DECISIONS OF 75th MEETING OF MEDICAL DEVICE BOARD HELD ON 05-12-2024

$\frac{\text{REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C \& D)}{\text{FOR LOCAL MAUFACTURE}}$

Sr.	Name & Address of	Name of Medical Devices With Size	Decision
No.	Establishment		
1	Medipak Ltd., 132/1,	Medisol CAPD 2 with drainage Bag	Approved
	Industrial Estate, Kot	(Dialysis Solution with 1.5% w/v Glucose)	
	Lakhpat, Lahore	Composition:	
	(ELM-0048)	Sodium Chloride 5.786g	
		Sodium Lactate Solution 7.847	
		(Sodium Lactate = $3.924g$)	
		Calcium Chloride 2H2O) 0.2573g	
		Magnesium Chloride 6H2O 0.1017g	
		Dextrose Anhydrous 15g	
		Class C	
		Class C Shelf Life: 36 Months	
		Fee: 25000	
2	N. 1. 1 T. 1 122/1	Fee Slip No. 393462850932	
2	Medipak Ltd., 132/1,	Medisol CAPD 3 with drainage Bag	Approved
	Industrial Estate, Kot	(Dialysis Solution with 4.25% w/v Glucose)	
	Lakhpat, Lahore	Composition:	
	(ELM-0048)	Sodium Chloride 5.786g	
		Sodium Lactate Solution 7.847	
		(Sodium Lactate = 3.924g)	
		Calcium Chloride 2H2O) 0.2573g	
		Magnesium Chloride 6H2O 0.1017g	
		Dextrose Anhydrous 42.5g	
		Class C	
		Shelf Life: 36 Months	
		Fee: 25000	
		Fee Slip No. 9165885175	
3	Medipak Ltd., 132/1,		Approved
	Industrial Estate, Kot	(Dialysis Solution with 2.27% w/v Glucose)	
	Lakhpat, Lahore	Composition:	
	(ELM-0048)	Sodium Chloride 5.786g	
		Sodium Lactate Solution 7.847	
		(Sodium Lactate = 3.924g)	
		Calcium Chloride 2H2O) 0.2573g	
		Magnesium Chloride 6H2O 0.1017g	
		Dextrose Anhydrous 22.7g	
		Class C	
		Shelf Life: 36 Months	
		Fee: 25000	
		Fee Slip No. 64170677	

5	Lab Diagnostic Systems (SMC) Pvt Ltd., Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi (ELM-0028) [549-7L] Nov-24 Apex Biotechnologies, Plot No. 8 Central Road Rawat, Rawalpindi (ELM-0086)	Glow-100 Fluorescence Immunoassay Analyzer Class A Shelf Life: 5 Years Fee: 5000 + 1000 Fee Slip No. 13643580187 & 652437943211 APL Diluent IVD diluent for Hematology analyzer Class: A Shelf Life: 2 years Fee:6000 Fee Slip No. 45981189 Pack size: 20L	Approved
6	Apex Biotechnologies, Plot No. 8 Central Road Rawat, Rawalpindi (ELM-0086)	APL CRT-4 Biochemistry Reagent for Electrolyte Analyzer Class: B Shelf Life: 2 years Fee:25000 Fee Slip No. 45981189 Pack size: 1x4 pouch	Approved
7	Apex Biotechnologies, Plot No. 8 Central Road Rawat, Rawalpindi (ELM-0086)	APL Lyse IVD Lytic Agent for Hematology Analyzer Class: A Shelf Life: 2 years Fee:6000 Fee Slip No. 645488517268 Pack size: 1L, 500mL	Approved.

8 Apex Biotechno No. 8 Central Rawalpindi (ELM-0086)	Road Rawat, Her And Cla She Fee	L Cleanse IVD C matology alyzer ass: A elf Life: 2 years a:6000 c Slip No. 6454885172 ck size: 1L, 5L		for	Approved
9. M/s Alsons Ind Ltd., S/18 S.I.T 75730 (ELM-0021) Approved Section Continuous Pos Pressure (CPAP/	C.E., Karachi, ICU Cla on She sitive Airway Fee	NNOVENT (AVB-10 J Ventilator ass C elf life: 05 Years o: 25,000/- o No: 716692778	00)		Keeping in view the reports on Electro-Medical Device Evaluation Form (Pakistan Manufactured Ventilators System) by Pakistan Engineering Council (PEC), Certification of safety of alnnovent issued by Advisor on Innovation-Pakistan Engineering Council (PEC) & Clinical Validation & DSMB reports of extended clinical trials of Alnnovent (AVB-100) and the decision of 52nd meeting of Clinical Studies committee (CSC), the case was deliberated in detail & approved the registration of product ALNNOVENT (AVB-100) ICU Ventilator.

$\frac{\text{REGISTRATION/ENLISTMENT OF MEDICAL DEVICES (CLASS A, B, C \& D)}{\text{FOR IMPORT (FORM-7A/6A)}}$

Name	Name
Address of Importer	SBK INTERNATIONAL,
	Address of Importer
	23, VALLEY ROAD, STREET 3, WESTRIDGE 1, RAWALPINDI
Detail of ELM/ELI	ELI-00100
Name	(LEGAL MANUFACTEURER)
Address of	Anqing Kangmingna Packaging Co. L:td KMN Industrial Park, Jingshi Road,
Manufacturer	Big Bridge Development Zone, Anqing Anhui, China
Brand Name	MEDIBELL

	(Packing material Pouches)
Decision	Approved

Name	Name		
Address of Importer	MOD Scientific Traders		
	Address of Importer		
	3-Syed Mouj Darya Road Lahore.		
Detail of ELM/ELI	ELI-00655		
Name	(LEGAL MANUFACTEURER)		
Address of	ZHE Jiang Orient Biotech Co Ltd		
Manufacturer	(Manufacturing site)		
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,		
	China		
Brand Name	Ace-check		
	Dengue NS1 Antigen		
Decision	Deferred since the applied product is not mentioned in provide CE		
	certificate.		

Case No.3

Name	Name	
Address of Importer	MOD Scientific Traders	
	Address of Importer	
	3-Syed Mouj Darya Road Lahore.	
Detail of ELM/ELI	ELI-00655	
Name	(LEGAL MANUFACTEURER)	
Address of	ZHE Jiang Orient Biotech Co Ltd	
Manufacturer	(Manufacturing site)	
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,	
	China	
Brand Name	Ace-check	
	H. Pylori Rapid Test	
Decision	Deferred since the applied product is not mentioned in provide CE	
	certificate.	

Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	Malaria Rapid Test
Decision	Deferred since the applied product is not mentioned in provide CE
	certificate.

Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	Hepatitis B Surface Antigen Rapid Test
Decision	Deferred since the applied product is not mentioned in provide CE
	certificate.

Case No.6

Case No.0			
Name	Name		
Address of Importer	MOD Scientific Traders		
	Address of Importer		
	3-Syed Mouj Darya Road Lahore.		
Detail of ELM/ELI	ELI-00655		
Name	(LEGAL MANUFACTEURER)		
Address of	ZHE Jiang Orient Biotech Co Ltd		
Manufacturer	(Manufacturing site)		
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,		
	China		
Brand Name	Ace-check		
	Tuberculosis IgG/IgM Antibody Rapid Test		
Decision	Deferred since the applied product is not mentioned in provide CE		
	certificate.		

Case 110.7	_ _	
Name	Name	
Address of Importer	MOD Scientific Traders	
	Address of Importer	
	3-Syed Mouj Darya Road Lahore.	
Detail of ELM/ELI	ELI-00655	
Name Address	(LEGAL MANUFACTEURER)	
of Manufacturer	ZHE Jiang Orient Biotech Co Ltd	
	(Manufacturing site)	
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,	
	China	
Brand Name	Ace-check	
	Hepatitis C Virus Rapid Test	
Decision	Deferred since the applied product is not mentioned in provide CE	
	certificate. Also provide the Design Examination certificate.	

Name	Name		
Address of Importer	MOD Scientific Traders		
	Address of Importer		
	3-Syed Mouj Darya Road Lahore.		
Detail of ELM/ELI	ELI-00655		
Name Address	(LEGAL MANUFACTEURER)		
of	ZHE Jiang Orient Biotech Co Ltd		
Manufacturer	(Manufacturing site)		
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,		
	China		
Brand Name	Ace-check		
	Syphilis Rapid Test Device		
Decision	Deferred since the applied product is not mentioned in provide CE		
	certificate.		

Case No.9

Case No.9	
Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of	ZHE Jiang Orient Biotech Co Ltd
Manufacturer	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	HIV 1/2 Human Immunodeficiency Virus Rapid Test
Decision	Deferred since the applied product is not mentioned in provide CE
	certificate.

Cast 110.10	
Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	Helicobacter Pylori Antigen Rapid Test (Feces)
Decision	Deferred since the applied product is not mentioned in provide CE
	certificate.

Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of	ZHE Jiang Orient Biotech Co Ltd
Manufacturer	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	Troponin I Rapid Test
Decision	Deferred since the applied product is not mentioned in provide CE
	certificate.

Case No.12

Case No.12	
Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	HCG Rapid Test
Decision	Approved

Name	Name
Address of Importer	MOD Scientific Traders
•	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site)
	3787#, East Yanguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang,
	China
Brand Name	Ace-check
	Fecal Occult Blood Rapid Test
Decision	Deferred since the applied product is not mentioned in provide CE certificate.

Case 110.14	
Name	Name
Address of Importer	MOD Scientific Traders
	Address of Importer
	3-Syed Mouj Darya Road Lahore.
Detail of ELM/ELI	ELI-00655
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	ZHE Jiang Orient Biotech Co Ltd
	(Manufacturing site): 3787#, East Yanguang Avenue, Dipu Street, Anji
	313300, Huzhou, Zhejiang, China
Brand Name	Ace-check
	LH Ovulation Rapid Test
Decision	Approved

Case No.15

Name	MED LAB SERVICES
Address of Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,
	Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	LEGAL MANUFACTEURER
Address of	HLB Panagene Co., Ltd
Manufacturer	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.
	Telephone numbers: +82 042 861 9295
	Fax numbers: +82 042 936 9290
	Email addresses: info@panagene.com
	Official website: www.panagene.com
	Status of the manufacturer: Publicly listed company
Brand Name	PNA Clamp™ KRAS Mutation Detection Kit
Decision	Approved

Name	MED LAB SERVICES
Address of Importer	
	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,
	Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023

Name	LEGAL MANUFACTEURER
Address of	HLB Panagene Co., Ltd
Manufacturer	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.
	Telephone numbers: +82 042 861 9295
	Fax numbers: +82 042 936 9290
	Email addresses: info@panagene.com
	Official website: www.panagene.com
	Status of the manufacturer: Publicly listed company
Name of exporting	Republic of Korea.
country	
Brand Name	PNAClamp TM BRAF Mutation Detection Kit
Decision	Approved

Case MU.17	
Name	MED LAB SERVICES
Address of Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
_	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial
	Center, Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	LEGAL MANUFACTEURER
Address of Manufacturer	HLB Panagene Co., Ltd
	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.
	Telephone numbers: +82 042 861 9295
	Fax numbers: +82 042 936 9290
	Email addresses: info@panagene.com
	Official website: www.panagene.com
	Status of the manufacturer: Publicly listed company
Brand Name	PNAClamp™ EGFR Mutation Detection Kit
Decision	Approved

Name	MED LAB SERVICES
Address of Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
_	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,
	Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	LEGAL MANUFACTEURER
Address of	HLB Panagene Co., Ltd
Manufacturer	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.

	Telephone numbers: +82 042 861 9295
	Fax numbers: +82 042 936 9290
	Email addresses: info@panagene.com
	Official website: www.panagene.com
	Status of the manufacturer: Publicly listed company
Brand Name	PNAClamp™ IDH1 Mutation Detection Kit
Decision	Approved

Cast 110.17	
Name	MED LAB SERVICES
Address of Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,
	Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
7.7	
Name	LEGAL MANUFACTEURER
Address of	HLB Panagene Co., Ltd
Manufacturer	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.
	Telephone numbers: +82 042 861 9295
	Fax numbers: +82 042 936 9290
	Email addresses: info@panagene.com
	Official website: www.panagene.com
	Status of the manufacturer: Publicly listed company
Brand Name	PNAClamp™ IDH2 Mutation Detection Kit
Decision	Approved

Name	MED LAB SERVICES
Address of Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,
	Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,
	Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	LEGAL MANUFACTEURER
	HLB Panagene Co., Ltd

Address of	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.	
Manufacturer	Telephone numbers: +82 042 861 9295	
	Fax numbers: +82 042 936 9290	
	Email addresses: info@panagene.com	
	Official website: www.panagene.com	
	Status of the manufacturer: Publicly listed company	
Brand Name	PNAClamp TM NRAS Mutation Detection Kit	
Decision	Approved	

Name	MED LAB SERVICES	
Address of Importer		
	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3,	
	Rawalpindi.	
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center,	
	Satellite Town, Rawalpindi	
Detail of	License no: ELI-00056	
ELM/ELI		
	• Date of issuance: 03/08/2018	
	• Applied for renewal: 25/05/2023	
Name	LEGAL MANUFACTEURER	
Address of	HLB Panagene Co., Ltd	
Manufacturer	Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea.	
	Telephone numbers: +82 042 861 9295	
	Fax numbers: +82 042 936 9290	
	Email addresses: info@panagene.com	
	Official website: www.panagene.com	
	Status of the manufacturer: Publicly listed company	
Brand Name	PNAClamp™ PIK3CA Mutation Detection Kit	
Decision	Approved	

_ase 110.22	
Name Address of	MED LAB SERVICES
Importer	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial
	Center, Satellite Town, Rawalpindi
Detail of	License no: ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	LEGAL MANUFACTEURER

Address of Manufacturer	HLB Panagene Co., Ltd Address: 54, Techno 10-ro, Yuesong-gu, Daejeon 34027, Republic of Korea. Telephone numbers: +82 042 861 9295 Fax numbers: +82 042 936 9290 Email addresses: info@panagene.com Official website: www.panagene.com Status of the manufacturer: Publicly listed company
Brand Name Decision	PNAClamp™ TERT Mutation Detection Kit Approved

ase 110.23	_
Name	MED LAB SERVICES
Address of Importer	
_	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme
	3, Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial
	Center, Satellite Town, Rawalpindi
Detail of	Establishment License No. ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
	**
Name	GeneProof a. s
Address of	
Manufacturer	Address: Vídeňská 101/119, Dolní Heršpice 619 00 Brno Czech
	Republic
	Tel no: +420 543 211 679
	Fax no: +420 516 770 824
	E-mail address: info@geneproof.com
	Website: http://www.geneproof.com
	Status of Manufacturer: joint-stock company
Brand Name	GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit
Decision	Approved

Name	MED LAB SERVICES
Address of Importer	
	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme
	3, Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial
	Center, Satellite Town, Rawalpindi
Detail of	Establishment License No. ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023

Name	GeneProof a. s
Address of	
Manufacturer	Address: Vídeňská 101/119, Dolní Heršpice 619 00 Brno Czech
	Republic
	Tel no: +420 543 211 679
	Fax no: +420 516 770 824
	E-mail address: info@geneproof.com
	Website: http://www.geneproof.com
	Status of Manufacturer: joint-stock company
Brand Name	GeneProof Epstein-Barr Virus (EBV) PCR Kit
Decision	Approved

ase No.25	
Name	MED LAB SERVICES
Address of Importer	
•	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme
	3, Rawalpindi.
	Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial
	Center, Satellite Town, Rawalpindi
Detail of	Establishment License No. ELI-00056
ELM/ELI	
	• Date of issuance: 03/08/2018
	• Applied for renewal: 25/05/2023
Name	GeneProof a. s
Address of	
Manufacturer	Address: Vídeňská 101/119, Dolní Heršpice 619 00 Brno Czech
	Republic
	Tel no: +420 543 211 679
	Fax no: +420 516 770 824
	E-mail address: info@geneproof.com
	Website: http://www.geneproof.com
	Status of Manufacturer: joint-stock company
Name of exporting	Czech Republic
country	
Brand Name	GeneProof Varicella-Zoster Virus (VZV) PCR Kit
Country of origin	FSC: Czech Republic (Original)
FSC	Validity Date: 14/02/2025
Decision	Approved

Name	S.J TRADERS
	Office No. 14, 3rd Floor, Majeed Plaza, Bank Road, Saddar,
Address of Importer	Rawalpindi
Detail of ELM / ELI	ELI-00531
Name	FIAB

Address of MANUFACTURER	SPA- SEDE LEGALE: VIA P. COSTOLI, 4-50039 VICCHIO-FIRENZE, ITALY
Brand Name	DEFEBRILLATION EURO DEFI PADS
Generic Name	DEFEBRILLATION EURO DEFI PADS
Decision	Approved

Name	S.J TRADERS
	Office No. 14, 3rd Floor, Majeed Plaza, Bank Road, Saddar,
Address of Importer	Rawalpindi
Detail of ELM / ELI	ELI-00531
Name	FIAB
Address of MANUFACTURER	SPA SEDE LEGALE: VIA P. COSTOLI, 4-50039 VICCHIO-
	FIRENZE, ITALY
Brand Name	FIAB
Generic Name	GROUNDING PADS
	Approved.
	The firm is advised to submit the fee & Application Form
Decision	for Reuseable grounding pads.

