO781R, PO782R, PO783R, PO958R, PO959R, PM940R, PM953R, PM954R, PM957R, PM970R, PM971R, PM973R, PM974R, PM975R, PM976R, PM977R, PM978R, PM981R, PM982R, PM983P, PM986P, PM987P, PM992R, PO784R, PO785R, PO786R, PO787R, PO788R, PO789R.	
788.	<p>M/s Meher Enterprises. 1st floor Az-Zainab Court, Campbell Street, Karachi.</p> <p>(ELI - 00241)</p> <p>Date of R& I 08.06.2023</p> <p>Fee Challan No. 323385543330 PKR 5000/- Dated: 21-11-2022</p>	<p>(LEGAL MANUFACTURER) Name: Zhongshan HANQI MEDICAL Equipment Technology Co. Ltd. Address: No. 08-101 South 1st Street, Lianfeng Xingfu 2nd Road Xiaolan Town, Zhingshan, Guangdong Province, China</p>	<p>Walker – walking Aid</p> <p>Model: HQ213L, HQ213L-5", HQ213L-S, HQ215L, HQ223L, HQ261L, HQ262L, HQ263L-S, HQ263L-L, HQ265L, HQ265L-5, HQ266L, HQ266L-S-3", HQ266L-L, HQ2821</p> <p>Class-A FSC (China): Validity Date: 21-02-2024 LOA Validity: 14-01-2027 ISO Validity: 02-11-2024</p>	Approved.
789.	<p>M/s Meher Enterprises. 1st floor Az-Zainab Court, Campbell Street, Karachi.</p>	<p>(LEGAL MANUFACTURER) Name: Zhongshan HANQI MEDICAL Equipment Technology Co. Ltd.</p>	<p>Manual Hospital Bed</p> <p>Model: HQ-S101ABL, HQ-ETO1, HQ-S201ABL, HQ-S201AZL, HQ-S301AZ.</p>	Approved.

	<p>(ELI - 00241)</p> <p>Date of R& I 08.06.2023 PKR 5000/- Dated: 21-11-2022</p>	<p>Address: No. 08-101 South 1st Street, Lianfeng Xingfu 2nd Road Xiaolan Town, Zhingshan, Guangdong Province, China</p>	<p>Class-A FSC (China): Validity Date: 21-02-2024 LOA Validity: 14-01-2027 ISO Validity: 02-11-2024</p>	
790.	<p>M/s Meher Enterprises. 1st floor Az-Zainab Court, Campbell Street, Karachi.</p> <p>(ELI - 00241)</p> <p>Date of R& I 08.06.2023 PKR 5000/- Dated: 21-11-2022</p>	<p>(LEGAL MANUFACTURER) Name: Zhongshan HANQI MEDICAL Equipment Technology Co. Ltd. Address: No. 08-101 South 1st Street, Lianfeng Xingfu 2nd Road Xiaolan Town, Zhingshan, Guangdong Province, China</p>	<p>Medical Walking stick / Crutch / Cane</p> <p>Model: HQ311L, HQ320L, HQ327L, HQ329L, HQ330L, HQ338L, HQ339L, HQ349L, HQ336L, HQ323L, HQ332L, HQ333L, HQ337L, HQ325L-S, HQ325L-M, HQ325L-L, HQ326, HQ 322L, HQ324L, HQ334L</p> <p>Class-A FSC (China): Validity Date: 21-02-2024 LOA Validity: 14-01-2027 ISO Validity: 02-11-2024</p>	Approved.
791.	<p>M/s Meher Enterprises. 1st floor Az-Zainab Court, Campbell Street, Karachi.</p> <p>(ELI - 00241)</p> <p>Date of R& I 08.06.2023 PKR 5000/- Dated: 21-11-2022</p>	<p>(LEGAL MANUFACTURER) Name: Zhongshan HANQI MEDICAL Equipment Technology Co. Ltd. Address: No. 08-101 South 1st Street, Lianfeng Xingfu 2nd Road Xiaolan Town, Zhingshan, Guangdong Province, China</p>	<p>Manual Wheelchair</p> <p>Model: Q863L, HQ958L, HQ863L-12, IHQ905L, 11Q007L, HQ908L, HQ801L, HQ903L, HQ868L, HQ976L, HQ972, HQ951, HQ809, HQ608, HQ609, HQ603GC, HQ903, HQ609GC.</p> <p>Class-A FSC (China): Validity Date: 16-09-2024 LOA Validity: 14-01-2027 ISO Validity: 02-11-2024</p>	Approved.
792.	<p>M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi Pakistan. 75290 ELI- 00520 Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 443414335343, dated 28.05.2022</p>	<p>M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County, Shijiazhuang, Hebei, China</p>	<p>ORTHOTIC JOINTS BARS SYSTEM (Artificial body parts Prosthetic & Orthotic)</p> <p>Model: mentioned below Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027</p>	Approved
Model				

OR = 13 - SS
OR= 17 - SS
OR= 19 - SS
OR= 13- AL
OR= 17 – SS
OR = 19 - AL
OIR=13
OS= 17 - SS
OS= 19 - SS
OS = 17AL
OS=19-AL
OLS-19-SS
OLS=20-AL
OLR-19

793.	M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi Pakistan. 75290 ELI- 00520 Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 003898109, dated 28.05.2022	M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County, Shijiazhuang, Hebei, China	PROSTHETIC ADAPTER FAMILY (Artificial body parts Prosthetic &Orthotic) Model: as per FSC Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027	Approved
794.	M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi Pakistan. 75290 ELI- 00520 Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 7503929857 , dated 28.05.2022	M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County, Shijiazhuang, Hebei, China	PROSTHETIC FEET FAMILY (Artificial body parts Prosthetic &Orthotic) Model: as per FSC Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027	Approved
795.	M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi Pakistan. 75290 ELI- 00520 Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 2767661551 , dated 28.05.2022	M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County, Shijiazhuang, Hebei, China	PROSTHETIC FOAM COVERS ETC (Artificial body parts Prosthetic &Orthotic) Model: as per FSC Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027	Approved
796.	M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi	M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County,	PROSTHETIC HANDS & COSMATIC GLOVES (Artificial body parts Prosthetic &Orthotic)	Approved

	<p>Pakistan. 75290 ELI- 00520</p> <p>Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 735669685645, dated 28.05.2022</p>	Shijiazhuang, Hebei, China	<p>Model: as per FSC Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027</p>	
797.	<p>M/s A.H. SONS E-10 Naveed Bungalows, 17 Gulistan-e Jauhar 75290 Karachi Pakistan. 75290 ELI- 00520</p> <p>Diary No.13017 Date of R& I 28-05- 2022 Fee Rs. 5,030/ through slip no. 6315020440,dated 28.05.2022</p>	M/s Hebei Baisite Prosthetic Orthotic Technology Co, Ltd. East of Xibaitang Village, Zhengding County, Shijiazhuang, Hebei, China	<p>PROSTHETIC HANDS & COSMATIC GLOVES (Artificial body parts Prosthetic &Orthotic</p> <p>Model: as per FSC Class-A MD Group: Family FSC (China): Validity Date: 09-11-2025 LOA Validity: 07-09-2025 ISO Validity: 03-06-2027</p>	Approved
798.	<p>Name Sohail Corporation Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 17 April 2024 Fee Challan Rs.5,000/ through slip no. 485453205366, dated 05/04/2024</p>	<p>Legal Manufacturer: Name: M/s: Jiangsu Sunclean Medical Co., Ltd</p> <p>Manufacturer Address: Manufacturing Site: located at: No.11 Fenghuang South Road, Hutang Town, Wujin District 213162 Changzhou City, Jiangsu Province, China</p> <p>EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 17-12-2025</p>	<p>Metro Alcohol Swab</p> <p>Class: A Specifications: 30*30mm;30*35mm; 30*55mm;30*65mm; 30*70mm;40*80mm; 40*40mm; Model 30*30mm;30*35mm; 30*55mm;30*65mm; 30*70mm;40*80mm; 40*40mm;</p> <p>LOA Validity: 12-08-2028</p> <p>FSC Validity (country of origin): 21-11-2027</p> <p>Shelf life: 5 Years Storage condition: Ambient Temperature</p>	Approved
799.	<p>Name Sohail Corporation Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p>	<p>Legal Manufacturer: Name: M/s TOP GLOVE SDN BHD</p> <p>Manufacturer Address: Manufacturing Site: located at Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E.,</p>	<p>Metro Disposable Latex Examination Powdered Gloves</p> <p>Sizes: S,M,L,XL Class: A LOA Validity: 28-11-2028</p>	bonree

	<p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 27-May-2024</p> <p>Fee Rs. 5,000/ through slip no.1311785349, dated 13-03-2024</p>	Malaysia.	<p>FSC Validity (<i>country of origin</i>): 30-05-2027</p> <p>EC Certificate validity: 03-01-2028</p> <p>ISO 13485 Certificate validity: 30-04-2026</p> <p>Shelf life: 5 Years</p> <p>Storage condition: Ambient Temperature</p>	
800.	<p>Name Sohail Corporation Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 24 Nov-2023</p> <p>Fee Rs. 25,000/ through slip no. 66048892371, dated 25/10/2023</p>	<p>Legal Manufacturer: Name: M/s: Bonree Medical Co., Ltd.</p> <p>Manufacturer Address: Manufacturing Site: located at: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, PEOPLE' REPUBLIC OF CHINA.</p> <p>EC Certificate validity: 26-05-2024</p> <p>ISO 13485 Certificate validity: 31-07-2025</p>	<p>Metro Nebulizer Mask</p> <p>Class: B</p> <p>Models: 6ml: Adult standard, Pediatric Standard, Adult Elongated, Pediatric Elongated 8ml: Adult standard, Pediatric Standard, Adult Elongated, Pediatric Elongated</p> <p>LOA Validity: 22-09-2026</p> <p>FSC Validity (<i>country of origin</i>): 09-05-2023</p> <p>Shelf life: 5 years</p> <p>Storage condition: Ambient Temperature</p>	Approved. Registration letter shall be issued after provision of valid free sale certificate.
801.	<p>Name Sohail Corporation Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 23-Dec-2022</p> <p>Fee Rs. 25,000/ through slip no. 27567864, dated 20.12.2022</p>	<p>Legal Manufacturer: Name: M/s: Beijing Jinhua Biological Technology CO., Ltd.</p> <p>Manufacturer Address: Manufacturing Site: Room 402, Building 3, No. 2 Xingye Street, Beijing Economic Technological Development Area, 100176, Beijing, P. R. China.</p>	<p>Metro (One Step hCG Rapid Pregnancy Test Strip)</p> <p>Class: B</p> <p>LOA Validity: 08-07-2027</p> <p>FSC Validity (<i>country of origin</i>): 19-04-2024</p> <p>EC Certificate validity: 23-14-2024</p> <p>ISO 13485 Certificate validity: 23-04-2024</p> <p>Shelf life: 5 Years</p> <p>Storage condition: Ambient Temperature</p>	Approved. Registration letter shall be issued after provision of valid free sale certificate.
802.	<p>Name Sohail Corporation Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p>	<p>Legal Manufacturer: Name: M/s: Suzhou Health Plastic Products Co ltd.</p> <p>Manufacturer Address: Manufacturing Site: located at: No.699, Ping'an Road,</p>	<p>Metro Disposable Heparin Cap</p> <p>Model; Yellow, Dyososma</p> <p>Class: B</p> <p>LOA Validity: 28-03-2028</p>	Approved

	<p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 24-November-2023</p> <p>Fee Rs. 25,000/ through slip no. 19172765, dated 25/10/2023</p>	<p>Linhu Town Wuzhong District, 215105 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA.</p>	<p>FSC Validity (country of origin): 21-04-2025</p> <p>EC Certificate validity: 26-05-2024</p> <p>ISO 13485 Certificate validity: 29-08-2025</p> <p>Shelf life: 5 years</p> <p>Storage condition: Ambient Temperature</p>	
803.	<p>Name Sohail Corporation</p> <p>Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 23- Dec-2024</p> <p>Fee Challan Rs. 31,030/- through slip no: 1959970258 dated December 11th, 2024</p>	<p>Legal Manufacturer: Name: M/s: Bonree Medical Co., Ltd.</p> <p>Manufacturer Address: Manufacturing Site: located at: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, PEOPLE' REPUBLIC OF CHINA.</p>	<p>Metro Oxygen Mask</p> <p>Models: Adult standard, Pediatric Standard, Adult Elongated, Pediatric Elongated</p> <p>Class: B</p> <p>LOA Validity: 23-09-2026</p> <p>FSC Validity (country of origin): 09-05-2023</p> <p>EC Certificate validity: 26-05-2024</p> <p>ISO 13485 Certificate validity: 31-07-2025</p> <p>Shelf life: 5 years</p> <p>Storage condition: Ambient Temperature</p>	<p>Approved. Registration letter shall be issued after provision of valid free sale certificate.</p>
804.	<p>Name Sohail Corporation</p> <p>Address of Importer Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 05- Dec-2024</p> <p>Fee Challan Rs. 31000/- through slip no: 07440658898 dated 25/11/2024</p>	<p>Legal Manufacturer: Name: M/s: Jiangxi Fenglin Medical Appliances Co., Ltd</p> <p>Manufacturer Address: Fulin Road, Fuzhou City, Jiangxi Province, 344100, China.</p> <p>EC Certificate validity: 27-05-2024 (Updated CE Confirmation Letter is submitted)</p> <p>ISO 13485 Certificate validity: 12-11-2026</p> <p>LOA Validity: 08-04-2029</p> <p>FSC Validity (country of origin): 29-05-2025</p>	<p>Metro Sterile Disposable Iv Cannula for Single Use</p> <p>Class: B</p> <p>Models: IV-Y161. IV-Y16II, IV-YIBI, IV-Y1811. IV-Y201, IV-Y2011. IV-Y221. IV-Y22II. IV-Y241、 IV-Y24II, IV-Y261、 IV-Y261:IV-A16、 IV-816、 IV-C16、 IV-D16. IV-A18. IV-B18, IV-C18. IV-DIS. IV-A20, IV-820. IV-CID. IV-D29. IV-A22. IV-822. IV-C22. IV-D22、 IV-A24, IV-824, IV-C24. IV-D24, IV-A26.TV-B26、 TV-C26, TV-1026.</p> <p>Shelf life: 5 years</p> <p>Storage condition: Ambient Temperature</p>	<p>Approved. .</p>
805.	<p>Name Sohail Corporation</p> <p>Address of Importer</p>	<p>Legal Manufacturer: Name: M/s: Hubei Yin shun</p>	<p>Metro Disposable Face Mask</p> <p>Model; 17.5x9.5</p> <p>Class: A</p>	<p>Approved</p>

	<p>Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan.</p> <p>(ELI-00676) D.O.I: 07-05-2021</p> <p>Date of R& I 23- Dec-2024</p> <p>Fee Challan Rs.30000/- through slip no: 532273718189 dated 11/12/2024</p>	<p>Protective Equipment Co., Ltd.</p> <p>Manufacturer Address: Room 7-15-401, Modern Sino-Canada Science and Technology City, Liukou Industrial Park, Xiantao City, Hubei Province, China.</p>	<p>LOA Validity: 24-05-2029</p> <p>FSC Validity (<i>country of origin</i>): 17-10-2026</p> <p>EC Certificate validity: 07-10-2025</p> <p>ISO 13485 Certificate validity: 07-10-2025</p> <p>Shelf life: Storage condition: Ambient Temperature</p>	
806.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi.</p> <p>(ELI-00832) D.O.I: 13-12-2021</p> <p>Dy. No.: 9152 DRAP (R&I) Dated: 08-10-2024</p> <p>Fee Challan No.: 3751304206 PKR: 6,000/- Dated: 21-09-2024</p>	<p>Legal Manufacturer: Name: Yangzhou SuXiang Medical Instrument Co., Ltd.</p> <p>Manufacturer Address: West side of Baoyuan Road, Industrial Concentration Zone, Anyi Town, Baoying County, Yangzhou City, Jiangsu Province, China.</p>	<p>Pacco Alcohol Pad</p> <p>Class: A</p> <p>MD group: Rule 1</p> <p>LOA Validity: 21-08-2028</p> <p>FSC Validity (<i>country of origin</i>): 28-08-2025</p> <p>EC Certificate validity: 25-02-2027</p> <p>ISO 13485 Certificate validity: valid</p> <p>Shelf life: 5 Years</p> <p>Storage condition: In cool well ventilated area.</p>	Approved
807.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi.</p> <p>(ELI-00832) D.O.I: 13-12-2021</p> <p>Dy. No.: 9152 DRAP (R&I) Dated: 08-10-2024</p> <p>Fee Challan No.: 9314768270</p> <p>PKR:31,000 /- Dated: 21-09-2024</p>	<p>Legal Manufacturer: Name: Jiangsu Rongye Technology Co. Ltd.</p> <p>Manufacturer Address: Touqiao Town, Yangzhou City, Jiangsu Province, China.</p>	<p>Pacco Nelaton Catheter</p> <p>Class:B</p> <p>MD group:</p> <p>LOA Validity: 26-07-2028</p> <p>FSC Validity (<i>country of origin</i>): 18-11-2024</p> <p>EC Certificate validity: 26-05-2024</p> <p>ISO 13485 Certificate validity: 13-07-2024</p> <p>Shelf life: 5 years</p> <p>Storage condition: In cool well ventilated area.</p>	Approved. Registration letter shall be issued after provision of valid EC and free sale certificate.
808.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi.</p>	<p>Legal Manufacturer: Name: Jiangsu Rongye Technology Co. Ltd.</p> <p>Manufacturer Address: Touqiao Town, Yangzhou</p>	<p>Pacco Urinary Drainage Bag</p> <p>Class: B</p> <p>MD group:</p> <p>LOA Validity: 26-07-2028</p> <p>FSC Validity</p>	Approved.

	<p>(ELI-00832) D.O.I: 13-12-2021 Dy. No.: 9152 DRAP (R&I) Dated: 08-10-2024 Fee Challan No.: 85321474965</p> <p>PKR:31,000/- Dated: 21-09-2024</p>	<p>City, Jiangsu Province, China.</p>	<p><i>(country of origin):</i> 18-11-2024 EU Certificate validity: 27-09-2027 ISO 13485 Certificate validity: 13-07-2024 Shelf life: 5 years Storage condition: In cool well ventilated area.</p>	
809.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: 9152 DRAP (R&I) Dated: 08-10-2024 Fee Challan No.: 63239711859 PKR:6,000/- Dated: 21-09-2024</p>	<p>Legal Manufacturer: Name: Zhejiang Huikang Medicinal Articles Co., Ltd.</p> <p>Manufacturer Address: No.8 Hetian Road, Shangxi Town, Yiwu City, Zhejiang Province, China.</p>	<p>Pacco Non Woven Dressing Roll</p> <p>Class: A MD group: LOA Validity: 29-11-2028 FSC Validity <i>(country of origin):</i> 02-09-2024 EC Certificate validity: 24-05-2024 ISO 13485 Certificate validity: 08-09-2025 Shelf life: 3 years Storage condition: Should be stored in a clean room with a temperature of 0°c to 30°c</p>	<p>Approved. Registration letter shall be issued after provision of valid free sale certificate.</p>
810.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: 9152 DRAP (R&I) Dated: 08-10-2024 Fee Challan No.: 780143943253 PKR:31,000/- Dated: 21-09-2024</p>	<p>Legal Manufacturer: Name: Ningbo Luke Medical Devices Co., Ltd.</p> <p>Manufacturer Address: No.178 Gujiayan, Qishan Village, Yangming Street, Yuyao City, China.</p>	<p>Pacco Plus Nebulizer Mask</p> <p>Class: B MD group: LOA Validity: 16-11-2026 FSC Validity <i>(country of origin):</i> 19-02-2025 EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 03-01-2026 Shelf life: 5 years Storage condition: Store in a dry, ventilated, non- corrosive gas environment, away from ignition sources and inflammables.</p>	<p>Approved. Registration letter shall be issued after provision of valid EC and free sale certificate.</p>
811.	<p>M/s QASIM TRADERS</p> <p>Office No. Shop No.7</p>	<p>Legal Manufacturer: Name: Nantong Diagnos Biotechnology</p>	<p>PACCO - HCG Pregnancy Test Strip</p> <p>Class: B</p>	<p>Approved. Registration letter shall be issued after provision of</p>