Case No. 28

Case 110. 20	
Name	S.J TRADERS
	Office No. 14, 3rd Floor, Majeed Plaza, Bank Road, Saddar,
Address of Importer	Rawalpindi
Detail of ELM / ELI	ELI-00531
Name	FIAB
Address of MANUFACTURER	SPA- SEDE LEGALE: VIA P. COSTOLI, 4-50039 VICCHIO-FIRENZE, ITALY
Brand Name	FIAB
Generic Name	Electrosurgical Pencils
	The board Approved both types but the firm will submit
	the fee & Application for Reusable Electro pencils before
Decision	issuance of Registration letter.

Name	Global Marketing Services
Address of Importer	Address of Importer
_	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M.A Med Alliance

	(Manufacturing site) M.A Med Alliance SA Rue de Rive 5 1260 Nyon Switzerland
Brand Name	SELUTION SLR™ 018 PTA Balloon Catheter
Decision	Approved. CE certificate was updated in the meeting

Name	Global Marketing Services
Address of Importer	Address of Importer
_	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M.A Med Alliance
	(Manufacturing site)
	M.A Med Alliance SA Rue de Rive 5 1260 Nyon Switzerland
Brand Name	Selution SLR TM 014 PTCA Balloon Catheter
Decision	Approved update in the meeting about LoA

Case No. 31

Case 110. 51	
Name	Global Marketing Services
Address of Importer	Address of Importer
	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	Abbott Medical (also known as St.Jude Medical), Puerto Rico, LLC, Lot
Manufacturer	A, Interior-No-2, St KM 67.5 Santana Industrial Park, Arecibo, PR USA,
	00612
	(Manufacturing site)
	Abbott Medical (also known as St.Jude Medical), Plot 102, Lebuhraya
	Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia,
	Country: Malaysia
	Abbott Medical (also known as St.Jude Medical), 15900 Valley View
	Court Sylmar, CA 91342, USA
Brand Name	Zenex MRI (Single Chamber Inductive Pacemaker, MR Conditional)
Decision	Approved update in the meeting about LoA

Name	Global Marketing Services
	E.
Address of Importer	Address of Importer
_	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	Abbott Medical (also known as St.Jude Medical), Puerto Rico, LLC, Lot A,
Manufacturer	Interior-No-2, St KM 67.5 Santana Industrial Park, Arecibo, PR USA,
	00612
	(Manufacturing site)

	Abbott Medical (also known as St.Jude Medical), Plot 102, Lebuhraya
	Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia,
	Country: Malaysia
	Abbott Medical (also known as St.Jude Medical), 15900 Valley View Court Sylmar, CA 91342, USA
Brand Name	Zenex MRI (Dual Chamber Inductive Pacemaker, MR Conditional)
Decision	Approved LOA was updared in the meeting

Cast 110. 55	-
Name	Name
Address of Importer	Global Marketing Services
	Address of Importer
	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	Abbott Medical (also known as St.Jude Medical), Puerto Rico, LLC, Lot
Manufacturer	A, Interior-No-2, St KM 67.5 Santana Industrial Park, Arecibo, PR USA,
	00612
	(Manufacturing site)
	Abbott Medical (also known as St.Jude Medical), Plot 102, Lebuhraya
	Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia,
	Country: Malaysia
	•
	Abbott Medical (also known as St.Jude Medical), 15900 Valley View
	Court Sylmar, CA 91342, USA
Brand Name	Zenus MRI (Single Chamber Inductive Pacemaker, MR Conditional)
	, ,
Decision	Approved LOA was updated in the meeting.

Name	Global Marketing Services
Address of Importer	Address of Importer
	111, Hali Road, Westridge 1, Rawalpindi, Pakistan
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	Abbott Medical (also known as St.Jude Medical), Puerto Rico, LLC, Lot
Manufacturer	A, Interior-No-2, St KM 67.5 Santana Industrial Park, Arecibo, PR USA,
	00612
	(Manufacturing site)
	Abbott Medical (also known as St.Jude Medical), Plot 102, Lebuhraya
	Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia,
	Country: Malaysia
	Abbott Medical (also known as St.Jude Medical), 15900 Valley View
	Court Sylmar, CA 91342, USA
Brand Name	Zenus MRI (Dual Chamber Inductive Pacemaker, MR Conditional)
Decision	Approved subject to submission of updated and notarized LOA.

Name	Name
Address of Importer	M/s S.J TRADERS
P	Address of Importer
	Office No. 14, 3 rd Floor, Majeed Plaza, Bank Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-00531
Name	FIAB
Address of	SPA - SEDE LEGALE: VIA
Manufacturer	P. COSTOLI, 4-50039
	VICCHIO - FIRENZE
	ITALY.
D IN	CDIVE EACY I CALLED A
Brand Name	SPIKE EASY LC ULTRA
Generic Name	SPIKE LC LEADS FOR TEMPORARY CARDIAC PACING
Decision	Approved.

Case No.36.

Cast 110.50.	
Name	Name
Address of Importer	M/s Hikmat Trading Company.
	Address of Importer
	Address: E/8, Naveed Bungalows, Block 17, Gulshan-e-Jauher, Karachi
Detail of ELM/ELI	ELI-00551
Name	(LEGAL MANUFACTEURER)
Address of	Shenzhen Medke Technology Co., Ltd
Manufacturer	401, 503, Bldg. A1, Anle Ind. Zone, No.172 Hancheng RD. Sanwei Community,
	Hangcheng Streer, Baoan District, Shenzhen, PEOPLE'S REPUBLIC OF
	CHINA 518126
	(Manufacturing site)
	Shenzhen Medke Technology Co., Ltd
	401, 503, Bldg. A1, Anle Ind. Zone, No.172 Hancheng RD. Sanwei Community,
	Hangcheng Streer, Baoan District, Shenzhen, PEOPLE'S REPUBLIC OF
	CHINA 518126
Brand Name	Disposable SpO2 Sensors
Decision	Approved subject to Brand name of the device.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
	Philips Medical Systems Nederland B.V

Address of	Address:
Manufacturer	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 3 M12
	(Image guide Therapy System)
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
_	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 5 M12
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Case No. 39

Case No. 39	
Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 5 M20
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips

	Azurion 7 B12
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 3 M15
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Case No. 42

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 7 M12
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 7 M20
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Azurion 7 B20
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Case No. 45

Case No. 45	
Name	Name
Address of Importer	Matora Digionics Pvt Ltd
	Address of Importer
	7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab
Detail of ELM/ELI	ELI-00083
Name	(LEGAL MANUFACTEURER)
Address of	Philips Medical Systems Nederland B.V
Manufacturer	Address:
	Veenpluis 6 5684PC Best, Netherlands
Brand Name	Philips
	Hemodynamic Application
Decision	Approved.
	The firm is advised to submit updated FQA certificate.

Name	Name
Address of Importer	M/s Vertex Medical Pvt Ltd.
	Address of Importer
	Address: 401-402, Block – F, Johar Town Lahore.
Detail of ELM/ELI	ELI-00150
Name	(LEGAL MANUFACTEURER)
Address of	Shanghai Drager Medical Instruments Co., Ltd. 3 #, No. 229 HuPo Road,
Manufacturer	Shanghai International Medical Zone, Pudong New Area 201321 Shanghai,
	People's Republic China
	(Manufacturing site)
	Shanghai Drager Medical Instruments Co., Ltd. 3 #, No. 229 HuPo Road,
	Shanghai International Medical Zone, Pudong New Area 201321 Shanghai,
	People's Republic China
Brand Name	Dräger
	Patient Monitor
Decision	The Board approved all types but the firm will submit fee for remaining
	two models before issuance of Registration letters.

Name	Name
Address of Importer	M/s Vertex Medical Pvt Ltd.
	Address of Importer
	Address: 401-402, Block – F, Johar Town Lahore.
Detail of ELM/ELI	ELI-00150
Name	(LEGAL MANUFACTEURER)
Address of	Drägerwerk AG & Co. KGaA Moislinger Allee 53–55, 23542 Lübeck, Germany
Manufacturer	
Brand Name	Dräger Atlan
	Anesthesia Workstation/ Anesthesia Machine
Decision	Approved.

Case No. 48

Case 110. 40	
Name	Name
Address of Importer	M/S Health Tec
_	Address of Importer
	10-B, Street 24, Valley Road, Westridge-1, Rawalpindi. Pakistan
Detail of ELI	ELI-00046
Name	(LEGAL MANUFACTEURER)
Address of	M/S SP Medical
Manufacturer	(Manufacturing site)
	Mollevej 1, DK-4653, Karise, Denmark.
Brand Name	Champion PTCA Guide Wire (PTCA Guide wire)
	CAR Type
Decision	Approved.

Case No. 49

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Hemodialysis Catheter Kit, single lumen
Decision	The board approved all three types but the firm will submit fee & Application
	Forms before issuance of registration letter.

Name	Name
Address of Importer	United Healthcare
_	Address of Importer

	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
D . '1 CELL/ELL	FI I 00202
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Central Venous Catheter Kit, Single Lumen
Decision	The board approved all three types but the firm will submit fee for remaining two
	types before issuance of registration letter.

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Disposable Silicone Foley Catheters
Decision	The board approved all three types but the firm will submit fee for remaining
	two types before issuance of registration letter.

Case No. 52

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Disposable Blood Pressure Transducers & Accessories
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293

Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Disposable Fistula Needles
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Disposable Stopcocks
Decision	Approved

Case No. 55

Name	Name
Address of	United Healthcare
Importer	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed
	Disposable Blood Lines
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Qingdao DMD Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113
	Qingdao, PEOPLE'S REPUBLIC OF CHINA
Brand Name	Safety

	Ligating Clip-Ti
Free Sales Certificate	Valid till: 25-04-2025
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Qingdao DMD Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 873 Heyuan Road, Hetao Street, Hongdao Economic Zone, 266113
	Qingdao, PEOPLE'S REPUBLIC OF CHINA
Brand Name	Safety
	Ligating Clip-Polymer
Decision	Approved

Case No. 58

Name	Name
Address of Importer	United Healthcare
_	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFSILK
	Sterile Non-Absorbable Silk Braided Suture with or without Needles
Decision	Approved

Name	Name
Address of Importer	United Healthcare
_	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFILON
	Sterile Non-Absorbable Nylon/Polyamide Monofilament Suture with or
	without Needles
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFIBOND
	Sterile Non-Absorbable Polyester Braided Suture With Or Without Needles
Decision	Approved

Case No. 61

asc 110. U1	
Name	Name
Address of Importer	United Healthcare
•	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFLENE
	Sterile Non-Absorbable Polypropylene Monofilament Suture With Or Without
	Needles
Decision	Approved

use 110. 02		
Name	Name	
Address of Importer	United Healthcare	
	Address of Importer	
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.	
Detail of ELM/ELI	ELI- 00293	
Name	LEGAL MANUFACTURER:	
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.	
Manufacturer	Manufacturing Site:	
	No. 128 West Meigao Road, Huaian, Jiangsu, China	
Brand Name	SAFCRYL 910	
	Sterile Absorbable Polyglactin 910 (PGLA) Suture With Or Without Needles	
Decision	Approved	

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
D . 1 CELM/ELL	ELL 00202
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFCRYL
	Sterile Absorbable Polyglycolic Acid (PGA) Suture With Or Without Needles
Decision	Approved

Case No. 64

asc 110. UT	
Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFANON
	Sterile Absorbable Polydioxanone (PDO) Suture With Or Without Needles
Decision	Approved

Case No. 65

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaian Pingan Medical Instrument Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 128 West Meigao Road, Huaian, Jiangsu, China
Brand Name	SAFARONE
	Sterile Absorbable Poliglecaprone (PGCL) Suture, With Or Without Needles
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.

Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Guangdong Baihe Medical Technology Co., Ltd
Manufacturer	Manufacturing Site:
	No. 89 Taoyuan East Road, Nanhai, Foshan, Guangdong City, China
Brand Name	Starmed Disposable Hemodialysers
Decision	Approved

Name	Name
Address of Importer	United Healthcare
_	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s. Innolatex SDN BDN
Manufacturer	Manufacturing Site:
	Lot No., 591& 594, Persiaran Raja Lumu, Pandamaran Industrial Estate Port
	Klang, 42000 Pelabuhan Klang, Selangor, Malaysia
Brand Name	Safe In Ultra (Plain)
Decision	Approved

Case No. 68

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s. Innolatex SDN BDN
Manufacturer	
	Manufacturing Site:
	Lot No., 591& 594, Persiaran Raja Lumu, Pandamaran Industrial Estate Port
	Klang, 42000 Pelabuhan Klang, Selangor, Malaysia
Brand Name	Safe In Ultra (Dotted)
Decision	Approved

Name	Name
Address of Importer	United Healthcare
•	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China

Brand Name	STAR RAPID (ABSORBABLE SUTURE WITH OR WITHOUT NEEDLE-RAPID PGA)
Decision	Appoved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARMONO
	ABSORBABLE PGCL MONOFAST SUTURE WITH OR WITHOUT
	NEEDLE
Decision	Appoved

Case No. 71

Case No. 71	
Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARGEN
	ABSORBABLE PDO (POLYDIOXANONE)SUTURE WITH OR WITHOUT
	NEEDLE
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARCRYL
	ABSORBABLE PGA (POLYGLYCOLIC) SUTURE WITH OR WITHOUT
	NEEDLES
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARCRYL 910
	(ABSORBABLE SUTURE WITH OR WITHOUT NEEDLES-PGLA
	(GLYCOLIDE-CO-L-LACTIDE)
Decision	Approved

Case No. 74

Case No. 74	
Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARSILK (NON-ABSORBABLE SUTURE WITH OR WITHOUT
	NEEDLE-SILK BRAIDED SUTURE)
Decision	Approved

Case 110. 73	·
Name	Name
Address of Importer	United Healthcare
_	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARBOND
	(NON-ABSORBABLE SUTURE WITH OR WITHOUT NEEDLES-
	POLYESTER BRAIDED SUTURE)
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARLON (NON-ABSORBABLE SUTURE WITH OR WITHOUT
	NEEDLES-NYLON SUTURE)
Decision	Approved

Case No. 77

Case 110. 11	
Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STARLENE
	(NON-ABSORBABLE SUTURE WITH OR WITHOUT NEEDLES-
	POLYPROPYLENE SUTURE)
Decision	Approved

Name	Name
Address of Importer	United Healthcare
•	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STAR
	STERILE SURIGICAL BLADE-CARBON STEEL
Decision	Approved

Name	Name
Address of Importer	United Healthcare
	Address of Importer
	Plot 330/A 2 nd Floor, Block 3, DMCHS, Alamgir Road, Karachi.
Detail of ELM/ELI	ELI- 00293
Name	LEGAL MANUFACTURER:
Address of	M/s Huaiyin Medical Instruments Co., Ltd.
Manufacturer	Manufacturing Site:
	No. 8 West Ming Yuan Road, 223003, Huaian China
Brand Name	STAR
	STERILE SURIGICAL BLADE-STAINLESS STEEL
Decision	Approved

Case No. 80

Case No. ou	
Name	Name
Address of Importer	Krestacorp
	Address of Importer
	76-C, 3 rd Floor, SuitNo. 02, Khayaban-e-jami, sreet No. 09, D.H.A Phase 07,
	Karachi
Detail of ELM/ELI	ELI- 00258
Name	LEGAL MANUFACTURER:
Address of	M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt.
Manufacturer	34, Jalan Johor, 82000, Pontian Johor DarulTakzim, Malaysia.
Brand Name	KLIMAX FLAME & ICE
	Natural rubber Latex Male condoms
Decision	Deferred for the provision of original documents and original, valid and
	attested FSC.

Name	Name
Address of Importer	Krestacorp
	Address of Importer 76-C, 3 rd Floor, SuitNo. 02, Khayaban-e-jami, sreet No. 09, D.H.A Phase 07, Karachi
Detail of ELM/ELI	ELI- 00258
Name	LEGAL MANUFACTURER:
Address of	M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt.
Manufacturer	34, Jalan Johor, 82000, Pontian Johor DarulTakzim, Malaysia.
Brand Name	KLIMAX XL
	Natural rubber Latex Male condoms
Decision	Approved subject to submission of original LOA, notarized ISO 13485and CE certificate.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
Manufacturer	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	C-reactive Protein (hsCRP&CRP) Rapid Test Kit
	·
Decision	Approved. The firm is advised to submit valid ISO 13485 certificate.

Case No. 83

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
Manufacturer	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	D-Dimer (DD) Rapid Test Kit
	· · · · · ·
Decision	Approved subject to brand name and valid ISO 13485 certificate.

Name	Name: Sure Bio- Diagnostics & Pharmaceuticals
Address of Importer	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
Manufacturer	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	Hemoglobin A1c (HbA1c) Rapid test Kit
Decision	Approved subject to brand name and valid ISO 13485 certificate.

Case 110. 05	
Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat
	Express Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of Manufacturer	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun
	1st Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	Cardiac Troponin I (cTnI) Rapid Test Kit
Decision	Approved subject to brand name and valid ISO 13485 certificate.

Case No. 86

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
radics of importer	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
D-4-21 - f	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
Manufacturer	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	Thyroid Hormones
	Triiodothyronine (T3)
	Thyroxine (T4)
	Free T3 (FT3)
	Free T4 (FT4)
	Thyroid-stimulating Hormone (TSH)
Decision	The board approved all the applied products as kits but the firm will submit fee
	for each kit before the issuance of registration letter.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
	M/s. Guangzhou Decheng Biotechnology Co., Ltd.

Address of	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
Manufacturer	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	Vitamin D Rapid Test Kit
Decision	Approved subject to brand name and valid ISO 13485 certificate.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Guangzhou Decheng Biotechnology Co., Ltd.
Manufacturer	Company Address: Floor 3/4/5/7, Building A1, No.12, Nanyun 1st
	Road, Science City Guangzhou China
	Contact: +86-020-2855-7192
	Website: www.docheckbio.com
Brand Name	Immunofluorescence Analyzer and Incubator
Decision	The board approved both the products subject to Brand name and the firm will
	submit fee & for incunbator before the issuance of registration letter.

Case No. 89	
Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Blood Gas Analyzer PT1000
Decision	Approved subject to brand name.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
_	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Blood Gas Testing Cartridge
Decision	Approved subject to brand name.

Case No. 91

Case 110. 71	
Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Cardiac Marker hs-cTnI
Decision	Approved subject to brand name.

Case 110. 72	
Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.

Address of Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator. No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, China Contact: +86-27-65523649 Website: www.easydiagnosis.com
Brand Name	N-Terminal pro brain Natriuretic Peptide
Decision	Approved subject to brand name.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Creatine Kinase Isoenzyme (CK-MB) Test Kit (Immunofluorescence Method)
Decision	Approved subject to brand name.

Name	Name: Sure Bio- Diagnostics & Pharmaceuticals
Address of Importer	Address of Importer
•	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Cytokines, Interleukin 6 (IL-6) Test Kit
Decision	Approved subject to brand name.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
_	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Fluorescence Immunity Analyzer Model: QFT9000
Decision	Approved subject to brand name.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Thyroid Function Marker (Cluster of FT3- Free Triiodothyronine
	(fT3) Test Kit (Immunofluorescence Method,
	FT4- Free Thyroxine (FT4) Test Kit (Immunofluorescence Method,
	T3- Total Triiodothyronine (T3) Test Kit (Immunofluorescence Method,
	T4 Total Thyroxine (T4) Test Kit (Immunofluorescence Method,
	TSH Thyroid Stimulating Hormone (TSH) Test Kit.
Decision	The board approved all the applied products as kits subject to Brand name but
	the firm will submit fee for each kit before the issuance of registration letter.

Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
•	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	Vitamin D Test Kit
Decision	Approved subject to brand name.

Case No. 98

Case 110. 70	
Name	Name: Sure Bio- Diagnostics & Pharmaceuticals
Address of Importer	Address of Importer
_	EE-10, Defence View Phase-II, Near Igra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan
	Optics Valley International Biopharmaceutical Enterprise Accelerator.
	No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074
	Wuhan, China
	Contact: +86-27-65523649
	Website: www.easydiagnosis.com
Brand Name	{Hemoglobin AIC (HbAIc) Test Kit}
Decision	Approved subject to brand name.

Cuse 1101 77	
Name	Name
Address of Importer	Sure Bio- Diagnostics & Pharmaceuticals
	Address of Importer
	EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express
	Way, Karachi.
Detail of	Establishment License No. ELI-00084
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Manufacturer	

	Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator. No.388, Gaoxin 2 nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, China Contact: +86-27-65523649 Website: www.easydiagnosis.com
Brand Name	Easy Diagnosis Biomedicine D-Dimer (cluster of D Dimer, Cystatin C, Ferritin (Fer) Test, Gastrin 17, Procalcitonin (PCT) Test Kit, PGI/PGIIcombo test kit, S100-β protein (S100-β) Test Kit, Serum Amyloid A (SAA) Test Kit, β Human Chorionic Gonadotropin (β-HCG) Test Kit, Beta 2 Microglobulin (β2-MG) Test Kit)
Decision	Deferred. Multiple products applied. Apply separately for each depending upon the Class of Medical device.

Case No. 100	
Name	M/s Biotech Services, 746- Shadman-1 Lahore (Pakistan)
Address of Importer	
Detail of ELM/ELI	ELI- 00715
Name	(Legal Manufacturer)
Address of	INNOMED MEDICAL ZRT.,
Manufacturer	(Manufacturing Site); 1146-Budapest, Szabó József U. 12. Hungary
Duand Name	CardioAid® 360-B
Brand Name	Defibrillator
Decision	The board approved all 3 types but the firm will submit fee & Form 7 for each
	type before issuance of Registration letter.

Case 101:

case 101.	
Name	Name: F.W Distributor
Address of Importer	Address of Importer
	Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-00221
Name	(Legal Manufacturer)
Address of	Coloplast A/A
Manufacturer	(Manufacturing site)
	Holtedam 1, 3050 Humlebaek, Denmark
Brand Name	Folysil Foley Silicone catheter
Decision	Deferred for the submission of following shortcomings:
	Updated LOA and FSC.
	Stability Studies for the claimed shelf life.
	Updated & notarized ISO 13485 & FQA certificates.

Case 102:

Name	Name: Gulfam Brothers
Address of Importer	Address of Importer
	Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore
	H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore
Detail of ELM/ELI	ELI-00028
Name	(Legal Manufacteurer)

Address of Manufacturer	Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI. (Manufacturing site)
	Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.
Brand Name	CONFORT Vacuum Assisted Wound Closure Set with Silver Vacuum Assisted Wound Closure Set with Silver
Decision	Deferred for submission of valid FSC, ISO 13485 and CE certificate. Revised Form-7A duly signed and stamped.

Case 103:

Name	Name: Gulfam Brothers
Address of Importer	Address of Importer
	Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore
	H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore
Detail of ELM/ELI	ELI-00028
Name	(Legal Manufacteurer)
Address of	Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI.
Manufacturer	(Manufacturing site)
	Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.
Brand Name	CONFORT Vacuum Assisted Wound Closure Set Hydrophobic
	Vacuum Assisted Wound Closure Set Hydrophobic
Decision	Deferred for the submission of valid FSC, ISO 13485 and Ce
	certificate.Revised Form-7A duly signed and stamped.

Case 104:

Name	Name: Gulfam Brothers
Address of	Address of Importer
Importer	Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore
	H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore
Detail of ELM/ELI	ELI-00028
Name	(Legal Manufacteurer)
Address of	Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI.
Manufacturer	(Manufacturing site)
	Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.
Brand Name	CONFORT Vacuum Assisted Wound Closure Set Spiral
	Vacuum Assisted Wound Closure Spiral
Decision	Deferred for the submission of valid FSC, ISO 13485 and Ce certificate. Revised
	Form-7A duly signed and stamped.

Case 105:

Cast 103.	
Name	Name: Gulfam Brothers
Address of Importer	Address of Importer
	Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore
	H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore
Detail of ELM/ELI	ELI-00028
Name	(Legal Manufacteurer)

Address of Manufacturer	Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI. (Manufacturing site)
	Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.
Brand Name	CONFORT Canister 1000ML (Stop & Filter) Canister 1000ML (Stops& Filter)
Decision	Approved subject to submission of valid FSC, ISO 13485 and CE certificate. Revised Form-7A duly signed and stamped.

Case 106:

Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacteurer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Toxoplasma IgG
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 107:

_asc 107.	
Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacteurer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Toxoplasma IgM (Code: 81041)
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 108:

Name	Name
Address of Importer	Future Scientific
	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacteurer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	

	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Herpes Simplex 1+2 IgG
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 109:

Name	Name
Address of Importer	Future Scientific
	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Herpes Simplex 1+2 IgM
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 110:

_asc 110.	
Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacteurer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Rubella IgG
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 111:

Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacteurer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Rubella IgM
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 112:

Name	Name
Address of Importer	Sorabjee Patel & Co.
	Address of Importer
	45 Badri Building I.I Chundrigar Road, Karachi
Detail of ELM/ELI	ELI-00067
Name	(Legal Manufacteurer)
Address of	Rayner Intraocular Lenses Limited
Manufacturer	(Manufacturing site)
	The Ridley Innovation Centre 10 Dominion Way Worthing West Sussex BN14 8AQ, United Kingdom
Brand Name	RayOne EMV Toric W00-RAO210T Enhanced Monofocal IOL
Decision	Approved

Case 113:

Name	Name
Address of Importer	Sorabjee Patel & Co.
	Address of Importer
	45 Badri Building I.I Chundrigar Road, Karachi
Detail of ELM/ELI	ELI-00067
Name	(Legal Manufacteurer)
Address of	Rayner Intraocular Lenses Limited
Manufacturer	(Manufacturing site)
	The Ridley Innovation Centre 10 Dominion Way Worthing West Sussex BN14 8AQ, United Kingdom
Brand Name	RayOne Trifocal Toric W00-RAO613Z
Decision	Approved

Case 114:

Name	Name
Address of Importer	Sorabjee Patel & Co.
	Address of Importer
	45 Badri Building I.I Chundrigar Road, Karachi
Detail of ELM/ELI	ELI-00067
Name	(Legal Manufacturer)
Address of	Rayner Intraocular Lenses Limited
Manufacturer	(Manufacturing site)
	The Ridley Innovation Centre 10 Dominion Way Worthing West Sussex BN14 8AQ, United Kingdom
Brand Name	EMV W00-RAO200E
	Enhanced Monofocal IOL
Decision	Approved

Case 115:

Name	Name
Address of Importer	Wirha & Co.
	Address of Importer
	First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-01261
Name	(Legal Manufacturer)
Address of	Sozhou Laishi Transfusion Equipment Co.,
Manufacturer	(Manufacturing site)
	Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China
Brand Name	Suzhou Disposable Plastic Blood Bag Single Bag
Decision	Deferred for the provision of updated and notarized DEC certificates

Case 116:

Name	Name
Address of Importer	Wirha & Co.
	Address of Importer
	First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-01261
Name	(Legal Manufacturer)
Address of	Sozhou Laishi Transfusion Equipment Co.,
Manufacturer	(Manufacturing site)
	Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China
Brand Name	Suzhou Disposable Plastic Blood Bag Double Bag
Decision	Deferred for the provision of updated and notarized DEC certificates

Case 117:

Name	Name
Address of Importer	Wirha & Co.
	Address of Importer
	First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-01261
Name	(Legal Manufacturer)
Address of	Sozhou Laishi Transfusion Equipment Co.,
Manufacturer	(Manufacturing site)
	Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China
Brand Name	Suzhou Disposable Plastic Blood Bag Triple Bag
Decision	Deferred for the provision of updated and notarized DEC certificates

Case 118:

Name	Name: Wirha & Co.
Address of Importer	Address of Importer
	First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-01261
Name	(Legal Manufacteurer)
Address of	Sozhou Laishi Transfusion Equipment Co.,
Manufacturer	(Manufacturing site)
	Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China
Brand Name	Suzhou Disposable Plastic Blood Bag Quadruple Bags
Decision	Deferred for the provision of updated and notarized DEC certificates

Case 119:

Name	Name: Wirha & Co.
Address of Importer	Address of Importer
	First Floor A1 Haj Plaza 111/D, Murree Road, Saddar, Rawalpindi
Detail of ELM/ELI	ELI-01261
Name	(Legal Manufacturer): Sozhou Laishi Transfusion Equipment Co.,
Address of	(Manufacturing site)
Manufacturer	Changsheng Rd., Tongli Town, Wujiang District, Suzhou City, 215217 Jiangsu Province, P.R.China
Brand Name	Suzhou Transfusion Sets with Needle for Single Use
Decision	Approved.
	The firm is advised to submit the updated & notarized CE/FQA certificate.

Case 120:

Name	Name: Cardio Life
Address of Importer	Address of Importer
_	House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3
	Rawalpindi
Detail of ELM/ELI	ELI-00984
Name	(Legal Manufacteurer): Bioline Fios Cirurgicos LTDA
Address of	(Manufacturing site)
Manufacturer	AV. Maranhao, N 500, Bairro Jundiai, Cep 75.110-470 Anapolis – GO Brazil
Brand Name	WAXBIO-CERA PARA OSSO
	Bone Wax-Wax Bio Sterile Surgical Hemostates
Decision	Deferred for the provision of following:
	Credentials.
	Class of medical device
	ISO 13485 in Portuguese, provide English version.
	CE & Ref. FSC.
	Manufacturing and stability studies.
	EP Checklist

Case 121:

Jasc 121.	
Name	Name: Cardio Life
Address of Importer	Address of Importer
	House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3
	Rawalpindi
Detail of ELM/ELI	ELI-00984
Name	(Legal Manufacteurer)
Address of	Bioline Fios Cirurgicos LTDA
Manufacturer	(Manufacturing site)
	AV. Maranhao, N 500, Bairro Jundiai, Cep 75.110-470 Anapolis – GO Brazil
Brand Name	Biofita-Surgical-Tapes
Decision	Deferred for the provision of following:
	Credentials.
	ISO 13485 in Portuguese, provide English version.
	CE & Ref. FSC.
	Manufacturing and stability studies.
	EP Checklist

Case 123:

ase 123:	
Name	Name: Radiant Medical (Pvt) Ltd.,
Address of Importer	Address of Importer
	06-Sher Shah Block New Garden Town, Lahore
Detail of ELM/ELI	ELI-00135
Name	(Legal Manufacteurer)
Address of	Gemss Healthcare Co., Ltd.,
Manufacturer	(Manufacturing site)
	1F, 822, Bogwang-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10952, Republic of Korea
Brand Name	HORIZON X-Ray Machine
Decision	Deferred for the provision of following:
	Legal Agreement is between M/s Carestream Health, INC, New York, USA and M/s Radiant Medical Private Limited, Lahore. Whereas the product is manufactured by M/s Gemss Healthcare Co., Ltd.,1F, 822, Bogwang-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10952, Republic of Korea. Provided linkup letter between M/s Carestream Health, INC, New York, USA and M/s Gemss Healthcare Co., Ltd, Korea. XVISION is to apply separately.

Case 124:

Name	Name
Address of Importer	Dove Pharma Co.,
	Address of Importer
	21-G/1 Johar Town, Lahore
Detail of ELM/ELI	ELI-00135
Name	(Legal Manufacteurer)

Address of Manufacturer	SOTHEMA, (Manufacturing site) I.Z Bouskoura, Casablanca (P.O. Box N° 1, 27182, Morocco
Brand Name	Artrovial Hyaluronic Acid ready to use syringe
Decision	Deferred for the provision of following: Updated & notarized LOA Updated & notarized ISO Updated & notarized FQA Updated & attested FSC Credential as per MDB- 3 rd meeting

Case 125:

Name	Name
Address of Importer	Chogori Medtech Private Limited.,
	Address of Importer
	15-UGF Landmark Plaza, Registered Office, , Jail Road, Gulberg III, Lahore
Detail of ELM/ELI	ELI-01042
Name	(Legal Manufacteurer)
Address of	Pressure Products Medical Device Manufacturing
Manufacturer	(Manufacturing site)
	1 School Street, Morton, PA19070, USA
Brand Name	SafeSept
	Transseptal Guidewire
Decision	Approved subject to updated FQA and DEC.
	Stability studies data for the claimed shelf life.

Case 126:

Name	Name
Address of Importer	Medicamp International
	Address of Importer
	Office No. 1, First Floor, Raja Naseer Plaza, New Abadi Morgah, Rawalpindi
Detail of ELM/ELI	ELI-00200
Name	(Legal Manufacteurer)
Address of	Changzhou WeiPu Medical Devices co. Ltd.,
Manufacturer	(Manufacturing site)
	No. 1-5, ChuangXin Avenue, Xinbei District, Changzhou Jiangsu,China
Brand Name	Weipu Medical
	Disposable Endo Linear Cutter Stapler and Reloading Unit
Decision	Approved Disposable Endo Linear Cutter subject to updated and original
	documents.
	Updated FSC, FQA certificate and Stability studies data for the claimed shelf
	life.
	Firm is advisred to apply separately for Linear Stapler and reloads as well and separate the applied codes accordingly.

Case 127:

Name	Name
Address of Importer	Aesthetic Life
	Address of Importer
	4 th Floor, Plot 16-C, Ittehad Commercial Area, , Khyaban e Nishat, DHA Phase
	VI, Karachi
Detail of ELM/ELI	ELI-01029
Name	(Legal Manufacteurer)
Address of	IBSA Farmaceutici Italia Srl
Manufacturer	(Manufacturing site)
	Via Martiri di Cefalonia 2 -26900 Lodi, Italy
Brand Name	Profhilo
	Hilow Hyaluronic Acid Sodium Salt for Intradermal Use
Decision	Approved

Case 128:

Name	Name
Address of Importer	Aesthetic Life
	Address of Importer
	4 th Floor, Plot 16-C, Ittehad Commercial Area, , Khyaban e Nishat, DHA Phase
	VI, Karachi
Detail of ELM/ELI	ELI-01029
Name	(Legal Manufacteurer)
Address of	IBSA Farmaceutici Italia Srl
Manufacturer	(Manufacturing site)
	Via Martiri di Cefalonia 2 -26900 Lodi, Italy
Brand Name	Profhilo Body
	Hilow Hyaluronic Acid Sodium Salt for Intradermal Use
Decision	Approved

Case 129:

Name	Name: Aesthetic Life
Address of Importer	Address of Importer
	4 th Floor, Plot 16-C, Ittehad Commercial Area, , Khyaban e Nishat, DHA Phase
	VI, Karachi
Detail of ELM/ELI	ELI-01029
Name	(Legal Manufacteurer): Euromi Biosciences
Address of	(Manufacturing site)
Manufacturer	Zoning Industriel des Plenesses 11 Rue Des Nouvelles Technologies 4821 Andrimont, Belgium.
Brand Name	Cereform®
	Round Shape Smooth Silicone Gel Filled Breast Implants
Decision	Approved subject to valid Design Examination certificate and codes of the applied product.

Case 130:

Name	Name
Address of Importer	Aesthetic Life
	Address of Importer
	4 th Floor, Plot 16-C, Ittehad Commercial Area, , Khyaban e Nishat, DHA Phase
	VI, Karachi
Detail of ELM/ELI	ELI-01029
Name	(Legal Manufacteurer)
Address of	Zerone Co., Ltd., (Shini IT UTO Bldg, Danjeong-dong)
Manufacturer	(Manufacturing site)
	810, LS-ro 13, Gunpo-si, Gyeonggi-do, Republic of Korea
Brand Name	Ultra-Z
	Ultrasonic Surgical Unit
Decision	Approved subject to submission of valid CE and DEC.

Case 131:

Name	Name
Address of Importer	Ontech Corporation
	Address of Importer
	B-154, Block 13-D/2, Gulshan-e-Iqbal, Karachi
Detail of ELM/ELI	ELI-00289
Name	(Legal Manufacteurer)
Address of	Quanta System S.p.A
Manufacturer	(Manufacturing site)
	Via Acquedotto 109 21017 Samarate (VA) Italy
Brand Name	LaserClast Thulium Power
	Thulium Fiber Surgical Laser
Decision	Approved subject to submission of valid ISO 13485 and CE certificate.

Case 131:

Name	Name
Address of Importer	Medisurg Innovatives Health Care (Private) Limited.
	Address of Importer
	Suite No. 106, Business Avenue PECHS, Shahrah-e-Faisal, Karachi
Detail of ELM/ELI	ELI-00242
Name	(Legal Manufacteurer)
Address of	Optimed Medizinische Instrumente GmbH
Manufacturer	(Manufacturing site)
	Ferdinand-Porsche-Strasse 11, 76275 Ettlingen, Germany
Brand Name	Tentos
	Auto-expansible stent system(4F/5F)
Decision	Approved subject to submission of updated ISO 13485 certificate.

Case 132:

Name	Name
Address of Importer	Taj Diagnostics
	Address of Importer
	Shop No. G-166, Maryam Market, M.A Jinnah Road, Saddar, Karachi
Detail of ELM/ELI	ELI-00589
Name	(Legal Manufacteurer)
Address of	InTec Products, INC,
Manufacturer	(Manufacturing site)
	332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022, Xiamen, Fujian, P.R. China
Brand Name	InTec
	Rapid Anti-HCV Test
Decision	Approved.
	The firm is advised to submit updated CE and DEC certificate.

Case 133:

Name	Name
Address of	Taj Diagnostics
Importer	Address of Importer
	Shop No. G-166, Maryam Market, M.A Jinnah Road, Saddar, Karachi
Detail of ELM/ELI	ELI-00589
Name	(Legal Manufacturer)
Address of	InTec Products, INC,
Manufacturer	(Manufacturing site)
	332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022, Xiamen, Fujian, P.R. China
Brand Name	InTec
	One Step Anti -HIV (1&2) Test
Decision	Approved subject to submission of valid CE and DEC.

Case 134:

Name	Name
Address of Importer	Medtronic Pakistan (Pvt) Ltd.,
	Address of Importer
	Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09,
	Clifton,Karachi
Detail of ELM/ELI	ELI-00273
Name	(Legal Manufacturer)
Address of	Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA, 55432
Manufacturer	(Manufacturing site)
	Covidien Located at Michael Collins Road, H91, W9N4 Mervue, Galway, Ireland
Brand Name	Nitron Cryoconsole
	Cryoconsole
Decision	Approved

Case 135:

Name	Name
Address of	Med Art Pakistan
Importer	Address of Importer
	A-175 Block 13-C KDA Scheme 24, Gulshan-e-Iqbal, Karachi
Detail of ELM/ELI	ELI-00024
Name	(Legal Manufacteurer)
Address of	Biopolymer GmbH & Co.
Manufacturer	(Manufacturing site)
	KG Wahlsmuhler Strabe 18, 19073 Dummer
Brand Name	Crespine Gel
	(2ml refilled Syringe)
Decision	Approved subject to submission of valid CE and DEC.

Case 136:

Name	Name
Address of Importer	Getz Pharma (Pvt) Ltd.,
	Address of Importer
	Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
Detail of ELM/ELI	ELI-00471
Name	(Legal Manufacteurer)
Address of	Jiangsu Kanghua Medical Equipment Co. Ltd.,
Manufacturer	(Manufacturing site)
	Sanhekou Changzhou, Jiangsu, 213115, P.R. China
Brand Name	Semaget
	Disposable Syringe
Decision	Approved

Case 137

Name	Name
Address of Importer	Imtiaz Brothers
	Address of Importer
	Suite No. 7B, 2 nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore
Detail of ELM/ELI	ELI-00133
Name	(Legal Manufacteurer)
Address of	Life Medical Equipment (Guangzhou) Co., Ltd.,
Manufacturer	(Manufacturing site)
	5 th Floor, 13 Building, 827 Xicha Road, Baiyun District, Guangzhou, 510407, P.R. China
Brand Name	Life Medical Arterial Venous (A.V) Cannula (Butterfly Kit)
Decision	Approved.
	The firm is advised to submit updated ISO 13485 and CE certificate.

Case 138:

Name	Name
Address of Importer	Imtiaz Brothers
	Address of Importer
	Suite No. 7B, 2 nd Floor, Abrar Business Center, 25 Main Wahdat Road,
	Lahore
Detail of ELM/ELI	ELI-00133
Name	(Legal Manufacturer)
Address of	Copper Medical Technology Co., Ltd,
Manufacturer	(Manufacturing site)
	Factory Building B1 (101-201) Glory Industrial Factory Zone, No. 2 Baolong 5 Road, Longgang, Shenzhen, 518116 Guangdong, People's Republic of China
Brand Name	Copper Disposable Ureteral Stent Set
Decision	Approved subject to submission of valid CE certificate.

Case 139:

<u> </u>	
Name	Name
Address of Importer	Imtiaz Brothers
	Address of Importer
	Suite No. 7B, 2 nd Floor, Abrar Business Center, 25 Main Wahdat Road,
	Lahore
Detail of ELM/ELI	ELI-00133
Name	(Legal Manufacturer)
Address of	Shandong Ruyue Medical Technology Co., LTd.,
Manufacturer	(Manufacturing site)
	No. 555, New 5 th Road (Northof Xinwu Road, West of Gaojiu Road), High Tech Industrial Development Zone, Binzhou City, 256600 Shandong, P.R. China
Brand Name	Ruyue
	Disposable Infusion Set with Needle
Decision	Approved subject to submission of valid CE certificate.

Name	Name	
Address of Importer	M/s Popular International (Pvt) Ltd,	
	Address of Importer	
	141 Justice Inamullah road ,Block 7 & 8 , KMCHS ,Karachi, Sindh, Pakistan	
Detail of ELM/ELI	ELI-00091	
Name	(LEGAL MANUFACTEURER)	
Address of	M/s Wuhan Gigaa Optronics Technology Co. Ltd. 5,6/F, Unit A,B, Building B8,	
Manufacturer	Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake	
	Development Zone, Wuhan	
Brand Name	GIGAA LASER	
	MEDICAL DIODE LASER SYSTEM	
Decision	Approved	

Name	Name	
Address of Importer	M/s Popular International (Pvt) Ltd,	
	Address of Importer	
	141 Justice Inamullah road ,Block 7 & 8 , KMCHS ,Karachi, Sindh, Pakistan	
Detail of ELM/ELI	ELI-00091	
Name	Legal Manufacturer:	
Address of	M/s INTEGRA LIFESCIENCES, 1100 Campus Drive, Princeton New Jersey	
Manufacturer	08540	
	Manufactured by:	
	M/s Integra Lifesciences Corporation 4900 Charlemar Drive, Building A	
	Cincinnati, Oh 45227	
	M/s Integra Lifesciences (Ireland) Limited Ida Buisiness and Technology Park	
	Sragh Tullamore, Offaly Ireland	
	M/s Integra Neurosciences Pr Road 402 North, Km 1.2 Anasco, Pr Usa 00610	
Brand Name	CUSA CLARITY	
	(ULTRASONIC ASPIRATION SYSTEM)	
Decision	Approved.	
	Original FSC is submitted.	