	<p>Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: 9152 DRAP (R&I) Dated: Fee Challan No.: 14200893953 PKR: 25,000/- Dated: 13-08-2023</p>	<p>Co., Ltd. Manufacturer Address: 2nd floor, building 6 Electronic information industrial park No 2 Haiyang South Road, Chengnan Street 226500 Rugao City, Jiangsu City, People's Republic of China</p>	<p>MD group: LOA Validity: 26-07-2028 FSC Validity <i>(country of origin):</i> 11-11-2024 EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 09-09-2025 Shelf life: 5 years Storage condition: Store in a dry, ventilated, non- corrosive gas environment, away from ignition sources and inflammables.</p>	<p>valid EC and free sale certificate.</p>
812.	<p>M/s QASIM TRADERS Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: Dated: Fee Challan No.: 30901598 PKR:6,000 /- Dated: 21-10-2024</p>	<p>Legal Manufacturer: Name: TG Medical SDN BHD Manufacturer Address: Lot No. 5091, Jalan Teratai, Batu 5 Off Jalan Meru 41050 Klang, Selangor D.E, Malaysia.</p>	<p>PACCO – EXAMINATION GLOVES Class: A MD group: LOA Validity: 16-05-2029 FSC Validity <i>(country of origin):</i> 16-05-2029 EC Certificate validity: 31-12-2028 ISO 13485 Certificate validity: 06-08-2024 Shelf life: 5 years Storage condition: The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight</p>	<p>Approved. .</p>
813.	<p>M/s QASIM TRADERS Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: Dated: Fee Challan No.: 51736308219 PKR:31,000/- Dated: 21-10-2024</p>	<p>Legal Manufacturer: Name: TG Medical SDN BHD Manufacturer Address: Lot No. 5091, Jalan Teratai, Batu 5 Off Jalan Meru 41050 Klang, Selangor D.E, Malaysia.</p>	<p>PACCO – SURGICAL GLOVES Class: B MD group: LOA Validity: 16-05-2029 FSC Validity <i>(country of origin):</i> 16-05-2029 EC Certificate validity: 31-12-2028 ISO 13485 Certificate validity: 06-08-2024 Shelf life: 5 years Storage condition:</p>	<p>Approved.</p>

			The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight	
814.	M/s QASIM TRADERS Office No. Shop No.7 Medicine Center Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00832) D.O.I: 13-12-2021 Dy. No.: Dated: Fee Challan No.: 8709143728 PKR: 31,000/- Dated: 23-12-2024	Legal Manufacturer: Name: Jiangsu Zhiyu Medical Instrument Co., Ltd. Manufacturer Address: No.88, Nan Yuan Road, Industrial Park, West Taixing, 254000, Jiangsu Province, P.R.China.	PACCO PLUS Sterile Infusion Set for Single Use (with Needles) Class: B MD group: LOA Validity: 30-05-2029 FSC Validity <i>(country of origin):</i> 19-03-2025 EC Certificate validity: 31-12-2028 ISO 13485 Certificate validity: 22-09-2027 Shelf life: 3 years Storage condition: Store at room temperature	Approved.
815.	M/s Altimi Biosciences (Private) Limited House of Altimi, Suite No. 201, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-00575) D.O.I: 13-12-2021 Dy. No.: 2123 Dated: Fee Challan No.: 4303770319 PKR: 210000/- Dated: 31-10-2024	Legal Manufacturer: Name: Randox Laboratories Limited. Manufacturer Address: 55Diamond Road, Crumlin Co. Antrim, Northern Ireland, United Kingdom.	RX MODENA REAGENTS Class: B MD group: Cluster LOA Validity: 25-11-2029 FSC (country of origin- UK): Validity: 26-05-2026 EC Certificate validity: 26-05-2025 ISO 13485 Certificate validity: 05-11-2025	Approved
816.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2129 Dated: 28-01-2025 Fee Challan No.: 928378456122 PKR: 31000/- Dated: 07-01-2025	Legal Manufacturer: Name: Terang Nusa (Malaysia) Sdn.Bhd Manufacturer Address: 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan, Malaysia.	Nuzone X2 – Sterile Polychloroprene Surgical Powder Free Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-2-2026 FSC (country of origin): Validity: not provided EC Certificate validity: 26-05-2025 ISO 13485 Certificate validity: 31-10-2027	Approved

			DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a cool and dry place.	
817.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2124 Dated: 28-01-2025 Fee Challan No.: 03448234608 PKR: 31000/- Dated: 07-01-2025	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Sterile Latex Surgical Powdered Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a dry condition.	Approved
818.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2125 Dated: 28-01-2025 Fee Challan No.: 03448234608 PKR: 31000/- Dated: 07-01-2025	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Sterile Latex Surgical Powder Free Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a dry condition.	Approved
819.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2126 Dated: 28-01-2025 Fee Challan No.: 5895271454 PKR: 6000/-	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Latex examination polymer Powder Free Gloves. Sizes: XS, S, M, L, XL Class: A MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024	Approved

	Dated: 07-01-2025		Shelf life: 05 years Storage conditions: Store in a dry condition.	
820.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2135 Dated: 28-01-2025 Fee Challan No.: 649247714573 PKR: 6000/- Dated: 07-01-2025	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Latex examination Powdered Gloves. Sizes: XS, S, M, L, XL Class: A MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a dry condition.	Approved
821.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2128 Dated: 28-01-2025 Fee Challan No.: 2994080301 PKR: 6000/- Dated: 07-01-2025	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Latex examination Powder Free Gloves. Sizes: XS, S, M, L, XL Class: A MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a dry condition.	Approved
822.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2127 Dated: 28-01-2025 Fee Challan No.: 28441599 PKR: 6000/- Dated: 07-01-2025	Legal Manufacturer Name: TG Medical Sdn. Bhd. Manufacturer Address: Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E, Malaysia.	Nitrile examination Powder Free Gloves. Sizes: XS, S, M, L, XL Class: A MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a dry condition.	Approved
823.	M/s Rosaceae (Private) Limited. House of Altimi, Suite	Legal Manufacturer Name: Terang Nusa (Malaysia)	Sterile Polyisoprene Surgical Powder Free Gloves (blend).	Approved

	<p>No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2130 Dated: 28-01-2025 Fee Challan No.: 0816985392 PKR: 6000/- Dated: 07-01-2025</p>	<p>Sdn.Bhd Manufacturer Address: 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan, Malaysia.</p>	<p>Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: 26-05-2025 ISO 13485 Certificate validity: 31-10-2027 DOC (Germany): Dated: 09-12-2024 Shelf life: 05 years Storage conditions: Store in a cool and dry place. Open box should be shielded from exposure to direct sun or fluorescent lighting.</p>	
824.	<p>M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2131 Dated: 28-01-2025 Fee Challan No.: 8503008125 PKR: 31000/- Dated: 07-01-2025</p>	<p>Legal Manufacturer Name: Terang Nusa (Malaysia) Sdn.Bhd Manufacturer Address: 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan, Malaysia.</p>	<p>Fusion Evolution – Sterile Polyisoprene Surgical powder free Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: 26-05-2025 ISO 13485 Certificate validity: 31-10-2027 DOC (Germany): Dated: 09-12-2024 Shelf life: 03 years Storage conditions: Store in a cool and dry place. Open box should be shielded from exposure to direct sun or fluorescent lighting.</p>	Approved
825.	<p>M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2132 Dated: 28-01-2025 Fee Challan No.: 8616113308</p>	<p>Legal Manufacturer Name: Sentiex Sdn. Bhd. Manufacturer Address: Lot 7, Jalan Hi-Tech 12, Zon Industrial Fasa 3, 09090 Kulim Hi-Tech Park, Kedah D.A Malaysia.</p>	<p>Finessis Corium – Sterile Flexylon Surgical powder free Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity:</p>	Approved

	PKR: 31000/- Dated: 07-01-2025		ISO 13485 Certificate validity: 10-06-2027 DOC (Germany): Dated: 09-12-2024 Shelf life: 03 years Storage conditions: Store in a cool and dry place. Open box should be shielded from exposure to direct sun or fluorescent lighting.	
826.	M/s Rosaceae (Private) Limited. House of Altimi, Suite No. 301, Plot # 21-C, Khalid Commercial Street No. 04, Phase VII (EXT) DHA Karachi. (ELI-01280) Dy. No.: 2133 Dated: 28-01-2025 Fee Challan No.: 687006840106 PKR: 62000/- Dated: 07-01-2025	Legal Manufacturer Name: Sentiex Sdn. Bhd. Manufacturer Address: Lot 7, Jalan Hi-Tech 12, Zon Industrial Fasa 3, 09090 Kulim Hi-Tech Park, Kedah D.A Malaysia.	Finessis aEGIS – Sterile Flexylon Surgical powder free Gloves. Sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: C MD group: Single LOA Validity: 20-12-2026 FSC (country of origin): Validity: not provided EC Certificate validity: ISO 13485 Certificate validity: 10-06-2027 DOC (Germany): Dated: 09-12-2024 Shelf life: 03 years Storage conditions: Store in a cool and dry place. Open box should be shielded from exposure to direct sun or fluorescent lighting.	Approved
827.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) D.O.I: 06-02-2020 DRAP (R&I) date 09-05-2024 Fee Challan No.: 485612059500 PKR: 50000/- Dated: 19-04-2024	Legal Manufacturer Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (natural rubber latex male condom) OK Delay 4's OK Delay 3's Class: C MD group: family LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026 Shelf life: 5 years Storage condition: 28°C to 35°C	Approved
828.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext.	Legal Manufacturer Name: M/s Thai Nippon Rubber Industry public company limited,	Josh Family 3 Josh Lahori Tikka 4's Josh Menthol 3's Josh Menthol 4's Josh Sindhri 4's	Deferred for the opinion of Council of Islamic Ideology Pakistan

	<p>Karachi Pakistan.</p> <p>(ELI-00515) D.O.I: 06-02-2020</p> <p>Fee Challan No.: 199587339 PKR: 50000/- Dated: 21-12-2022</p>	<p>Address: Headquarter: I Charoenrat Road, Thungwatdon,Sathon, Bangkok 10120, Thailand Factory: 789/139, Moo I, Pinthong Industrial Estate, Nongkham, Sriracha, Choburi 20110, Thailand.</p>	<p>Josh Strawberry 3's Josh Strawberry 4's</p> <p>Class: C MD group: family LOA Validity: 04-10-2028 FSC Validity (17-07-2026) Thailand EU Quality Management Certificate validity:30-05-2027 ISO 13485 Certificate validity: 07-02-2026 Shelf life: 5 years Storage condition: 28°C to 35°C</p>	
829.	<p>DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan.</p> <p>(ELI-00515) D.O.I: 06-02-2020</p> <p>DRAP (R&I) date 13-06-2024</p> <p>Fee Challan No.: 237861046725 PKR: 50000/- Dated: 31-05-2024</p>	<p>Legal Manufacturer: Name: Injeflex Industria E Comercio De, Dispositivos, Produtos Medicos LTDA</p> <p>Address: Rua Cipriano Barata 575 - yila Monumento Sao Paulo - Sp,)4205-000, Brazil</p>	<p>Copper Intrauterine Devices Heer ML Cu 375 (IUCD ML Cu 375)</p> <p>Class: D MD group: single LOA Validity: 20-09-2027 FSC Validity (14-04-2028) Brazil. ISO 13485 Certificate validity: 20-11-2025 Shelf life: 7 years Storage condition: 18°C to 30°C</p>	Approved
830.	<p>M/s DKT Pakistan Pvt Ltd. Plot 34-C, Khalid commercial street-1, DHA Phase-7 Extension, Karachi. (ELI-00515) 10579 DRAP R& I: Dated: 02-07-2024 Fee Challan No. 83922446667 PKR 50,000/- Dated: 05-03-2024</p>	<p>(Legal Manufacturer)</p> <p>Name: M/s Pregna International Ltd. Address: Plot 219, Survey No. 168, Dabhel Industrial Co-Operative Soc. Ltd. Dhabel, Daman (U.T), India.</p> <p>Gamma Sterilization: Name: M/s Agrosurg Irradiators, Vasai, India Pvt. Ltd. Address: k-222 Ansa Ind Estate, Mumbai, Maharashtra, India.</p> <p>Name: M/s A.V Processors Pvt. Ltd. Address: E-52, Additional Ambarnath MIDC, Anand Nagar, Ambaranth (E),</p>	<p>Brand name: HEER Device name: CU 375 Sleek - intrauterine device (IUD)</p> <p>MD Group: Single Class: D Shelf life: 05 years Storage Conditions: 18 – 30°C</p> <p>LOA Validity: 01-01-2027 ISO 13485 Validity: 12-12-2027 Issued by DNV Norway FSC Validity: (India) <i>Country of Oirgin –</i> N/A only date of issuance mentioned i.e. 27-12-2023. Validity of EC Certificare issued by DNV Norway:</p>	Approved as Class C Medical Device

		District Thane, Maharashtra, India.	12-12-2027	
831.	<p>DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan.</p> <p>(ELI-00515) D.O.I: 06-02-2020</p> <p>DRAP (R&I) date 10-12-2024</p> <p>Fee Challan No.: 5579369600 PKR: 6000/- Dated: 05-12-2024</p>	<p>Legal Manufacturer: Name: M/s Woman Care Global</p> <p>Address: 1640 Roanoke Blvd. Salem, VA 24153, United States of America.</p>	<p>Double Valve Aspirator, REF: DVS-SU & REF: DVS-S10)</p> <p>Class: A MD group: single LOA Validity: 01-02-2027 FSC Validity (19-05-2026) USA EU Quality management certificate: 17-01-2028 ISO 13485 Certificate validity: 31-08-2026 Shelf life: For DVS-SU: 5 Years For DVS-S10: 3 Years Storage condition: 15°C to 30°C</p>	Approved
832.	<p>DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan.</p> <p>(ELI-00515) D.O.I: 06-02-2020</p> <p>DRAP (R&I) date 10-12-2024</p> <p>Fee Challan No.: 2716666435 PKR: 6000/- Dated: 05-12-2024</p>	<p>Legal Manufacturer: Name: M/s Woman Care Global</p> <p>Address: 1640 Roanoke Blvd. Salem, VA 24153, United States of America.</p>	<p>Single Valve Aspirator, REF: SVS-LF; SVS-S10)</p> <p>Class: A MD group: single LOA Validity: 01-02-2027 FSC Validity (19-05-2026) USA EU Quality management certificate: 17-01-2028 ISO 13485 Certificate validity: 31-08-2026 Shelf life: For SVS-LF: 5 years For SVS-S10: 3 years</p> <p>Storage condition: 15°C to 30°C</p>	Approved
833.	<p>DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan.</p> <p>(ELI-00515) D.O.I: 06-02-2020</p> <p>DRAP (R&I) date 10-12-2024</p> <p>Fee Challan No.: 9065863757</p>	<p>Legal Manufacturer: Name: M/s Woman Care Global</p> <p>Address: 1640 Roanoke Blvd. Salem, VA 24153, United States of America.</p>	<p>Flexible Karman Cannulas (FC4 ; FC5 ; FC6 ; FC7 ; FC8 ; FC9 ; FC10 ; FC12)</p> <p>Class: A MD group: single LOA Validity: 01-02-2027 FSC Validity (19-05-2026) USA EU Quality management certificate: 17-01-2028 ISO 13485 Certificate validity: 31-08-2026 Shelf life: 5 Years</p>	Approved

	PKR: 6000/- Dated: 05-12-2024		Storage condition: 15°C to 30°C	
834.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) D.O.I: 06-02-2020 DRAP (R&I) date 23-12-2020 Fee Challan No.: 2036887 PKR: 5000/- Dated: 22-12-2020	Legal Manufacturer: Name: M/s Woman Care Global Address: 1640 Roanoke Blvd. Salem, VA 24153, United States of America.	Ipas MVA Plus Aspirator Class: A MD group: single LOA Validity: 01-02-2027 FSC Validity (19-05-2026) USA EU Quality management certificate: 17-01-2028 ISO 13485 Certificate validity: 31-08-2026 Shelf life: 5 years Storage condition: 15°C to 30°C	Approved
835.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) D.O.I: 06-02-2020 DRAP (R&I) date 23-12-2020 Fee Challan No.: 2036868 PKR: 5000/- Dated: 22-12-2020	Legal Manufacturer: Name: M/s Woman Care Global Address: 1640 Roanoke Blvd. Salem, VA 24153, United States of America.	Ipas EasyGrip® Cannulas <ul style="list-style-type: none"> • SR4 • SR5 • SR6 • SR7 • SR8 • SR9 • SR10 • SR12 Class: A MD group: single LOA Validity: 01-02-2027 FSC Validity (19-05-2026) USA EU Quality management certificate: 17-01-2028 ISO 13485 Certificate validity: 31-08-2026 Shelf life: 5 years Storage condition: 15°C to 30°C	Approved
836.	M/s DKT Pakistan Pvt Ltd. Plot 34-C, Khalid commercial street-1, DHA Phase-7 Extension, Karachi. (ELI-00515) 13033 DRAP R& I: Dated: 08-08-2024 Fee Challan No. 5216717469 PKR 50,000/-	(Legal Manufacturer) Name: M/s Shandong Ande Healthcare Apparatus Ltd. Address: No. 999 Zunxian Road, New & Hi-Tech Zone, Zibo, Shandong, P.R. China. LOA Validity: 14-08-2026 ISO 13485 Validity: 19-08-2025	Disposable Trocar for Contraceptive Implant Model/specifications: CCZ-X: 1.8, 2.1, 2.4, 2.7, 3.0, 3.4; CCZ-K: 0.4, 0.45, 0.5, 0.55, 0.6, 0.7, 0.8, 0.9, 1.1, 1.2, 1.6, 1.8, 2.1, 2.4, 2.7, 3.0, 3.4; JYZ-Y: 3.0 x 73; JYZ 3.0x 76 MD Group: Single	Approved

	Dated: 27-06-2024	FSC Validity: (China) <i>Country of Origin</i> - 22-09-2026 FQA validity: 19-08-2027	Class: D Shelf life: 05 years Storage Conditions: Packaged product should be stored in a non-corrosive, cool, dry, well ventilated, clean environment.	
837.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) Fee Slip No.: 0666515453 PKR: 62000/-	Legal Manufacturer: Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (Male Latex Condom) OK Dotted 4's OK Dotted 3's Class: C LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026 Shelf life: 05 years Storage condition: 28°C to 35°C	Approved
838.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) Fee Slip No.: 1107977967 PKR: 62000/-	Legal Manufacturer: Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (Male Latex Condom) OK Gold Extra 4's OK Gold Extra 3's Class: C LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026 Shelf life: 05 years Storage condition: 28°C to 35°C	Approved
839.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) Fee Slip No.: 594348009 PKR: 62000/-	Legal Manufacturer: Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (Male Latex Condom) OK Gold Ice on fire 4's OK Gold Ice on fire 3's Class: C LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026	Approved subject to change of brand name

			Shelf life: 05 years Storage condition: 28°C to 35°C	
840.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) Fee Slip No.: 87603941 PKR: 62000/-	Legal Manufacturer: Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (Male Latex Condom) OK Gold infinity 4's OK Gold infinity 3's Class: C LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026 Shelf life: 05 years Storage condition: 28°C to 35°C	Approved
841.	DKT Pakistan Private Limited, Plot No. 34-C, Khalid Commercial, Street-1, DHA Phase-7, Ext. Karachi Pakistan. (ELI-00515) Fee Slip No.: 58599419213 PKR: 62000/-	Legal Manufacturer: Name: M/s Eurolatex. Sdn. Bhd. Address: Plot No. 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia.	OK (Male Latex Condom) OK Gold skin to skin 4's OK Gold skin to skin 3's Class: C LOA Validity: 04-10-2028 FSC Validity (16.01.2025) Malaysia. EU Quality Management Certificate validity: 25-08-2027 ISO 13485 Certificate validity: 08-10-2026 Shelf life: 05 years Storage condition: 28°C to 35°C	Approved
842.	Hospital Supply Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005) Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-	Inceler medikal Saghk Hizmetleri Sanayi Ticaret Limited, Sirketi, Lvedik O.S.B. Mah. Ari S.S 1472. Cad..SK. No.120/, YENIMAHALLE ANKARA, TURKEY	LITHOBOX ZERO intracorporeal Combined Ultrasonic Pneumatic Kidney Stone Crushing Device Class C Shelf life: N/A Storage Condition: -10 to 50° C Codes & Sizes As per FSC MD group: Set LOA Validity:	Deferred for clarification/provision of followings:- • Firm apply INCELER brand name in the application Form whereas in the LOA brand name is written as LITHOBOX ZERO. All documents are scan copies