Case No. 142

Name	Name
Address of Importer	M/s Popular International (Pvt) Ltd,
	Address of Importer
	141 Justice Inamullah road ,Block 7 & 8 , KMCHS ,Karachi, Sindh, Pakistan
Detail of ELM/ELI	ELI-00091
Name	Legal Manufacturer:
Address of	M/s INTEGRA LIFESCIENCES, 1100 Campus Drive, Princeton New Jersey
Manufacturer	08540
	Manufactured by:
	M/s Integra Lifesciences Corporation 4900 Charlemar Drive, Building A
	Cincinnati, Oh 45227
	M/s Integra Lifesciences (Ireland) Limited Ida Buisiness and Technology Park
	Sragh Tullamore, Offaly Ireland
	M/s Integra Neurosciences Pr Road 402 North, Km 1.2 Anasco, Pr Usa 00610
Brand Name	CUSA EXCEL
	(ULTRASONIC ASPIRATION SYSTEM)
Decision	Approved.
	Original FSC is submitted.

Name	Name
Address of Importer	M/s Popular International (Pvt) Ltd,
•	Address of Importer
	141 Justice Inamullah road ,Block 7 & 8 , KMCHS ,Karachi, Sindh, Pakistan
Detail of ELM/ELI	ELI-00091
Name	Legal Manufacturer (MAH)
Address of	Baxter Healthcare SA 8010 Zurich Switzerland
Manufacturer	Manufacturing/Design Facility
	Baxter Healthcare Corp.
	21026 Alexander Court Hayward, CA 94545 USA Ph: (510) 723 2000

Brand Name	COSEAL
	SURGICAL SEALANT
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Popular International (Pvt) Ltd,
	Address of Importer
	141 Justice Inamullah road ,Block 7 & 8 , KMCHS ,Karachi, Sindh, Pakistan
Detail of ELM/ELI	ELI-00091
Name	Legal Manufacturer (MAH)
Address of	Baxter Healthcare SA 8010 Zurich Switzerland
Manufacturer	Manufacturing/Design Facility
	Baxter Healthcare Corp.
	21026 Alexander Court Hayward, CA 94545 USA Ph: (510) 723 2000
	Contract Manufacturing Organization:
	Baxter AG – Shire 1221 Vienna Austria
Brand Name	FLOSEAL
	HEMOSTATIC MATRIX
Decision	The board decided to give personal hearing to both the firms regarding the
	sole agency agreement.

Name	Name:
Address of Importer	Zhangjiakou Dongfang Pharmaceutical Pakistan (Private) Limited.
	Address of Importer:
	D-2, 2nd Floor, Westland Trade Center, Plot No. C-5, Block 7/8 KCHSU, Shaheed E Millat Road Karachi.
Detail of ELM/ELI	ELI- 00374 (Renewal Reference No. 86A5A2824C) dated 4th April 2024
Name	LEGAL MANUFACTURER:
Address of Manufacturer	Zhengzhou Yupintang Medical Instrument Co., Ltd. No. 602, Block 4, No.27. Fenglin Road, Zhengzhou High-Tech Industrial Development Zone, Henan Province, China.
Brand Name	Hydrocool Gel Patch
Generic name	Cooling Gel Patch
Decision	Approved.

Name	Name:
Address of Importer	Zhangjiakou Dongfang Pharmaceutical Pakistan (Private) Limited.
	Address of Importer:
	D-2, 2nd Floor, Westland Trade Center, Plot No. C-5, Block 7/8 KCHSU, Shaheed E Millat Road Karachi.
Detail of ELM/ELI	ELI- 00374 (Renewal Reference No. 86A5A2824C) dated 4th April
	2024
Name	LEGAL MANUFACTURER:
Address of Manufacturer	Zhengzhou Yupintang Medical Instrument Co., Ltd. No. 602, Block 4, No.27. Fenglin Road, Zhengzhou High-Tech Industrial Development Zone, Henan Province, China.
Brand Name	Far Infrared Patch
Generic name	Far Infrared Patch
Decision	Approved.

Case No. 147

Name	Name
Address of Importer	Maxitech Pharma (Private) Limited
	Address of Importer
	Plot No. E-178, S.I.T.E, Super Highway, Phase II, Karachi, Pakistan
Detail of ELM/ELI	ELI-00769
Name	(LEGAL MANUFACTEURER)
Address of	SIFI . S.P.A Via Ercole Patti n.3 Lavinaio Aci S. Antonia CT 95025 Italy
Manufacturer	
Brand Name	Mini 4 Ready
	Posterior chamber IOL
Decision	Approved

Name	Name
Address of Importer	Maxitech Pharma (Private) Limited
	Address of Importer
	Plot No. E-178, S.I.T.E, Super Highway, Phase II, Karachi, Pakistan
Detail of ELM/ELI	ELI-00769
Name	(LEGAL MANUFACTEURER)
Address of	SIFI. S.P.A Via Ercole Patti n.3 Lavinaio Aci S. Antonia CT 95025 Italy
Manufacturer	
Brand Name	Mini Toric Ready
	Aspheric Acrylic IOL.
Decision	Approved

Name	KRESTACORP
Address of Importer	76-C, 3rd Floor, Suit No. 02, Khayaban-e-Jami,
-	Street No. 9 D.H.A. Phase 07 Karachi. Tel: 021-35311802-3, 0302-
	8251449
Detail of ELM/ELI	ELI-00258
Name	
Address of Manufacturer	M/s JEI DANIEL (JD) BIOTECH CORP, address are A201, 1 Building, NO. 69 Huan Yang Road, Jinan, Shandong, China Tel: +86(531) 82373551 Fax:+86(531) 82373522 https://www.jeidanielbiotech.com
Brand Name	ONE TEST Rapid Self Pregnancy Test strip
Decision	Approved

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi

Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN DISPOSABLE SILICONE FOLEY CATHETER
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma
_	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road,
	Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong
	Province, P.R.China
Brand Name	ECAN
	DISPOSABLE ENDOTRACHEAL TUBE
Decision	The board decided to give personal hearing to both the firms regarding the
	sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	DISPOSABLE ENDOBRONCHIAL TUBE
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	Urine Bag
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Case No. 154

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	Disposable Latex Foley Catheter, Sterile
Remarks	The subject device is already addressed in previous MDB meeting for Hashir surgical, Peshawar. The legal manufacturer has also issued the termination agreement to M/s Hashir surgixals, Peshawar.
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma

	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road,
	Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
	Flovince, F.R.China
Brand Name	ECAN
	Disposable Suction Connecting Tube
Remarks	The subject device is already addressed in previous MDB meeting for
	Hashir surgical, Peshawar. The legal manufacturer has also issued the
	termination agreement to M/s Hashir surgixals, Peshawar.
Decision	The board decided to give personal hearing to both the firms regarding the
	sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	Disposable Oxygen Mask
Remarks	The subject device is already addressed in previous MDB meeting for Hashir surgical, Peshawar. The legal manufacturer has also issued the termination agreement to M/s Hashir surgixals, Peshawar.
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name	
Address of Importer	M/s Biocare Pharma	

	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	Disposable Nebulizer Mask Set
Remarks	The subject device is already addressed in previous MDB meeting for Hashir surgical, Peshawar. The legal manufacturer has also issued the termination agreement to M/s Hashir surgixals, Peshawar.
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma
	Address of Importer
	Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Guangdong Ecan Medical Co.,Ltd: Building 1, No. 222, Xindu Road, Chengjiao Street Conghua District 510920 Guangzhou City, Guangdong Province, P.R.China
Brand Name	ECAN
	NASAL OXYGEN CANNULA
Remarks	The subject device is already addressed in previous MDB meeting for Hashir surgical, Peshawar. The legal manufacturer has also issued the termination agreement to M/s Hashir surgixals, Peshawar.
Decision	The board decided to give personal hearing to both the firms regarding the sole agency agreement.

Name	Name
Address of Importer	M/s Biocare Pharma,

	Address of Importer B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road, High-Tech zone, Zibo city, Shandong Province China
Brand Name	Evafix 3-WAY STOPCOCK
Decision	Approved only Three-way Stopcock with extension tubing 7cm, 10cm & 15cm and apply separately for Three-way Stopcock Plain.

Name	Name
Address of Importer	M/s Biocare Pharma,
_	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
Brand Name	Hapool Blood Transfusion Set
Decision	Approved.

Case No. 161

Name	Name
Address of Importer	M/s Biocare Pharma,
	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
Brand Name	Hapool Insulin Syringes
Decision	Approved.

WD 1101 101	
Name	Name
Address of Importer	M/s Biocare Pharma,
_	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	

	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road, High-Tech zone, Zibo city, Shandong Province China
Brand Name	EVA INTRAVENOUS INFUSION SET WITH BURETTE
Decision	Approved.

Name	Name
Address of Importer	M/s Biocare Pharma,
	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
Brand Name	Infusion Set
Decision	Approved only Infusion set with Y port. Apply separately for Infusion Set
	Plain & Infusion set with air liquid stop

Case No. 164

Casc 110. 107	
Name	Name
Address of Importer	M/s Biocare Pharma,
_	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
Brand Name	Hapool IV-Flow Regulator
Decision	Approved only IV flow regulator microscale/double scale. Apply separately
	for IV flow regulator single scale

Name	Name
Address of Importer	M/s Biocare Pharma,
	Address of Importer
	B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi
Detail of ELM/ELI	ELI-00634
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
	(Manufacturing site)
	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road,
	High-Tech zone, Zibo city, Shandong Province China
Brand Name	Hapool Heparin Cap/ IV Stopper
Decision	Deferred for the clarification of the applied class of the product along with
	revised application Form & relevant Fee.

Name	Name
Address of Importer	MA TRADERS
_	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Oxygen Nasal Cannula for Single Use "Adult, Peads, Neonate")
Decision	The Board Approved all the three types but the firm will submit the fee and
	application Forms for other two types before issuance of registration letter.

Case No. 167

Name	Name
Address of Importer	MA TRADERS
•	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Suction Catheter)
Decision	Approved

Case 110. 100	
Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable AV Fistula Needle)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Hollow Fiber Hemodialyzer)
Decision	Approved

Case No. 169

Case 110. 109	
Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Endotracheal Tube, Cuffed)
Decision	Approved subject to submission of fee and appliacation Form for uncuffed type.

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Feeding Tube Single Use)
Decision	Approved

Cast 110. 171	
Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Stomach Tube)
Decision	Approved

Case No. 172

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Burette Type IV Infusion set)
Decision	Approved

Case No. 175	
Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(IV Catheter for Single Use Pen type withY connector)
Decision	Approved subject to submission of fee for Y-connector type.

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Extension Tube for Single Use)
Decision	Approved

Case No. 175

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Sterile Insulin Syringes for Single Use)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Blood Collection Needle for Single Use)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Sterile Blood Transfusion Set for Single Use)
Decision	Approved

Case No. 178

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Sterile Disposable Syringe for Single Use)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Silicon Foley Catheter for Single Use)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Latex Foley Catheter for Single Use)
Decision	Approved

Case No. 181

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Sterile Latex Surgical Glove Powder Free for Single Use)
Decision	Approved

Name	Name
Address of Importer	MA TRADERS
	Address of Importer
	Khan G Arked main Gulbahar Road Back Side Gulbahar Police Station,
	Peshawar
Detail of ELI	ELI- 00601
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	(Manufacturing site)
	39 South Shengli RD, Jinxian County 331700 Nanchang, Jiangxi Province,
	China.
Brand Name	MED SURG
	(Disposable Dialysis Tubing Single Use)
Decision	Approved

Name	Name: B.N TRADING COMPANY
Address of Importer	Address of Importer
	Office # 207, 2 nd Floor, Makkah Tower Namak Mandi Peshawar City
Detail of ELI	ELI- 00647
Name	(LEGAL MANUFACTEURER)
Address of	Jiangsu Webest Medical Product Co., Ltd.,
Manufacturer	(Manufacturing site)
	No.5 Yingchun Road., Industrial Park., 211700 Xuyi., JiangSu, China
Brand Name	Best Life
	(I.V. Cannula) with wing with injection port Type
Decision	Approved

Case No. 184

Name	Name: BN TRADING COMPANY
Address of Importer	Address of Importer
	Office # 207, 2 nd Floor, Makkah Tower Namak Mandi Peshawar City
Detail of ELI	ELI- 00647
Name	(LEGAL MANUFACTEURER)
Address of	Jiangsu Webest Medical Product Co., Ltd.,
Manufacturer	(Manufacturing site)
	No.5 Yingchun Road., Industrial Park., 211700 Xuyi., JiangSu, China
Brand Name	Best Life
	(I.V. Cannula) with wing with heparin cap
Decision	Approved

Case No. 185

Name	Name: B.N TRADING COMPANY
Address of Importer	Address of Importer
	Office # 207, 2 nd Floor, Makkah Tower Namak Mandi Peshawar City
Detail of ELI	ELI- 00647
Name	(LEGAL MANUFACTEURER)
Address of	M/S Tianchang City Anrui Medical Equipments Co., Ltd
Manufacturer	Renhe Industrial District, Tianchang City, Anhui Province,
	China, 239331;
	0086-550-7834188; 0086-550-7834699
Brand Name	BESTLIFE
	(Latex Surgical Gloves)
Decision	Approved subject to submission of fee for Powdered type.

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Enticos 4 SR
	Implantable Single Chamber Pacemaker with Sensor (SR)
Decision	Approved

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Brand Name	Enticos 4 DR Implantable Single Chamber Pacemaker with Sensor (DR)
Decision	Approved

Case No.188

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Brand Name	Reocor Dual Chamber External Pacemaker
Decision	Approved

Case No.189

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
_	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Brand Name	Amvia Edge DR-T Dual-Chamber Implantable Pacemaker
Decision	Approved

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Brand Name	Amvia Edge SR-T Single-Chamber Implantable Pacemaker
Decision	Approved

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Amvia Edge HF-T QP
Country of	FSC:
originFSC	Germany Issuance Date: 25-03-2020
Decision	Approved

Case No.192

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Amvia Sky SR-T Single-Chamber Implantable Pacemaker
Decision	Approved

Case No.193

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Amvia Sky HF-T Triple-Chamber Implantable Pacemaker
Decision	Approved

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Amvia Sky HF-T QP Triple-Chamber Implantable Pacemaker
Decision	Approved

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Amvia Sky DR-T Single-Chamber Implantable Pacemaker
Decision	Approved

Case No.196

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Solvia Rise SR-T MR Conditional Single-Chamber Pacemaker
Decision	Approved

Case No.197

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Solvia Rise DR-T MR Conditional Single-Chamber Pacemaker
Decision	Approved

Name	Name
Address of Importer	M/s Flowtronix Systems
	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name Address	(LEGAL MANUFACTEURER)
of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Cardio Messenger Smart 4G (Tele Monitoring Systems)
Decision	Approved subject to Brand name of the device.

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
_	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Biotronik SE & Co., KG Woermannkehre 1, 12359 Berlin, Germany.
Manufacturer	
Brand Name	Reocor Single Chamber (External Pacemaker)
Decision	Approved

Case No.200

Name	Name: M/s Flowtronix Systems
Address of Importer	Address of Importer
	Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi.
Detail of ELM/ELI	ELI- 00217
Name	(LEGAL MANUFACTEURER)
Address of	M/s Tianjin Plastics Research Institute Co., Ltd., No.24, Keda 1 Road, TEDA
Manufacturer	(Jinnan) Microelectronics Park, Jinnan District, Tianjin, China.
Brand Name	Extra Corporeal Circuit Tube
Decision	Approved subject to Brand name of the device.