			<p>31-12-2025.</p> <p>FSC (Turkey) (country of origin): Issuance date: 28-11-2022</p> <p>FQA validity: 27-04-2024 Extension letter attached</p> <p>ISO 13485 validity: 09-04-2026 (Kiwa)</p>	
843.	<p>Hospital Supply Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005)</p> <p>Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-</p>	<p>Inceler medikal Saghk Hizmetleri Sanayi Ticaret Limited, Sirketi, Lvedik O.S.B. Mah. Ari S.S 1472. Cad..SK. No.120/, YENIMAHALLE ANKARA, TURKEY</p>	<p>LITHOBOX intracorporeal Pneumatic Lithotripter System</p> <p>Class C</p> <p>Shelf life: N/A</p> <p>Storage Condition: -10 to 50° C Codes & Sizes As per FSC</p> <p>MD group: Set</p> <p>LOA Validity: 31-12-2025.</p> <p>FSC (Turkey) (country of origin): Issuance date: 28-11-2022</p> <p>FQA validity: 27-04-2024 Extension letter attached</p> <p>ISO 13485 validity: 09-04-2026 (Kiwa)</p>	Approved
844.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)</p> <p>Diary Dated: 09-09-2024 Fee Challan No.: 58248290437 PKR: 50,000/-</p>	<p>Next Saglik Urunleri A.S (Next Shoulder Solution) Manufacturer's address: Ivedik OSB 88. Oto San. Sit. 3. Bolge 2284, Cd. NO. 101 Yenimalhalle-06378 Ankara-Turkiye</p>	<p>Next Shoulder Solution (Shoulder Prosthesis for reverse and anatomic technique)</p> <p>Class C</p> <p>Shelf life: 03 Years</p> <p>Storage Condition: Not provided</p> <p>Codes & Sizes As per FSC</p>	Approved

			<p>MD group: System</p> <p>LOA Validity: 13-08-2027</p> <p>FSC (Turkey) (country of origin): Issuance date: 16-12-2022</p> <p>FSC (Spain) Issuance Date: 23-09-2022</p> <p>FQA validity: 27-05-2024 (UDEM) Extension letter attached</p> <p>ISO 13485 validity: 02-12-2024 (Next)</p> <p>Design Examination Certificate Validity: 27-05-2024 Extension letter attached</p>	
845.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi</p> <p>(ELI-00257) Diary Dated: 09-09-2024 Fee Challan No.: 58248290437 PKR: 50,000/-</p>	<p>M/s Endovision Co., Ltd. 66-26 Dongnae-Ro, Dong- gu, Daegu, 41061 Republic of Korea</p>	<p>Unilateral Bi-Portal Endoscopic Spine Surgery</p> <p>Class C</p> <p>Shelf life: N/A</p> <p>Storage Condition: Not provided</p> <p>Codes & Sizes As per FSC</p> <p>MD group: System</p> <p>LOA Validity: 23-07-2026</p> <p>FSC (Korea) (country of origin): Issuance date: 13-08-2024</p> <p>FSC (Germany) Issuance date 29-08-2023</p> <p>FQA validity: 27-06-2023 (MTIC) ISO 13485 validity: 24-09-2025 (LL-C)</p>	Approved.

846.	<p>Rech International, 247/B, Block-6 P.E.C.H.S Karachi</p> <p>(ELI-00257) Diary Dated: 23-10-2024 Fee Challan No.: 1322163664 PKR: 62,000/-</p>	<p>Beijing Soniocmed Co Technologies, Room B-601, Building No.8, Yard No.1, Zhongguancun East Road, Haidian District, Beijing- 100084, China</p>	<p>Sonicmed Ultrasonic Surgical System</p> <p>Class C</p> <p>Shelf life: N/A</p> <p>Storage Condition: Not provided</p> <p>Codes & Sizes As per FSC</p> <p>MD group: System</p> <p>LOA Validity: 07-08-2029</p> <p>FSC (China) (country of origin): Validity: 12-08-2026</p> <p>FQA validity: 26-05-2024</p> <p>ISO 13485 validity: 26-06-2027</p>	<p>Approved.</p>
847.	<p>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN.</p> <p>Lic. No.ELI-00010 Date of issue: 03-08- 2018 Date of Renewal: 20- 06-2023</p> <p>Dy. No.: NIL DRAP (R&I) Dated: 22-10-2024 Fee Challan No.: 603713624 PKR: 62000/- Dated: 10-10-2024</p>	<p><u>M/s. MEDTRADE PRODUCTS Ltd</u> located at <u>Electra House, Electra Way , Crewe CW1 6GL UK</u></p>	<p>CELOX PPH (Uterine Haemostatic Tamponade) – REF: FG08838171</p> <p>Class: D</p> <p>MD group: Single</p> <p>LOA Validity: 26-06-2029</p> <p>FSC Validity (country of origin): 15-03-2028</p> <p>EC Certificate exp date: 15- 03-2027</p> <p>ISO 13485 Certificate validity: 26-04-2027</p> <p>Shelf life: 5 Years</p> <p>Storage condition: There is no special storage conditions required for the device.</p>	<p>Approved subject to FQA or FSc of RRA</p>
848.	<p>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400,</p>	<p>M/s DemeTECH Corporation located at 5980 Miami Lakes Drive, Miami Lakes, 33014, FL,USA.</p>	<p>Deme DIOX Barbed (Absorbable Polydioxanone Barbed Surgical Suture)</p> <p>Class: D</p>	<p>Approved subject to FQA or FSc of RRA</p>

	<p>PAKISTAN.</p> <p>Lic. No.ELI-00010 Date of issue: 03-08-2018 Date of Renewal: 20-06-2023</p> <p>Dy. No.: NIL DRAP (R&I) Dated: 23-10-2024 Fee Challan No.: 3217687152 PKR: 62000/- Dated: 17-10-2024</p>	<p>Tel: (305) 824-1048 Fax: (305) 437 7607</p>	<p>MD group: Single</p> <p>LOA Validity: 31-12-2027</p> <p>FSC Validity (<i>country of origin</i>): 16-02-2024</p> <p>EC Certificate issue date: 14-09-2023</p> <p>ISO 13485 Certificate validity: 10-07-2025</p> <p>Shelf life: 5 Years</p> <p>Storage condition: It is recommended that the Sutures are stored below 25 °C. Keep away from direct heat and moisture.</p>	
849.	<p>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN.</p> <p>Lic. No.ELI-00010 Date of issue: 03-08-2018 Date of Renewal: 20-06-2023</p> <p>Dy. No.: NIL DRAP (R&I) Dated: 22-10-2024 Fee Challan No.: 512260533 PKR: 62000/- Dated: 10-10-2024</p>	<p><u>M/s. MEDTRADE PRODUCTS Ltd</u> located at <u>Electra House, Electra Way , Crewe CW1 6GL UK</u></p>	<p>FOXSEAL Vented, Vented Chest Seal Dressing (REF: FG08814601)</p> <p>Class: C</p> <p>MD group: Single</p> <p>LOA Validity: 15-09-2029</p> <p>FSC Validity (<i>country of origin</i>): 31-12-2029</p> <p>EC Certificate issue date: 16-03-2024</p> <p>ISO 13485 Certificate validity: 26-04-2027</p> <p>Shelf life: 5 Years</p> <p>Storage condition: There is no special storage conditions required for the device.</p>	<p>Approved subject to FQA or FSc of RRA</p>
850.	<p>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN.</p> <p>Lic. No.ELI-00010 Date of issue: 03-08-2018 Date of Renewal: 20-06-2023</p>	<p><u>M/s. MEDTRADE PRODUCTS Ltd</u> located at <u>Electra House, Electra Way , Crewe CW1 6GL UK</u></p>	<p>FOXSEAL, Chest Seal Dressing (REF: FG08814441)</p> <p>Class: C</p> <p>MD group: Single</p> <p>LOA Validity: 15-09-2029</p> <p>FSC Validity (<i>country of origin</i>): 31-12-2029</p>	<p>Approved.</p>

	<p>Dy. No.: NIL DRAP (R&I) Dated: 22-10-2024 Fee Challan No.: 836640052217 PKR: 62000/- Dated: 10-10-2024</p>		<p>EC Certificate issue date: 16-03-2024</p> <p>ISO 13485 Certificate validity: 26-04-2027</p> <p>Shelf life: 5 Years</p> <p>Storage condition: There is no special storage conditions required for the device.</p>	
851.	<p>M/s Sure Bio-Diagnostics & Pharmaceuticals</p> <p>Address of Importer EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi.</p> <p>ELI-00084</p> <p>R&I Dated: 13 Dec 2024</p> <p>Fee Challan No.: 219428072288 PKR: 62000/-</p>	<p>M/s Ortho Clinical Diagnostics Company Address: Felindre Meadows, Pencoed, Bridgend, United Kingdom CF35 5PZ</p>	<p>Ortho BioVue System Blood Grouping Reagents ABD (DVI) Donor Confirmation Cassette & Blood Grouping Reagents (DVI Grouping Cassette)</p> <p>Class: D MD group: System/group LOA Validity: 12/31/2025 FSC RRA issuance date: 05-06-2024</p>	Approved.
852.	<p>M/s K.S. Agencies Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382)</p> <p>R&I Dated: 02/28/2024 Fee Challan No.: 06625747337 PKR: 50000/-</p>	<p>Shandong Weigao Blood Purification Products Co., Ltd No.20 Xingshan Road, Weihai Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, People's Republic of China</p>	<p>WEGO HOLLOW FIBER DIALYZER</p> <p>Class: C MD group: Single LOA Validity: 12/31/2025 FSC Validity: 10/26/2026</p> <p>Low Flux, Medium Flux, High Flux</p> <p>Codes as per FSC</p>	Approved.
853.	<p>M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. (ELI- 00109) 2361-P</p>	<p>Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France</p> <p>FSC France issuance 13.02.2019</p>	<p>CAPILLARYS PROTEIN(E) 6 Kit (Protein separation kit)</p> <p>Class: B</p> <p>Shelf life: 3 Years</p> <p>Configuratons: •CAPILLARYS PROTEIN(E) 6</p>	Approved