Case No.201

Name	Name: M/s Global Marketing Services
Address of Importer	Address of Importer
	111-B, Hali Road, Westridge 1, Rawalpindi.
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	M/s Interlab S.r.l. Via Rina Monti, 26 – 00155, Rome, Italy
Manufacturer	
Brand Name	Kit for Immunofixation
Decision	Approved subject to provision of valid FQA certificate and Brand name of the
	device.

Name	Name: M/s Global Marketing Services
	Address of Importer
_	111-B, Hali Road, Westridge 1, Rawalpindi.
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	M/s Interlab S.r.l. Via Rina Monti, 26 – 00155, Rome, Italy
Manufacturer	
Brand Name	Kit for Serum Protein
Decision	Approved subject to provision of valid FQA certificate and Brand name of the
	device.

Name	Name: M/s Global Marketing Services
Address of Importer	Address of Importer
	111-B, Hali Road, Westridge 1, Rawalpindi.
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	M/s M.A Med Alliance SA, Rue de Rive 5, 1260 Nyon, Switzerland
Manufacturer	
	Manufacturing Site:
	M/s Med Alliance LLC, 4 Jenner, Suite 190, 92618, Irvine, California, USA
Brand Name	SELUTION SLR 018 PTA Balloon Catheter (Invasive Balloon Catheter)
Decision	Approved

Case No.204

Name	Name: M/s Global Marketing Services
Address of Importer	Address of Importer
	111-B, Hali Road, Westridge 1, Rawalpindi.
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	M/s M.A Med Alliance SA, Rue de Rive 5, 1260 Nyon, Switzerland
Manufacturer	·
	Manufacturing Site:
	M/s Med Alliance LLC, 4 Jenner, Suite 190, 92618, Irvine, California, USA
Brand Name	SELUTION SLR 014 PTA Balloon Catheter (Invasive Balloon Catheter)
Decision	Approved

Case No.205

Name	Name: M/s Global Marketing Services
Address of Importer	Address of Importer
	111-B, Hali Road, Westridge 1, Rawalpindi.
Detail of ELM/ELI	ELI- 00109
Name	(LEGAL MANUFACTEURER)
Address of	M/s CenterPoint Systems LLC, 3338 Parkway Blvd, West Valley City, UT
Manufacturer	84119, USA
Brand Name	CPS Locator TM 3D Delivery System (Single Use Percutaneous Delivery System)
Decision	Approved

Name	Name: Cardiac Care
Address of Importer	Address of Importer:
	848-C Shadman -1, Lahore
Detail of ELM/ELI	ELI-00070
Name Address of	Intervascular SAS-Zone Industrielle Athelia 1-13705 La Ciotat Cedex-
Manufacturer	France.
	Tel No:+33 4 42 08 46 46
	www.getinge.com

	Authorized Representative.
	Getinge Group Middle East FZ-LLC 190 1 N. 19th Floor, Dubai Science
	Park(DSP) Towers-North, Dubai Science Park P.O. Box 214742, Dubai United
Brand Name	Hemashield Platinum Woven Double Velour Vascular Grafts
	(Hemashield Platinum Woven Straight Grafts)
Decision	Approved

Name	Name:
Address of Importer	Cardiac Care
	Address of Importer:
	848-C Shadman -1, Lahore
Detail of ELM/ELI	ELI-00070
Name Address of	Intervascular SAS-Zone Industrielle Athelia 1-13705 La Ciotat Cedex-
Manufacturer	France.
	Tel No:+33 4 42 08 46 46
	www.getinge.com
	Authorized Representative.
	Getinge Group Middle East FZ-LLC 190 1 N. 19th Floor, Dubai Science
	Park(DSP) Towers-North, Dubai Science Park P.O. Box 214742, Dubai United
Brand Name	Intergard Knitted Bifurcated Vascular Graft
Decision	Approved subject to submission of fee for each type.

Case No.208

asc 110.200	
Name	Name:
Address of Importer	Cardiac Care
	Address of Importer:
	848-C Shadman -1, Lahore
Detail of ELM/ELI	ELI-00070
Name Address of	Legal Manufacturer
Manufacturer	M/s Eurosets S.r.l. Strada Statale 12, n143 41036, Medolla (MO), Italy
Brand Name	Kompass A.L.One Oxygenator
Decision	Approved

Name	Name
Address of Importer	M/s. Currax Traders,
	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
D 137	
Brand Name	Janus Cup Acetabular Component
Decision	Approved

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo
Manufacturer	(MI), Italy.
Brand Name	Korus Stem Cemented (Femoral Stem hip Component)
Decision	Approved

Case No.211

asc 110.211	
Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
D 137	W. MOD BOR'S ALL W.
Brand Name	K-MOD PS Fixed Insert Knee component
Decision	Approved

Case No.212

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	K-MOD Patella (Patellar Component Cemented)
Decision	Approved

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	FIN CUP SYSTEM
Decision	Approved

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	DUALIS System (Acetabular Component Double Mobility Cup)
Decision	Approved

Case No.215

Name	Name:M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	K-MOD Knee Instruments (Knee Replacement Instruments)
Decision	Approved

Case No.216

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	K-MOD Fixed Cemented Tibia (PS Cemented Tibial Component)
Decision	Approved

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
_	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716

Name Address of Manufacturer	(LEGAL MANUFACTEURER) M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI), Italy.
Brand Name	K-MOD PS Cemented Femur (PS Fixed Cemented Femoral Component)
Decision	Approved

usc 110.210	
Name	Name
Address of Importer	M/s. Currax Traders,
	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	KORUS STEM INSTRUMENTS (Femoral Component Instruments)
Decision	Approved

Case No.219

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	MULLER CUP (Acetabular Cemented Cup)
Decision	Approved

Name	Name: M/s. Currax Traders,
Address of Importer	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop Railway
	Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo (MI),
Manufacturer	Italy.
Brand Name	Femoral Head (Femoral Component, CoCr Head, Ceramic Head, ZTA Head,
	INOX Head)
Decision	Approved subject to submission of fee and application Forms for different
	types of femoral heads depending upon the material used in the composition of
	the product.

Name	Name
Address of Importer	M/s. Currax Traders,
	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop
	Railway Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo
Manufacturer	(MI), Italy.
Brand Name	Uncemented Korus Stem 135 (Femoral Hip Component)
Decision	Approved

Case No.222

15C 110.222	T
Name	Name
Address of Importer	M/s. Currax Traders,
_	Address of Importer
	House No. 182, St. No. 02, Scheme No. 7, U-Block, CDL WorkShop
	Railway Pakistan, Rawalpindi.
Detail of ELM/ELI	ELI- 00716
Name	(LEGAL MANUFACTEURER)
Address of	M/s Gruppo Bioimpianti Srl Via Liguria 28, 20068 Peschiera Borromeo
Manufacturer	(MI), Italy.
Brand Name	FIN Cups System Instruments (Acetabular Components Instruments)
Decision	Approved

Case No.223

Name	Name
Address of Importer	M/s Al-Amin Associates
	Address of Importer
	125-Habitates Flats, Shadman-II, Lahore.
Detail of ELM/ELI	ELI- 00104
Name	(LEGAL MANUFACTEURER)
Address of	M/s Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA
Manufacturer	5095, Australia
Brand Name	Ultra Q Reflex Neo (Ophthalmic Lasers)
Decision	Approved

Name	Name: M/s Al-Amin Associates
Address of Importer	Address of Importer
	125-Habitates Flats, Shadman-II, Lahore.
Detail of ELM/ELI	ELI- 00104
Name	(LEGAL MANUFACTEURER)
Address of	M/s Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA
Manufacturer	5095, Australia
Brand Name	Tango Neo (Ophthalmic Lasers)
Decision	Approved

Name	Name
Address of Importer	M/s Al-Amin Associates
	Address of Importer
	125-Habitates Flats, Shadman-II, Lahore.
Detail of ELM/ELI	ELI- 00104
Name	(LEGAL MANUFACTEURER)
Address of	M/s Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA
Manufacturer	5095, Australia
Brand Name	Tango Reflex Neo (Ophthalmic Lasers)
Decision	Approved

Case No.226

Name`	Name
Address of Importer	M/s Al-Amin Associates
	Address of Importer
	125-Habitates Flats, Shadman-II, Lahore.
Detail of ELM/ELI	ELI- 00104
Name	(LEGAL MANUFACTEURER)
Address of	M/s Medical Communications GmbH, Max-Jarecki-Str. 8 69115
Manufacturer	Heidelberg, Germany
Brand Name	Ashvins Variant Heyex 2 / Heyex Pacs (Medical Diagnostic and Imaging
	Software)
Decision	Deferred for clarification of description of the applied product.

Case No.227

	Name
Address of Importer	M/s Al-Amin Associates
	Address of Importer
	125-Habitates Flats, Shadman-II, Lahore.
Detail of ELM/ELI	ELI- 00104
Name	(LEGAL MANUFACTEURER)
Address of	M/s Medical Communications GmbH, Max-Jarecki-Str. 8 69115 Heidelberg,
Manufacturer	Germany
Brand Name	Ashvins (Medical Diagnostic and Imaging Software)
Decision	Deferred for clarification of description of the applied product.

Name	Name
Address of Importer	M/s Universal Dental (Pvt) Ltd
	Address of Importer
	17-Mcleod Road, Lahore.
Detail of ELM/ELI	ELI- 00071
Name	(LEGAL MANUFACTEURER)
Address of	M/s CAVEX holland BV, Fustweg 5, 2031 CJ Haarlem, the Netherlands.
Manufacturer	
Brand Name	Cavex Alignate Impression Material
Decision	Deferred for clarification of CAVEX CA 37 Normal Set and CAVEX CA 37
	Fast Set.

Name	Name
Address of Importer	M/s Universal Dental (Pvt) Ltd
	Address of Importer
	17-Mcleod Road, Lahore.
Detail of ELM/ELI	ELI- 00071
Name	(LEGAL MANUFACTEURER)
Address of	M/s CAVEX holland BV, Fustweg 5, 2031 CJ Haarlem, the Netherlands.
Manufacturer	
Brand Name	Quadrant Universal LC Starter Kit Syringes
Decision	Approved

Case No.230

Name	Name
Address of Importer	M/s Universal Dental (Pvt) Ltd
	Address of Importer
	17-Mcleod Road, Lahore.
Detail of ELM/ELI	ELI- 00071
Name	(LEGAL MANUFACTEURER)
Address of	M/s Beviston GmbH Scharnstedter Weg 34-36 27639 Wurster Nordseekuste,
Manufacturer	Germany.
Brand Name	Bevisto-Instrumental Forte (Disinfectant for Medical Instruments)
Decision	Approved

Case No.231

asc 110.251	
Name	Name
Address of Importer	M/s Cor-Med
	Address of Importer
	2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi.
Detail of ELM/ELI	ELI- 00226
Name	(LEGAL MANUFACTEURER)
Address of	M/s Pul-Sar 4 Programmistov St., Bld.2, Dubna c., Moscow, Region Russia
Manufacturer	
Brand Name	HAEMOBLOCK Haemostatic Solution
Decision	Approved

Name	Name
Address of Importer	M/s Cor-Med
	Address of Importer
	2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi.
Detail of ELM/ELI	ELI- 00226
Name	(LEGAL MANUFACTEURER)
Address of	M/s Pul-Sar 4 Programmistov St., Bld.2, Dubna c., Moscow, Region Russia
Manufacturer	
Brand Name	Lymphoblock Surgical Solution
Decision	Approved

Name	Name
Address of Importer	M/s Digionics Pvt Ltd
	Address of Importer
	15 Shadman, Jail Road, Lahore.
Detail of ELM/ELI	ELI- 00371
Name	(LEGAL MANUFACTEURER)
Address of	M/s Technix S.p.A, Via Enrico Fermi, 45-24050-Grassobbio (Bg), Italy.
Manufacturer	
Brand Name	Technix TCA 7
	Mobile radioscopy and radiography equipment
Decision	Approved subject to provision of shelf life studies, updated CE certificate and
	manufacturing and QC tests.

Case No.234

Name	Name
Address of Importer	M/s Chemical House
	Address of Importer
	6-C Sikandar Malhi Road Canal Park, Gulberg-II, Lahore.
Detail of ELM/ELI	ELI- 00371
Name	(LEGAL MANUFACTEURER)
Address of	M/s BIO-RAD Laboratories, Inc. 9500 Jeronimo Rd, Irvine CA 92618, USA
Manufacturer	
Brand Name	Liquichek Material Serum Control (Multiple Clinical Chemistry Protein IVD
	Control)
Decision	Approved

Case No.235

Name	Name
Address of Importer	M/s Chemical House
	Address of Importer
	6-C Sikandar Malhi Road Canal Park, Gulberg-II, Lahore.
Detail of ELM/ELI	ELI- 00371
Name	(LEGAL MANUFACTEURER)
Address of	M/s BIO-RAD Laboratories, Inc. 9500 Jeronimo Rd, Irvine CA 92618, USA
Manufacturer	
Brand Name	Liquichek Pediatric Control (Multiple Clinical Chemistry Protein IVD Control)
Decision	Approved

Name	Name
Address of Importer	M/s Gentek pharma,
	Address of Importer
	Sultana Apartments, Ground Floor, A Block, Satellite Town, Rawalpindi
Detail of ELM/ELI	ELI- 01221
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s ERC Biyoteknoloji SAN VE Dis TIC A.S

	Address: Ahmet yesevi mah kerem sok ablok no.9 1B01 Pendik/Istanbul-
	Turkey
Brand Name	VISCOART (Absorbable Hyaluronic Acid Intraarticular Gel Implant + L-
	Proline)
	Intrarticular injection (Active ingredient: Hyaluronic Acid)
Decision	Approved.
	Design Examination Certificate is provided

Name	Name
Address of Importer	M/s Gentek pharma,
	Address of Importer
	Sultana Apartments, Ground Floor, A Block, Satellite Town, Rawalpindi
Detail of ELM/ELI	ELI- 01221
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s ERC Biyoteknoloji SAN VE Dis TIC A.S
	Address: Ahmet yesevi mah kerem sok ablok no.9 1B01 Pendik/Istanbul-
	Turkey
Brand Name	SUPINTRO (Absorbable Hyaluronic Acid Intraarticular Gel Implant + L-
	Proline/Glycine/N-Acetylglucosamine)
	Intraarticular injection (Active ingredient: Hyaluronic Acid)
Decision	Approved subject to submission of valid and notarized Design Examination
	certificate.

Case No.238

Name	Name
Address of Importer	M/s Hanson International,
	Address of Importer
	Office No.57-D, , Block DHA, EME Multan Road, Lahore.
Detail of ELM/ELI	ELI- 01221
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s Vansun Medical Equipment (Fujian) Co., LI Dun Industrial Zone, Lidun
	District Zhouning, 355402 Ningde City, Fujian People Republic of China.
Brand Name	HMD Disposable Syringes (1ml, 10ml, 20ml, 30ml, 50ml, 60ml)
Decision	Approved

Name	Name
Address of Importer	M/s Hanson International,
	Address of Importer
	Office No.57-D, , Block DHA, EME Multan Road, Lahore.
Detail of ELM/ELI	ELI- 01221
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s Vansun Medical Equipment (Fujian) Co., LI Dun Industrial Zone, Lidun
	District Zhouning, 355402 Ningde City, Fujian People Republic of China.
Brand Name	HMD Insulin Syringes (0.3ml, 0.5ml, 1.0ml)
Decision	Approved

Name	Name: M/s FDS (Pvt) Ltd.,
Address of Importer	Address of Importer
	Flat No.8, 1st Floor, Ganga Ram Mansion Shahrah-e-Quaid-e-Azam, Lahore.
Detail of ELM/ELI	ELI- 00475
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s Tianjin Zhengtian Medical Instrument Co., Ltd., No.318, Jingyi Road,
	Airport Economic Zone, Tianjin, 300308, China.
	Manufacturing Site:
	M/s Tianjin Zhengtian Medical Instrument Co., Ltd., Floor 2, South Workshop
	1, No.296, Jingyi Road, Airport Economic Zone, Tianjin, China
Brand Name	Irene HIP Systems
Decision	Approved

Case No.241

Case 110.241	-
Name	Name: Pak Punjab Cardex Medical System
Address of Importer	Address of Importer
_	Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore
Detail of ELM/ELI	ELI-00174
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Kossel Medtech (Suzhou) Co. Ltd
	Building 6, No.8 Jinfeng Road, Suzhou New District, 215163 P.R.China
Brand Name	Selethru SC PTCA Balloon Dilatation Catheter
Decision	Approved

Case No.242

Name	Name: Pak Punjab Cardex Medical System
Address of Importer	Address of Importer
	Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore
Detail of ELM/ELI	ELI-00174
Name	(LEGAL MANUFACTEURER)
Address of	Kossel Medtech (Suzhou) Co. Ltd
Manufacturer	Building 6, No.8 Jinfeng Road, Suzhou New District, 215163 P.R.China
Brand Name	Selethru NC PTCA Balloon Dilatation Catheter
Decision	Approved

Name	Name: Pak Punjab Cardex Medical System
Address of Importer	Address of Importer
	Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore
Detail of ELM/ELI	ELI-00174
Name	(LEGAL MANUFACTEURER)
Address of	Kossel Medtech (Suzhou) Co. Ltd
Manufacturer	Building 6, No.8 Jinfeng Road, Suzhou New District, 215163 P.R.China
Brand Name	Selebrek CTO Balloon Dilatation Catheter
Decision	Approved

Name	Name: M/s Better Vision (Private) Limited,
Address of Importer	Address of Importer
•	693/37-D, DHA-9 Town, Lahore
Detail of ELM/ELI	ELI-01128
Name	(LEGAL MANUFACTEURER)
Address of	M/s Bettervision Medical Technology Co., Ltd
Manufacturer	Building No.4, 1#C Production Plant Area, No.1611, West Huangjiahu Road,
	Nanchang Economic Development Zone, Nanchang City, Jiangxi Province,
	China
Brand Name	Bettervision Hydrophobic Aspheric Intraocular Lens (IOL)
Decision	Approved subject to valid and notarized Letter of Authorization and CE certificate.
	Credentials of manufacturer aboard as per approved format (MDB-03 rd
	meeting),

Case No.245

Name	Name: M/s Amtronech
Address of Importer	Address of Importer
	560, A Block Faisal Town, Lahore.
Detail of ELM/ELI	ELI- 00173
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s D.O. Weaver and Company Inc.,
	565 Nucla way, Unit B Aurora, Colorado 80011, USA
Brand Name	Nuprep Skin Prep Gel
Decision	Approved subject to submission of valid ISO-13485 & Free sale certificate.

Case No.246

Name	Name: M/s Amtronech
Address of Importer	Address of Importer
	560, A Block Faisal Town, Lahore.
Detail of ELM/ELI	ELI- 00173
Name Address	(LEGAL MANUFACTEURER)
of	M/s D.O. Weaver and Company Inc.,
Manufacturer	565 Nucla way, Unit B Aurora, Colorado 80011, USA
Brand Name	Ten20 Conductive Paste
Decision	Approved subject to submission of valid ISO-13485 & Free sale certificate.

Name	Name: M/s Amir Traders
Address of Importer	Address of Importer
	House # 43/A, Infantry Road, Lahore Cantt. Lahore.
Detail of ELM/ELI	ELI- 01139
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s OSSTEM Implant Co., Ltd., 66-16, Bansong-ro 513 Beon-gil, Haeundae-gu,
	Busan, 48002, Republic of Korea.

Brand Name	TS III SA Fixture_Pre Mount
	TSIII SA Implant
Decision	Approved subject to submission of valid FQA certificate.

Name	Name
Address of Importer	M/s Amir Traders
	Address of Importer
	House # 43/A, Infantry Road, Lahore Cantt. Lahore.
Detail of ELM/ELI	ELI- 01139
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s OSSTEM Implant Co., Ltd., 66-16, Bansong-ro 513 Beon-gil, Haeundae-
	gu, Busan, 48002, Republic of Korea.
Brand Name	TS III CA Fixture_Pre Mount
	TS III CA Implant
Decision	Approved subject to submission of valid FQA certificate.

Case No.249

Name	Name
Address of Importer	M/s Amir Traders
	Address of Importer
	House # 43/A, Infantry Road, Lahore Cantt. Lahore.
Detail of ELM/ELI	ELI- 01139
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s OSSTEM Implant Co., Ltd., 66-16, Bansong-ro 513 Beon-gil, Haeundae-
	gu, Busan, 48002, Republic of Korea.
Brand Name	SS II SA Fixture_Pre Mount
	SS II SA Implant
Decision	Approved subject to submission of valid FQA certificate.

Name	Name
Address of Importer	M/s Titlis Pharma (Private) Limited,
	Address of Importer
	528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
Detail of ELM/ELI	ELI- 00698
Name Address	(LEGAL MANUFACTEURER)
of Manufacturer	M/s Mentholatum Company Limited., 1 Redwood Avenue, Peel Park Campus,
	East Kilbride G74 5PE, Scotland, UK.
	Manufacturing Site:
	M/s Sinsin Pharmaceutical Co., Ltd., 9, Sogeongsandandong-ro, Sogeong-
	myeon, Sejong-si, Reuplic of Korea
Brand Name	Deep Freeze Pain Relief Cold Patches
Decision	Approved subject to Brand name and Class clarification.

Name	Name
Address of Importer	M/s Titlis Pharma (Private) Limited,
	Address of Importer
	528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
Detail of ELM/ELI	ELI- 00698
Name Address of	(LEGAL MANUFACTEURER)
Manufacturer	M/s Mentholatum Company Limited., 1 Redwood Avenue, Peel Park Campus,
	East Kilbride G74 5PE, Scotland, UK.
	Manufacturing Site:
	M/s Shanghai Yingdu Industry Co., Ltd., Dalun Industrial District, Jiangyan
	District, Taizhou City, Jiangyan Province 225504, China
Brand Name	Deep Heat Pain Relief Heat Patches/Back Patches
Decision	Approved subject to submission of valid Letter of Authorization and ISO-
	13485 certificate and Brand name. Also clarification of class of medical device

Case No.252

Name	Arrow Tech Medical Systems
Address of Importer	Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
	Address of Importer
	Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
Detail of ELM/ELI	ELI-00792 Dated: 21-09-2021
Name	(SHENZHEN ANKE HIGH-TECH CO., LTD)
Address of	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
Manufacturer	Bao'an District, Shenzhen, 518108, P.R. China
	<u>Tel:86-755-26688889</u>
	Website: www.anke.com
	(Manufacturing site)
	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
	Bao'an District, Shenzhen, 518108, P.R.China
Brand Name	Anke
Generic Name	Computed Tomography Scanner (CT Scanner)
Decision	Approved

Name	Arrow Tech Medical Systems
Address of Importer	Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
-	Address of Importer Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
Detail of ELM/ELI	ELI-00792 Dated: 21-09-2021
Name	(SHENZHEN ANKE HIGH-TECH CO., LTD)
Address of	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
Manufacturer	Bao'an District, Shenzhen, 518108, P.R. China
	<u>Tel:86-755-26688889</u>

	Website: www.anke.com
	(Manufacturing site)
	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
	Bao'an District, Shenzhen, 518108, P.R. China
Brand Name	Anke
Generic Name	Mammography scanner
Decision	Deferred since the device is not mentioned in provided FSC.

Cast 110.237	
Name	Arrow Tech Medical Systems
Address of Importer	Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
	Address of Importer
	Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue Area Islamabad.
Detail of ELM/ELI	ELI-00792 Dated: 21-09-2021
Name	(SHENZHEN ANKE HIGH-TECH CO., LTD)
Address of	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
Manufacturer	Bao'an District, Shenzhen, 518108, P.R. China
	<u>Tel:86-755-26688889</u>
	Website: www.anke.com
	(Manufacturing site)
	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
	Bao'an District, Shenzhen, 518108, P.R.China
Brand Name	Anke Magnetic Resonance Imaging (MRI)
Generic Name	
Decision	Deferred for the submission of differential fee of Class-C and separate fee and
	application Form for other models.

Name	Arrow Tech Medical Systems, Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq
Address of Importer	Road, Blue Area Islamabad.
1	
	Address of Importer: Unit # 6, 2 nd Floor, Aalay Plaza, Fazl-e-Haq Road, Blue
	Area Islamabad.
Detail of ELM/ELI	ELI-00792 Dated: 21-09-2021
Name	(SHENZHEN ANKE HIGH-TECH CO., LTD)
Address of	Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district,
Manufacturer	Bao'an District, Shenzhen, 518108, P.R. China
	<u>Tel:86-755-26688889</u>
	Website: www.anke.com
	(Manufacturing site) Block B, LingYa Industrial Zone, Tangtou No.1
	Road, Shiyan Sub-district, Bao'an District, Shenzhen, 518108, P.R.China
Brand Name	Anke
Generic Name	X-Ray Machine
Decision	Deferred for Clarification in generic name. in dossier it is ANKE Open MRI.

Name	Name; CLIFTON ENTERPRISES
Address of Importer	Address of Importer
	166 Shadman colony 1, Lahore
Detail of	Establishment License No. ELI-00690
ELM/ELI	
Name	LEGAL MANUFACTEURER
Address of	M/s. SUPERMAX GLOVE MANUFACTURING SDN. BHD
Manufacturer	
	Company Address: LOT 38, PUTRA INDUSTRIAL PARK, BUKIT RAHMAN PUTRA, 47000 SUNGAI BULOH, SELANGOR DARUL EHSAN, Malaysia Contact: 603-6145 2328 Website: http://www.supermax.com.my/
Brand Name	Medi-Pro Sterile Latex Surgical Gloves Powdered
Decision	Approved

Case No. 257

Name	Name: Orbit.AR (Private) Ltd
Address of	Address of Importer:
Importer	A-1 Block, Plot No 43, Haji
	Park, Ferozpur Road, Kasur, Pakistan
Detail of ELM/ELI	ELI-00830
	DATE OF ISSUE : 08/12/2021
Name	(LEGAL MANUFACTEURER)
Address of	JOYTECH Healthcare Co., Ltd.
Manufacturer	No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City,
	311100 Zhejiang, P.R. China
	Tel: 0086-571-81957767
	Fax: 0086-571-81957750
	<u>www.sejoy.com</u>
Brand Name	Blood Pressure Monitor
	Orbit – OBM 790
	Blood pressure monitor
Decision	Approved

Name	Name : Orbit.AR (Private) Ltd
Address of	Address of Importer: A-1 Block, Plot No 43, Haji Park, Ferozpur Road, Kasur,
Importer	Pakistan
Detail of ELM/ELI	ELI-00830
	DATE OF ISSUE: 08/12/2021
Name	(LEGAL MANUFACTEURER)
Address of	Cofoe Medical Technology Co., Ltd.
Manufacturer	816 Zhenhua Road, Yuhua District, Changsha City, Hunan Province, P. R.
	China,

	Tel: 0086-731-4008886170 <u>www.cofoe.com</u>
Brand Name	Orbit-OBM 786
	Blood pressure monitor
Decision	Approved

Name	Name
Address of Importer	Aqib Trading Company (Pvt) Limited
	Address of Importer
	Main GT Road Adamzai Akora Khattak Distt. Nowshera KPK Pakistan.
Detail of ELM/ELI	ELI- 00628
Name	(LEGAL MANUFACTEURER)
Address of	Jiangxi Hongda Medical Equipment Group Ltd.
Manufacturer	
	Address:
	NO.39 South Shengli RD. Jinxian county Jiangxi Province, China
Brand Name	AT-NG Stomach Tube for single use
Decision	Approved

Case No.260

Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus Cytomegalovirus IgG
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-2024.

Case 110.201	
Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer): Diesse Diagnostics Senese S.p.A
Address of	(Manufacturing site): Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Manufacturer	
Brand Name	Chorus Cytomegalovirus IgM
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-
	2024.

_asc 110.202	
Name	Name: Future Scientific
Address of Importer	Address of Importer
_	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus
	Measles IgG
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-
	2024.

Case 263:

case 205.	
Name	Name: Future Scientific
Address of Importer	Address of Importer
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus
	Epstein Barr VCA IgM II
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-
	2024.

Case No.264

Name	Name: Future Scientific
Address of Importer	Address of Importer: FS House, Opposite Street No. 4, Main Road Shaheen
	Town, Gangal West, Post Office, Fazaia Colony, Post Code 46330, Rawalpindi
Detail of ELM/ELI	ELI-00209
Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name	Chorus
	Mumps IgM
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-
	2024.

Name	Name: Future Scientific			
Address of Importer	Address of Importer: FS House, Opposite Street No. 4, Main Road Shaheen			
	Town, Gangal West, Post Office, Fazaia Colony, Post Code 46330, Rawalpindi			

Detail of ELM/ELI	ELI-00209				
Name	(Legal Manufacturer)				
Address of	Diesse Diagnostics Senese S.p.A				
Manufacturer	(Manufacturing site)				
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy				
Brand Name	Chorus				
	Mumps IgG				
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-				
	2024.				

Casc 110.200						
Name	Name					
Address of Importer	rter Future Scientific					
	Address of Importer					
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,					
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi					
Detail of ELM/ELI	ELI-00209					
Name	(Legal Manufacturer)					
Address of Diesse Diagnostics Senese S.p.A						
Manufacturer	(Manufacturing site)					
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy					
Brand Name	Chorus					
	Measles IgM					
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-2024.					

Case No.267

Name	Name					
Address of Importer	Future Scientific					
	Address of Importer					
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,					
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi					
Detail of ELM/ELI	ELI-00209					
Name	(Legal Manufacturer)					
Address of	Diesse Diagnostics Senese S.p.A					
Manufacturer	(Manufacturing site)					
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy					
Brand Name	Chorus					
	Varicella IgM					
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-2024.					

Name	Name				
Address of Importer	Future Scientific				
	Address of Importer				
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,				
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi				
Detail of ELM/ELI	ELI-00209				

Name	(Legal Manufacturer)
Address of	Diesse Diagnostics Senese S.p.A
Manufacturer	(Manufacturing site)
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy
Brand Name Chorus	
	Varicella IgG
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-
	2024.

Name	Name				
Address of Importer	Future Scientific				
	Address of Importer				
	FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West,				
	Post Office, Fazaia Colony, Post Code 46330, Rawalpindi				
Detail of ELM/ELI	ELI-00209				
Name	(Legal Manufacturer)				
Address of	Diesse Diagnostics Senese S.p.A				
Manufacturer	(Manufacturing site)				
	Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy				
Brand Name	Chorus				
	Aspergillus Galactomannan Ag				
Decision	Approved subject to revised fee for Class-C as per new SRO issued on 30-08-2024.				