			<p>Ref. 2003</p> <ul style="list-style-type: none"> •CAPILLARYS / MINICAP PROTEIN(E) 6 buffer •CAPILLARYS / MINICAP wash solution 	
854.	<p>M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>(ELI- 00109)</p> <p>R&I dated 30-11-2022 Fee challan No. 76661669112 dated 30-11-2022</p>	<p>Legal Manufacturer</p> <p>SEBIA</p> <p>(Manufacturing site) 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France</p> <p>Free Sale Certificate (FSC) Attached</p> <p>ISO: Attached</p> <p>CE Certificate validity date: N/A</p> <p>Design Examination Certificate N/A</p>	<p>CAPILLARYS HEMOGLOBIN(E) Kit Hemoglobin separation kit</p> <p>Class: B</p> <p>Shelf life: 3 Years</p> <p>Configurations:</p> <ul style="list-style-type: none"> • CAPILLARYS HEMOGLOBIN(E) • Ref. 2007 • CAPILLARYS / MINICAP HEMOGLOBIN(E) buffer • CAPILLARYS HEMOGLOBIN(E) hemolysing solution • CAPILLARYS / MINICAP wash solution 	Approved
855.	<p>M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>(ELI- 00109) 2359-P</p>	<p>Legal Manufacturer</p> <p>SEBIA located at, 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France</p> <p>FSC France issuance: 13.02.2019</p>	<p>CAPILLARYS Immunotyping Kit Monoclonal protein detection kit</p> <p>Class: B</p> <p>Shelf life: ...2 Years</p> <p>configurations:</p> <ul style="list-style-type: none"> • CAPILLARYS IMMUNOTYPING • Ref. 2100 • IMMUNOTYPING sample diluent • IMMUNOTYPING ELP solution • Antisera 	Approved
856.	<p>M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>(ELI- 00109) 3234-P</p>	<p>Legal Manufacturer</p> <p>BioMérieux Inc. 100 Rodolphe Street Durham, North Carolina 27712 – USA</p> <p>Authorized Representative</p> <p>BioMérieux SA 376 Chemin de l'Orme</p>	<p>BACT/ALERT® MP Reagent System Mycobacterium Detection Kit</p> <p>Class: B</p> <p>Shelf life: 12 months</p> <p>Codes: 414997 419744</p>	Approved

		69280 Marcy-l'Etoile France Free Sale Certificate (FSC) <u>13-01-2022</u>		
857.	M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. (ELI- 00109) 3387-P	Legal Manufacturer: <u>bioMerieux S.A.</u> located at 376, Chemin de l'Orme 69280 Marcy l'Etoile FRANCE Free Sale Certificate (FSC) 19-04-2022	VIDAS Anti-CHIKUNGUNYA IgG (CHKG) chikungunya virus detection kit Class: B Shelf life: 12 months Codes as per FSC: 423230-30	Approved
858.	M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. (ELI- 00109) 3384-P	Legal Manufacturer: <u>bioMerieux S.A</u> Manufacturing Site: 376,Chemin de l'Orme 69280 Marcy l'Etoile FRANCE Free Sale Certificate (FSC) 19-04-2022	VIDAS Anti-CHIKUNGUNYA IgM (CHKM) Chikungunya igM antibodies detection kit Class: B Shelf life: 12 months Codes as per: 423229 423229-30	Approved
859.	M/S Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. (ELI- 00109) 960-P	Legal Manufacturer: <u>bioMerieux S.A.</u> Manufacturing Site: 376, Chemin de l'Orme 69280 Marcy l'Etoile FRANCE Free Sale Certificate (FSC) 13-01-2022	VIDAS 3 Class: A Shelf life: N/A Codes as per FSC: 423694 412590 VIDAS ® 3 system VIDAS 3 V1.4 software	Approved

DEFERRED / APPROVED SUBJECT TO APPLICATION FOR ENLISTMENT REGISTRATION FOR IMPORT

S#	Importer Name	Manufacturer Details	Product Details	Decision
1.	M/s Kaumedex, E-14/2, New Super Town, Link-2, Defence Road, Lahore. (ELI-00162)	Legal Manufacture: M/s. Supermax Glove Manufacturing SDN BHD LOT 38, Putra Industrial Park, Bukit rahman Putra,	High-Max (Latex Examination gloves, Powdered) Class-A	Disposed off as was Rejected in M-17 and the case has been inadvertently added in the agenda.

	102-P	47000 Sungai Buloh, Selangor, Malaysia. FSC Malaysia 30-03-2025	Shelf life: 5 years Sizes as per FSC: XS, S, M, L & XL	
2.	Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road Saddar, Rawalpindi. ELI: 00919 3958-P 12-06-2023	Legal Manufacturer: M/s Eyekon Medical Inc. 2451 Enterprises Road Clearwater, Florida, USA 33763 Certificate of Exportability USA Valid till: 26/05/2023	Acuity Hydroflex ADV Advance Series (Hydrophilic Foldable IOL) Class-C Shelf Life: 5 Years Code: FS25B-UV	Approved
3.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3056-P 24-06-2022	Legal Manufacturer: Getinge Streicoll Medikal Aletler Sannyi Ve ticaret Anonim Sirketi Bestepe Mahallesi, Nergiz Sokak No: 7/2 ic Kapi No: 71 Yenimahalle Ankara Turkey FSC: Turkey Valid till: 07.12.2020	Stericool Hydrogen Peroxide Plasma Sterilizer (Low Temp Sterilizer) Class-C Shelf Life: N/A Codes & Sizes: As per FSC	Approved
4.	Wirha & Co. Address of Importer First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi ELI-01261	Legal Manufacturer) Suzhou Laishi Transfusion Equipment Co., (Manufacturing site) Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China Valid till: 22-10-2025	Suzhou Disposable Plastic Blood Bag Single Bag Class D Shelf life: 03 Years Codes & Sizes 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Approved
5.	Wirha & Co. Address of Importer First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi ELI-01261	Legal Manufacturer) Suzhou Laishi Transfusion Equipment Co., (Manufacturing site) Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China Valid till: 22-10-2025	Suzhou Disposable Plastic Blood Bag Double Bag Class D Shelf life: 03 Years Codes & Sizes 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Approved
6.	Wirha & Co. Address of Importer First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi ELI-01261	Legal Manufacturer) Suzhou Laishi Transfusion Equipment Co., (Manufacturing site) Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China Valid till: 22-10-2025	Suzhou Disposable Plastic Blood Bag Triple Bag Class D Shelf life: 03 Years Codes & Sizes 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Approved

7.	Wirha & Co. Address of Importer First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi ELI-01261	Legal Manufacturer) Suzhou Laishi Transfusion Equipment Co., (Manufacturing site) Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China Valid till: 22-10-2025	Suzhou Disposable Plastic Blood Bag Quadruple Bags Class D Shelf life: 03 Years Codes & Sizes 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Approved
8.	M/s Uniplan Trade International Pvt Ltd., 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore. (ELI-00132)	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Address: 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 1F 63ml CPDA- 1 PDS-V Class D Shelf life: 24 Months Codes & Sizes Compoflex® 1F 63ml CPDA- 1 PDS-V T111150	The Board decided to give final opportunity for personal hearing to both firms for the confirmation of valid letter of authorization in next meeting. In failure of appearance before the Board, ex-parte decision will be taken by the Board.
9.	M/s Uniplan Trade International Pvt Ltd., 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore. (ELI-00132)	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Address: 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 2F 63ml CPDA- 1 PDS-V Class D Shelf life: 24 Months Codes & Sizes Compoflex® 2F 63ml CPDA- 1 PDS-V T211150	The Board decided to give final opportunity for personal hearing to both firms for the confirmation of valid letter of authorization in next meeting. In failure of appearance before the Board, ex-parte decision will be taken by the Board.
10.	M/s Uniplan Trade International Pvt Ltd., 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore. (ELI-00132)	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Address: 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 3F 63ml CPDA- 1 PDS-V Class D Shelf life: 24 Months Codes & Sizes Compoflex® 3F 63ml CPDA- 1 PDS-V T331150	The Board decided to give final opportunity for personal hearing to both firms for the confirmation of valid letter of authorization in next meeting. In failure of appearance before the Board, ex-parte decision will be taken by the Board.
11.	M/s Uniplan Trade International Pvt Ltd., 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Address: 61346, Bad	Compoflex® 4F 63ml CPDA- 1 PDS-V Class D	The Board decided to give final opportunity for personal hearing to both firms for the confirmation of valid letter of

	(ELI-00132)	Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Shelf life: 24 Months Codes & Sizes Comproflex® 4F 63ml CPDA-1 PDS-V T431150	authorization in next meeting. In failure of appearance before the Board, ex-parte decision will be taken by the Board.
12.	Roys & Roys International 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Gate-3, Lahore ELI: 00708 4255-P 24-10-2023	Legal Manufacturer: M/s Suzhou Laishi Transfusion Equipment Co. Ltd Changshen Road, Tongli Town, Wujian City, Jiangsu Province- 215217, China FSC: China Valid Till: 2024/04/22	MEDIGAR Single Blood Bags (Plastic Blood Bag) Class-D Shelf Life: 2 years Sizes: 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Approved.
13.	M/s Easha Enterprises, 2B-04 Third Floor, Adyala Towers, Adyala Road, Rawalpindi	LEGAL MANUFACTURER M/s Biomedica Mexicana Company Address: Calzada Ermita Iztapalapa No.855 Colonia Santa Isabel, Mexico	Biomed® CSF Flow Shunt Control Valve Burr-Hole Class D Shelf life: 05 Years Codes & Sizes as per FSC VDVP-A16, VDVP16	Approved
14.	SM Impex Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah-e-Liaquat, Karachi, Pakistan (ELI-00473) 8569-R&I 16.03.2020 Evaluator AD-IX	Geotek Medikal Ve Saglik Hiz. Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey FSC: Turkey, valid till 3 rd December, 2023.	Maxicore Biopsy Gun & Needle Codes and sizes as per FSC Biopsy Gun: GBG01 Biopsy gun Needle: GPN1410, GPN1415, GPN1420, GPN1610, GPN1810, GPN1815, GPN1820, GPN1825, GPN1830, Class D Shelf life: 5 years	Approved
15.	S.M Impex office No. B-309,3 RD Floor, New challi trade centre, Shahrah-e-Liaquat, Karachi. (ELI-00473) Dossier# 1107-c/7A Diary# 35479 Date:07-12-22 Submitted Fee: 50,000/-PKR	Legal Manufacturer: Geotek Medikal Ve Saglik Hiz. Tic. San Ltd Sti. Address: Ivedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey FSC: Turkey Issued on: 04/12/2020	Geotek (Breast Localization Needle) Codes & Sizes: Sizes: 20GX10cm, 20GX12cm, 20GX15cm, 20GX5cm, 20GX7cm Codes: GBL2010, GBL2012, GBL2015,	Approved

	Challan No.: 7242163017 Evaluator DD-II		GBL2005, GBL2007, Class-D Shelf Life: 05 years	
16.	SM Impex Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah-e- Liaquat, Karachi, Pakistan (ELI-00473) 8569-R&I 16.03.2020 Evaluator AD-IX	Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey FSC: Turkey, valid till 3 rd December, 2023.	Maxicore Biopsy Needle Class-D Shelf life: 5 years Codes: GPN1410, GPN1415, GPN1420, GPN1610, GPN1810, GPN1815, GPN1820, GPN1825, GPN1830,	Approved
17.	Danish international Healthcare (Pvt) Ltd, 51-F, 2nd Floor , Main Boulevard, Punjab Co- operative Housing Society, Ghazi Road Lahore ELI: 00821	Legal Manufacturer: FHC, Inc. Corporate & Manufacturing 1201 main street Bowdoin Maine 04287 USA FSC No.1136-10-2020 U.S.A Valid till: 27.10.2022	FHC (Electrodes and Insertion Tubes) Codes & Sizes: As per FSC Class-C Shelf life: 3 years Fee: 50,000/- Date of Application: 13-06-2022	Approved
18.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 10-12-2022 Dated: 13-12-2022 Fee Challan No.: 63237703270 PKR: 50000/- Dated: 09-12-2022	Legal Manufacturer: Name: M/s. Suzhou Laishi Transfusion Equipment Co., Ltd. Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province,China. ISO 13485 Certificate validity: 28-08-2023 EC Certificate validity: 27-05-2024 Design examination certificate validity: 11-08-2023	M.I. BLOOD BAG CPDA-1 (TC) 500ML Ref: - NO. GXZZ20193101807 Controls: GXZZ20193101807 Certificate no. SSYJXC20222951 [Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)] Class: D MD group: SET LOA Validity: 31-10-2025 FSC Validity (country of origin): CHINA	Approved

			22-04-2024 Shelf life: 03 years Storage condition: stored at room temperature less than 30°C	
19.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 10-12-2022 Dy. No.: -DRAP (R&I) Dated: 13-12-2022 Fee Challan No.: 0896456368 PKR: 50000/- Dated: 09-12-2022	Legal Manufacturer: Name: M/s. Suzhou Laishi Transfusion Equipment Co., Ltd. Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, China.	M.I. BLOOD BAG CPDA-1 (TC) 250ML Ref:- NO.GXZZ20193101807 Controls: GXZZ20193101807 Certificate no.SSYJXC20222951 Class: D MD group: SET LOA Validity: 31-10-2025 FSC Validity (country of origin): CHINA 22-04-2024 EC Certificate validity: 27-05-2024 ISO 13485 Certificate validity: 28-08-2023 Design examination certificate validity: 11-08-2023 Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C	Approved
20.	M/s. Mehran International 498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 10-12-2022 Dy. No.: -DRAP (R&I) Dated: 13-12-2022 Fee Challan No.: 59654206 PKR: 50000/- Dated: 09-12-2022	Legal Manufacturer: Name: M/s. Suzhou Laishi Transfusion Equipment Co., Ltd. Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, China.	M.I. BLOOD BAG CPDA-1 (DC) 250ML Ref:- NO.GXZZ20193101807 Controls: GXZZ20193101807 Certificate no.SSYJXC20222951 Class: D MD group: SET LOA Validity: 31-10-2025 FSC Validity (country of origin): CHINA 22-04-2024 EC Certificate validity: 27-05-2024 ISO 13485 Certificate validity: 28-08-2023 Design examination certificate validity: 11-08-2023 Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C	Approved

21.	<p>M/s. Mehran International</p> <p>498-C, Feroz shah Mehta Road, Karachi. (ELI-00351)</p> <p>D.O.I: 10-12-2022</p> <p>Dy. No.: -DRAP (R&I)</p> <p>Dated: 13-12-2022</p> <p>Fee Challan No.: 6470369050</p> <p>PKR: 50000/-</p> <p>Dated: 09-12-2022</p>	<p>Legal Manufacturer: Name: M/s. Suzhou Laishi Transfusion Equipment Co., Ltd.</p> <p>Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, China.</p>	<p>M.I. BLOOD BAG CPDA-1 (DC) 500ML</p> <p>Ref:- NO.GXZZ20193101807</p> <p>Controls: GXZZ20193101807 Certificate no.SSYJXC20222951</p> <p>Class: D</p> <p>MD group: SET</p> <p>LOA Validity: 31-10-2025</p> <p>FSC Validity (country of origin): CHINA 22-04-2024</p> <p>EC Certificate validity: 27-05-2024</p> <p>ISO 13485 Certificate validity: 28-08-2023</p> <p>Design examination certificate validity: 11-08-2023</p> <p>Shelf life: FIVE YEARS</p> <p>Storage condition: stored at room temperature less than 30°C</p>	Approved
22.	<p>M/s. Mehran International</p> <p>498-C, Feroz shah Mehta Road, Karachi. (ELI-00351)</p> <p>D.O.I: 10-12-2022</p> <p>Dy. No.: -DRAP (R&I)</p> <p>Dated: 13-12-2022</p> <p>Fee Challan No.: 669874069</p> <p>PKR: 50000/-</p> <p>Dated: 09-12-2022</p>	<p>Legal Manufacturer: Name: M/s. Suzhou Laishi Transfusion Equipment Co., Ltd.</p> <p>Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, China.</p>	<p>M.I. BLOOD BAG CPDA-1 (QC) 250ML</p> <p>Ref:- NO.GXZZ20193101807</p> <p>Controls: GXZZ20193101807 Certificate no.SSYJXC20222951</p> <p>Class: D</p> <p>MD group: SET</p> <p>LOA Validity: 31-10-2025</p> <p>FSC Validity (country of origin): CHINA 22-04-2024</p> <p>EC Certificate validity: 27-05-2024</p> <p>ISO 13485 Certificate validity: 28-08-2023</p> <p>Design examination certificate validity: 11-08-2023</p> <p>Shelf life: FIVE YEARS</p> <p>Storage condition: stored at room temperature less than 30°C</p>	Approved
23.	<p>M/s. Mehran International</p>	<p>Legal Manufacturer: Name: M/s. Suzhou Laishi</p>	<p>M.I. BLOOD BAG CPDA-1 (QC) 500ML</p> <p>Ref:MODEL-</p>	Approved

	<p>498-C, Feroz shah Mehta Road, Karachi. (ELI-00351) D.O.I: 10-12-2022 Dy. No.: -DRAP (R&I) Dated: 13-12-2022 Fee Challan No.: 40872541182 PKR: 50000/- Dated: 09-12-2022</p>	<p>Transfusion Equipment Co., Ltd. Manufacturer Address: Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, China.</p>	<p>NO.GXZZ20193101807 Control: REG.NO.GXZZ20193101807 Certificate no.SSYJXC20222951 Class: D MD group: SET LOA Validity: 31-10-2025 FSC Validity <i>(country of origin): CHINA</i> 22-04-2024 EC Certificate validity: 27-05-2024 ISO 13485 Certificate validity: 28-08-2023 Design examination certificate validity: 11-08-2023 Shelf life: FIVE YEARS Storage condition: stored at room temperature less than 30°C</p>	
24.	<p>M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11-2022 Fee: Rs 25000/-</p>	<p>Legal manufacturer: TSK Laboratory Japan Address: 1510-1 SojaMachi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi,Tochigiken,328-0002 JAPAN. Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.</p>	<p>Brand Name: TSK Starcut Biopsy Needless Generic Name: semiautomatic biopsy needle Class-B Codes: SAG-14090 SAG-14130 SAG-14160 SAG-14220 SAG-16090 SAG-16130 SAG-16160 SAG-16220 SAG-18090 SAG-18130 SAG-18160 SAG-18220 SAG-20090 SAG-20130 SAG-20160 SAG-20220 SAG-14090C SAG-14130C SAG-14160C SAG-14220C SAG-16090C SAG-16130C SAG-16160C SAG-16220C SAG-18090C SAG-18130C SAG-18160C SAG-18200C SAG-18220C SAG-20090C SAG-20130C</p>	Approved

			SAG-20160C SAG-20220C	
25.	<p>M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11- 2022</p> <p>Fee: Rs 25000/-</p>	<p>Legal manufacturer: TSK Laboratory Japan Address: 1510-1 SojaMachi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi- shi,Tochigiken,328-0002 JAPAN.</p> <p>Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.</p>	<p>Brand Name: TSK Acecut Biopsy Needle Generic Name: biopsy needle</p> <p>Class: B Shelf Life: 05 years Storage Conditions: 15°C to 25°C</p> <p>Codes: ACE-110751 ACE-110752 ACE-110753 ACE-111151 ACE-111152 ACE-111153 ACE-111501 ACE-111502 ACE-111503 ACE-112001 ACE-112002 ACE-112003 ACE-140751 ACE-140752 ACE-140753 ACE-141151 ACE-141152 ACE-141153 ACE-141501 ACE-141502 ACE-141503 ACE-142001 ACE-142002 ACE-142003 ACE-160751 ACE-160752 ACE-160753 ACE-161151 ACE-161152 ACE-161153 ACE-161501 ACE-161502 ACE-161503 ACE-162001 ACE-162002 ACE-162003 ACE-180751 ACE-180752 ACE-180753 ACE-181151 ACE-181152 ACE-181153 ACE-181501 ACE-181502 ACE-181503 ACE-182001 ACE-182002 ACE-182003 ACE-200751 ACE-200752 ACE-200753 ACE-201151 ACE-201152 ACE-201153 ACE-201501 ACE-201502 ACE-201503 ACE-202001 ACE-202002 ACE-202003 ACE-140751C ACE-140752C ACE-140753C ACE-141151C ACE-141152C ACE-141153C ACE-141501C ACE-141502C ACE-141503C ACE-142001C ACE-142002C ACE-142003C ACE-160751C ACE-160752C ACE-160753C ACE-161151C ACE-161152C ACE-161153C ACE-161501C ACE-161502C ACE-161503C ACE-162001C ACE-162002C ACE-162003C ACE-180751C ACE-180752C ACE-180753C ACE-181151C ACE-181152C ACE-181153C ACE-181501C ACE-181502C ACE-181503C</p>	Approved

			ACE-182001C ACE-182002C ACE-182003C ACE-200751C ACE-200752C ACE-200753C ACE-201151C ACE-201152C ACE-201153C ACE-201501C ACE-201502C ACE-201503C ACE-202001C ACE-202002C ACE-202003C	
26.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSI ON: 04-11- 2022 Fee: Rs 25000/-	Legal manufacturer: TSk Laboratory Japan Address: 1510-1 SojaMachi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigiken,328-0002 JAPAN.	Brand Name: TSK Surelock BMB (Needle) Generic Name: bone marrow biopsy needle Codes: BTS-08100 BTS-08150 BTS-11100 BTS-11150 BTS-13065 BTS-13100 Class: B Shelf Life: 05 years	Approved
27.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSI ON: 04-11- 2022 Fee: Rs 25000/-	Legal manufacturer: TSk Laboratory Japan Address: 1510-1 SojaMachi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigiken,328-0002 JAPAN.	Brand Name: TSK SURECUT Biopsy Needle Generic Name: biopsy needle Class: B Codes: SUC-16050 SUC-16070 SUC- 16100 SUC-16120 SUC- 16150 SUC-18050 SUC- 18070 SUC-18100 SUC- 18120 SUC-18150 SUC- 21050 SUC-21070 SUC- 21100 SUC-21120 SUC- 21150 SUC-23050 SUC- 23070 SUC-23100 SUC- 23120 SUC-23150 Shelf Life: 05 years	Approved
28.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 Date Of Submissi On: 04-11-2022 Fee: Rs 25000/-	Legal manufacturer: TSk Laboratory Japan Address: 1510-1 SojaMachi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigiken,328-0002 JAPAN.	Brand Name: TSK Coaxial Guide needle Generic Name: biopsy needle Class: B Shelf Life: 05 years Codes: CGNACE-140751 CGNACE- 140752 CGNACE-140753 CGNACE-141151 CGNACE- 141152 CGNACE-141153 CGNACE-141501 CGNACE- 141502 CGNACE-141503 CGNACE-142001 CGNACE- 142002 CGNACE-142003	Approved

			CGNACE-160751 CGNACE-160752 CGNACE-160753 CGNACE-161151 CGNACE-161152 CGNACE-161153 CGNACE-161501 CGNACE-161502 CGNACE-161503 CGNACE-162001 CGNACE-162002 CGNACE-162003 CGNACE-180751 CGNACE-180752 CGNACE-180753 CGNACE-181151 CGNACE-181152 CGNACE-181153 CGNACE-181501 CGNACE-181502 CGNACE-181503 CGNACE-182001 CGNACE-182002 CGNACE-182003 CGNACE-200751 CGNACE-200752 CGNACE-200753 CGNACE-201151 CGNACE-201152 CGNACE-201153 CGNACE-201501 CGNACE-201502 CGNACE-201503 CGNACE-202001 CGNACE-202002 CGNACE-202003 CGN-14090 CGN-14130 CGN-14160 CGN-14220 CGN-16090 CGN-16130 CGN-16160 CGN-16220 CGN-18090 CGN-18130 CGN-18160 CGN-18220 CGN-20090 CGN-20130 CGN-20160 CGN-20220	
29.	AK Traders 123-Canal Bank Housing Scheme, Harbanspura, Lahore. ELI: 01035 Dossier# 3989-P Submission date: 06/07/2023 Fee submitted: 50,000/- Challan No. 472968130532 Evaluator: DD-II	<u>Legal Manufacturer:</u> Hngzhou Rejoin Mastin Medical Co., Ltd, Floors 1st and 2nd, 10IB No. 22 xiyan Road Yuhnag Economic & technological Development Zone, Linping district, 311100 Hangzhou Zhejiang, People's Republic of China FSC: China Valid till: 204/01/08	Rejoin ET Button, Adjustable initial Class-C Shelf Life: not provided Codes & Sizes: not provided	Approved The firm will submit Brand name with product description, valid FSC, Shelf life. Multiple products submitted. No difference is provided
30.	AK Trader, <u>Address of Importer</u>	<u>Legal manufacturer:</u> Hangzhou Rejoin Mastin Medical Device Co., Ltd,	Rejoin Shaver Blade Class-C	Approved

	123-Canal Bank Housing Scheme, Harbanspura, Lahore. ELI- 01035 Dossier No. 4850-P 27-05-2024	Address: Floors 1 st and 2 nd , 101B, No. 22, Zinyan Road, Economic Technological Development Xone, Linping District, 311100 Hangzhou, Zhejiang, People's Republic China. FSC: China. Validity: 08 January 2024.	Shelf life: Sizes: Codes and sizes as per FSC	
31.	AK Trader, Address of Importer 123-Canal Bank Housing Scheme, Harbanspura, Lahore. ELI- 01035 Dossier No. 4851-P	Legal manufacturer: Hangzhou Rejoin Mastin Medical Device Co., Ltd, Address: Floors 1 st and 2 nd , 101B, No. 22, Zinyan Road, Economic Technological Development Xone, Linping District, 311100 Hangzhou, Zhejiang, People's Republic China. FSC: China. Validity: 08 January 2024.	Rejoin Anchor Class-C Shelf life: Sizes: Codes and sizes as per FSC	Approved
32.	M/s Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 3271-KP	Legal Manufacturer: Lake Regiion Medical Limited Butlersland, New Ross, Co Wesford Ireland Manufacturing Site: Brivant Limited Parkmore West Business Park Galway, Ireland FSC: U.S FDA Valid till: 12/06/2023	Victory TM 18 Polymer Tip Guidewire with Hydrophilic Coating (Guidewire for intravascular Interventional procedures) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC H74939232195120 H74939232195180 H74939232300120 H74939232300180 H74939233195250 H74939233195300 H74939233300250 H74939233300300	Approved
33.	Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4053-KP	Legal Manufacturer: Boston scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site:	Acurate neo 2 Transfemoral Delivery System (SYM-DS-010) (Cardiac Valves Transcatheter Implant) Codes & Sizes: (SYM-DS-010)	Approved

	Submission date: 02/08/2023 Fee submitted: 50,000/- PKR Challan# 8000517473 Evaluator: DD-II	Boston Scientific Limited Ballybrit Business Park, Galway, Ireland FSC: Ireland Date of Issue: 01/12/2022	Class-D Shelf life: 12 months	
34.	Ferozsons Laboratories Limited P.O. Ferozsons, Amangarh, Nowshera, KPK (ELI-00120) Dossier# 1056c/7A Submission date: 21/12/2022 Fee submitted: 50,000/- Challan No. 018349554948 Evaluator: DD-II	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing site: Statice SA 9 rue Thomas Edison Besancon, Franche- Comte France 25000 FSC :MHRA valid till 27-10-2022	Habib EndoHPB Bipolar Radiofrequency Catheter and adaptor cable bipolar Codes & Sizes: 8F/180cm in length Class-C Shelf Life: 03 years	Approved
35.	M/S Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1523-P Evaluator: AD-III	Legal Manufacturer: FFOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO Plain Gut Sutures (Sterile Absorbable surgical suture) Class-D Shelf Life: 5 years Code & Sizes: List provided	The board deferred the case for submission of FSC of reference country or CE marked document (Design Examination Certificate).
36.	M/S Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1522-P Evaluator: AD-III	Legal Manufacturer: FFOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO CHAROMIC CATGUT Sterile Absorbable Surgical Suture) Class-D Shelf Life: 5 years Codes: Not provided	The board deferred the case for final opportunity to provide the FSC of ref country or CE marked document (Design Examination Certificate).
37.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11- 2022 PKR 5000/- Dated: 15-01-2020	Legal manufacturer: <u>Zhangjiagang Shengang</u> <u>Medical Products Co. Ltd</u> <u>Address: Xican Village,</u> <u>Fenghuang town,</u> <u>Zhangjiagang City, China</u> <u>FSC – China</u> <u>Validity:</u> <u>21-08-2025</u>	Urine Bag 1000ml & 2000 ml Class-A Shelf Life: 05 years Storage Conditions: 05oC to 25oC EC certificate validity: 26-05-2024	Approved
38.	M/s: Medichem Enterprise Address: 331/C, Block no. 3,	Legal manufacturer: <u>Zhangjiagang Shengang</u> <u>Medical Products Co. Ltd</u>	Urine Meter Models:	Approved

	DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11- 2022 PKR 5000/- Dated: 15-01-2020	<u>Address: Xican Village, Fenghuang town, Zhangjiagang City, China</u> <u>FSC – China</u> <u>Validity:</u> <u>21-08-2025</u>	Urine meter (2200) Urine meter (2500) Urine meter (2700) Urine meter (3000) Urine meter (3100) Class-A Shelf Life: 05 years Storage Conditions: 15oC to 25oC EC certificate validity: 26-05-2024	
39.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11- 2022 PKR 5000/- Dated: 15-01-2020	<u>Legal manufacturer:</u> <u>Zhangjiagang Shengang Medical Products Co. Ltd</u> <u>Address: Xican Village, Fenghuang town, Zhangjiagang City, China</u> <u>FSC – China</u> <u>Validity:</u> <u>21-08-2025</u>	Suction Connecting Tube with Yankauer Handle Models: 9.33(F28) 10.00(F30) 10.67(F32) Class-A Shelf Life: 03 years Storage Conditions: 5oC to 25oC EC certificate validity: 26-05-2024	Approved
40.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE: OF SUBMISSION: 04-11- 2022 PKR 5000/- Dated: 15-01-2020	<u>Legal manufacturer:</u> <u>Zhangjiagang Shengang Medical Products Co. Ltd</u> <u>Address: Xican Village, Fenghuang town, Zhangjiagang City, China</u> <u>FSC – China</u> <u>Validity:</u> <u>21-08-2025</u>	Urine Bag 1000ml & 2000 ml Class-A Shelf Life: 05 years Storage Conditions: 05oC to 25oC EC certificate validity: 26-05-2024	Approved
41.	M/s HealthBee Projects Private Limited. Ground floor, Momi Plaza, Plot # 43, Business Square Phase 7, Bahria Town, District Rawalpindi. (ELI-00814) D.O.I: 24-11-2021 Dy. No.: 13072 DRAP (R&I) Dated: 09-08-2024	Legal Manufacturer: Name: M/s Maxigen Biotech Inc. (Main Manufacturer, design, development, manufacture, aseptic filling, Moist heat sterilization & distribution) Address 01: No. 88, Keji 1 st Road, Guishan District, Taoyuan City 33383, Taiwan (R.O.C). (Contract Sterilization- Gamma Sterilization)	ArtiBest Intra-Articular Injection Catalogue No.: AB-305 Product Specification: 3.0 ml containing 2.0% Sodium Hyaluronate Class: D MD group: not a group type Medical device. LOA Validity:	<i>Deferred for provision of Clarification of difference of name on fee challan.</i>

	<p>Fee Challan No.: 9427036167 PKR: 50000/- Dated: 09-08-2024</p>	<p>China Biotech Corporation Address 02: No. 10, 33rd road, Taichung Industrial Park, Taichung, Taiwan.</p> <p><i>(Contract Sterilizer-Ethylene Oxide Sterilization)</i> Taiwan Advanced Sterilization Technology Inc. Address 03: No. 17-1, Chien Kuo Road, Tan Tze, Taichung City, 427, Taiwan.</p>	<p>31-12-2026 FSC Validity: 13-10-2026 Shelf life: 03 years Storage Conditions: 2^oC – 25^oC</p>	
--	---	--	---	--

=====