Case No.270

Name	Name			
Address of Importer	AM Sales & Services, AM House 82-L Block 2 PECHS Karachi			
Detail of ELM/ELI	ELI-00244			
Name	(Legal Manufacturer)			
Address of Manufacturer	Nihon Kohden OrangeMed LLC. 1800 E Wilshire Avenue Santa Ana CA 92705 USA			
Brand Name	Nihon Kohden NKV-440 Ventilator System			
Decision	Approved			

Name	Name				
Address of Importer	AM Sales & Services, AM House 82-L Block 2 PECHS Karachi				
Detail of ELM/ELI	ELI-00244				
Name	(Legal Manufacturer)				
Address of Nihon Kohden OrangeMed LLC. 1800 E Wilshire Avenue Santa Ana C 92705 USA					
Brand Name	Nihon Kohden NKV-550 Ventilator System				
Decision	Approved subject to submission of fee and application Form for each applied model.				

S#	Name of Applicant(s)	Name of Manufacturer	Name of Medical Device	Decision
272	M/s Chohan &	Legal Manufacturer:	Aerobic & Anaerobic Blood	Deferred for
	Company.	Name:	Culture Bottles	provision of
	P-21, Bahadurabad	M/s Autobio Diagnostic		•Fee Challan
	Block 3, Karachi.	Co. Ltd.	Aerobic Culture Bottle FA;	mentioning
			Aerobic Culture Bottle PF;	name of the
	(ELI-00344)	Address 01:	Anaerobic Culture Bottle FN	proposed
		No. 87 Jingbei Yi Road,		Medical Device
	Dy. No.:	National Eco & Tech	Class: B	for registration /
	32555 DRAP (R&I)	Development Area,	MD group: Set	enlistment.
	Dated: 13-12-2021	Zhengzhou, China.	LOA Validity: 01-01-2027	•Justification of
	Fee Challan No.:	Address 02:	FSC Validity: 05-11-2021	grouping of
	92628703832	199, 15 th Eve, National	(expired)	aerobic &
	PKR: 25000/-	Eco & Tech Zone,	Shelf life: not mentioned	Anaerobic
	Dated: 12-08-2021	Zhengzhou, China.	Storage Conditions:	blood culture
			$2^{\circ}C - 25^{\circ}C$	bottles in one
				application.
				•DoC
				mentioning the
				Class of
				Device.
				•Proposed shelf
				life.
273	M/s HealthBee Projects	Legal Manufacturer:	ArtiBest Intra-Articular	Deferred for
	Private Limited.	Name:	Injection	provision of
	Ground floor, Momi	M/s Maxigen Biotech Inc.		•Clarification
	Plaza, Plot # 43,	(Main Manufacturer,	Catalogue No.: AB-305	of difference
	Business Square Phase	design, development,	Product Specification:	of name on fee
	7, Bahria Town, District	manufacture, aseptic	3.0 ml containing 2.0%	challan.
	Rawalpindi.	filling, Moist heat	Sodium Hyaluronate	
		sterilization &	Class: D	
	(ELI-00814)	distribution)	MD group: not a group type	
	D.O.I: 24-11-2021	Address 01:	Medical device.	
		No. 88, Keji 1 st Road,	LOA Validity: 31-12-2026	
	Dy. No.:	Guishan District, Taoyuan	FSC Validity: 13-10-2026	
	13072 DRAP (R&I)	City 33383, Taiwan	Shelf life: 03 years	
	Dated: 09-08-2024	(R.O.C).	Storage Conditions:	
	Fee Challan No.:	(C) (S) (1)	$2^{\circ}C - 25^{\circ}C$	
	9427036167	(Contract Sterilization-		
	PKR: 50000/-	Gamma Sterilization)		
	Dated: 09-08-2024	China Biotech		
		Corporation		
		Address 02:		
		No. 10, 33 rd road,		
		Taichung Industrial Park,		
		Taichung, Taiwan.		
		(C		
		(Contract Sterilizer-		
		Ethylene Oxide		
		Sterilization)		

274	Name M/s Getz Pharma (Pvt.)	Taiwan Advanced Sterilization Technology Inc. Address 03: No. 17-1, Chien Kuo Road, Tan Tze, Taichung City, 427, Taiwan. Name of Manufacturer M/s Shanghai Huarui	RESPOMATIC DPI Device	Approved.
	Ltd. Address of Importer 29-30- Sector 27, Korangi Industrial Area, Karachi, Pakistan (ELI-00471) Dy. No.: Dated: 08-06-2020 Fee Challan No.:	Aerosol Co., Ltd. Address of Manufacturer No. 222, Yuanchun Road, Pudong, Shanghai, China. Secondary Packaging Site: M/s Getz Pharma (Pvt.)	Class: A MD group: Single LOA Validity: 01-01-2027 FSC Validity: Original Legalized Certificate for exportation of Medical Products (Certificate No. 20180148) issued from China	
	1956156 PKR: 5000/- Dated: 04-06-2020	Ltd. Address: Plot no. 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan.	(Valid till 20-08-2020) – Valid at the time of dossier submission Shelf life: 3 Years (36 Months) Stability studies of batch at room temperature for 36 months. Storage Conditions: 2°C – 25°C	
275	Name M/s Getz Pharma (Pvt.) Ltd. Address of Importer 29-30- Sector 27, Korangi Industrial Area, Karachi, Pakistan (ELI-00471) Dy. No.: Dated: 24-04-2020 Fee Challan No.: 1956157 PKR: 5000/- Dated: 24-04-2020	Name of Manufacturer Name M/s Taian Dalu Medical Instrument Co., Ltd. Address of Manufacturer West Part of Yitianmen Street, Hi-tech Zone, Taian City, Shangdong, China.	DPI device for Inhalation Class: A MD group: Single LOA Validity: 01-01-2027 FSC Validity: Original Legalized Certificate for Exportation of Medical Products (Certificate No. 20190006) issued China (Valid till 24-12-2021) – Valid at the time of dossier submission Shelf life: 2 Years	Approved.
			Storage Conditions: 2°C – 25°C	

276	Name Abbott Laboratories (Pakistan) Ltd. Address of Importer Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) 03/08/2018 Dy. No.: Dated: 23-04-2024 Fee Challan No.: 946671161518 PKR: 50000/- Dated: 22-01-2024	Name of Manufacturer Name Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland Contract Manufacturing site address: Denka Co., Ltd Kagamida Factory 1359-1, Kagamida, Kigoshi Gosen-shi Niigata, 959-1695, Japan	ARCHITECT iValproic Acid Reagent Kit (IP35-25) ARCHITECT iValproic Acid Calibrator Kit (IP35-01) Class: C MD group: Kit FSC Validity: 26-09-2026 Shelf life: 18 months Storage Conditions: 2°C - 25°C	Approved.
277	Name Abbott Laboratories (Pakistan) Ltd. Address of Importer Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) 03/08/2018 Dy. No.: Dated: 26-04-2024 Fee Challan No.: 5612175880 PKR: 50000/- Dated: 28-02-2024	Name of Manufacturer Name Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland	ARCHITECT STAT CK-MB Reagent Kit 2K42-28/38, Shelf life: 18 months ARCHITECT STAT CK-MB Calibrators 2K42-01 Shelf life: 18 months and ARCHITECT STAT CK-MB Controls 2K42-10 Shelf life: 36 months Class: C MD group: Kit FSC Validity: May 2025. Storage Conditions: 2°C - 8°C	Approved.
278	Name Abbott Laboratories (Pakistan) Ltd. Address of Importer Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) 03/08/2018 Dy. No.: Dated: 26-04-2024 Fee Challan No.: 6720471985 PKR: 50000/- Dated: 28-02-2024	Name of Manufacturer Name Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland Fisher Diagnostics 8365 Valley Pike Middletown, VA 22645- 1905 USA Microgenics Corporation 46500 Kato Road Fremont, CA 94538-1905 USA	ARCHITECT STAT Myoglobin Reagent Kit 2K43-20 &2K43-25: Shelf life: 18 Months ARCHITECT STAT Myoglobin Calibrators 2K43-01: Shelf life: 18 Months ARCHITECT STAT Myoglobin Controls 2K43-10: Shelf life: 36 Months Class: C MD group: Kit FSC Validity: May 2025.	Approved.

279	M/s Intra Health 56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: 21483 (DRAP R&I) Dated: 21-12-2023 Fee Challan No.: 341680115 PKR: 25000/- Dated: 03-11-2023 M/s Intra Health	Name of Manufacturer Name M/s Jiangsu Webest Medical Products Co. Ltd. No. 05, Yingchun Road, Industrial Park, 211700 Xuyi, Jiangsu, China.	Storage Conditions: 2°C - 8°C Maxineon IV Catheter with wings and heparin cap. 16G, 18G, 20G, 22G, 24G Class: B FSC Validity: 23-04-2025. LOA Validity: 31-12-2028 Storage Conditions: Shelf life: 05 Years	Approved.
	56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: 21484 (DRAP R&I) Dated: 21-12-2023 Fee Challan No.: 9542659887 PKR: 25000/- Dated: 03-11-2023	Name M/s Jiangsu Webest Medical Products Co. Ltd. No. 05, Yingchun Road, Industrial Park, 211700 Xuyi, Jiangsu, China.	wings and injection port. 16G, 18G, 20G, 22G, 24G Class: B FSC Validity: 23-04-2025. LOA Validity: 31-12-2028 Storage Conditions: Shelf life: 05 Years	
281	M/s Intra Health 56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: Dated: 08-11-2023 Fee Challan No.: 563176322 PKR: 25000/- Dated: 10-11-2023	Name of Manufacturer Name M/s Jiangsu Webest Medical Products Co. Ltd. No. 05, Yingchun Road, Industrial Park, 211700 Xuyi, Jiangsu, China.	KAWA infusion set with burette 100 ml Class: B MD group: single FSC Validity: 23-04-2025. LOA Validity: 31-12-2028 Storage Conditions: Shelf life: 2 years	Approved.

282	M/s Intra Health 56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: 8432 (DRAP R&I) Dated: 13-06-2023 Fee Challan No.: 7126741162 PKR: 5000/- Dated: 03-11-2023	Name of Manufacturer Name M/s Top Glove sdn bhd. Lot 4969 Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia.	Sensifeel Plus Latex Examination Gloves, Powdered. (S,,M,L,XL, XS) Class: A FSC Validity: 12-08-2027. LOA Validity: 22-11-2027 Storage Conditions: at room temperature Shelf life: 5 years	Approved.
283	M/s Intra Health 56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: 8430 (DRAP R&I) Dated: 13-06-2023 Fee Challan No.: 954437828090 PKR: 5000/- Dated: 03-11-2023	Name of Manufacturer Name M/s Top Glove sdn bhd. Lot 4969 Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia.	Sensifeel Plus Latex Examination Gloves, Powder Free. (Plus,S,,M,L,XL, XS) Class: A FSC Validity: 12-08-2027. LOA Validity: 22-11-2027 Storage Conditions: at room temperature Shelf life: 5 years	Approved.
284	M/s Intra Health 56-A, Unit No. 01, Justice Inamullah Road, Block 7/8, KCHS Karachi (ELI-00049) D.O.I: 22-10-2018 Dy. No.: 8431 (DRAP R&I) Dated: 25-05-2023 Fee Challan No.: 897733703 PKR: 5000/- Dated: 05-04-2023	Name of Manufacturer Name M/s Top Glove sdn bhd. Lot 4969 Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia.	Sensifeel Plus Nitrile Examination Gloves, Powder Free. (Plus,S,,M,L,XL, XS) Class: A FSC Validity: 12-08-2027. LOA Validity: 22-11-2027 Storage Conditions: at room temperature Shelf life: 5 years	Approved.

286	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 1407727034 PKR: 5000/- Dated: 09-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic Development Zone, Anhui, China.	Siny – Single use Vacuum Blood Collection Tube (Clot Activator Tube) Sizes: as Free sale certificate Class: A LOA Validity: valid FSC Validity:25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
287	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 761699108 PKR: 5000/- Dated: 09-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic Development Zone, Anhui, China.	Siny- Single Use Vacuum Blood Collection Tube. Gel Tube (PET/Glass) Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: valid FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
288	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 25095171178 PKR: 5000/- Dated: 09-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic Development Zone, Anhui, China.	Siny – Single use Vacuum Blood Collection Tube (Sodium Fluoride Tube) (PET/Glass) 2ml, 3ml, 4ml & 5ml. Class: A LOA Validity: submitted FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
289	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.:	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic	Siny – Single use Vacuum Blood Collection Tube (Sodium Citrate Tube) (PET/Glass) 1.6ml, 2ml, 3ml,4ml, 5ml, Class: A LOA Validity: valid FSC Validity: 25-05-2025	Approved.

	Dated: 11-03-2024	Davidania at Zana	Shelf life: 24 months	
		Development Zone,		
	Fee Challan No.:	Anhui, China.	Storage Conditions:	
	47161549372		Room temperature	
	PKR: 5000/-			
200	Dated: 09-01-2024	T INT C	C	. 1
290	M/s Allied Surgicals.	Legal Manufacturer:	Siny – single use Vacuum	Approved.
	56/A-1, Justice	Name:	Blood Collection Tube	
	Inamullah Road, Block	M/s Anhui Sinic	Gel/Heparin Lihium tube	
	7/8, K.C.H.S., Karachi.	Laboratory Medicine	(Glass)	
		Technology Co. Ltd.	2ml, 3ml, 4ml, 5ml, 6ml, 7ml,	
	(ELI-00238)	Address 01:	8ml, 9ml, 10ml.	
	D.O.I: 22-10-2018	Sinic Science Park,	Class: A	
		Dongyi North Road,	LOA Validity: submitted	
	Dy. No.:	Tongeheng Economic	FSC Validity: 25-05-2025	
	Dated: 11-03-2024	Development Zone,	Shelf life: 24 months	
	Fee Challan No.:	Anhui, China.	Storage Conditions:	
	40118468865		Room temperature	
	PKR: 5000/-		_	
	Dated: 09-01-2024			
291	M/s Allied Surgicals.	Legal Manufacturer:	Siny - Single use Vacuum	Approved.
	56/A-1, Justice	Name:	Blood Collection Tube.	
	Inamullah Road, Block	M/s Anhui Sinic		
	7/8, K.C.H.S., Karachi.	Laboratory Medicine	Gel/sodium citrate tube	
		Technology Co. Ltd.	(Glass)	
	(ELI-00238)	Address 01:		
	D.O.I: 22-10-2018	Sinic Science Park,	2ml, 3ml, 4ml, 5ml, 6ml, 7ml,	
		Dongyi North Road,	8ml, 9ml, 10ml.	
	Dy. No.:	Tongeheng Economic		
	Dated: 11-03-2024	Development Zone,	Class: A	
	Fee Challan No.:	Anhui, China.	LOA Validity: submitted	
	13657146812	,	FSC Validity: 25-05-2025	
	PKR: 5000/-		Shelf life: 24 months	
	Dated: 09-01-2024		Storage Conditions:	
	2.000.03		Room temperature	
292	M/s Allied Surgicals.	Legal Manufacturer:	Siny – Single Use Vacuum	Approved.
	56/A-1, Justice	Name:	Blood Collection Tube.	rr
	Inamullah Road, Block	M/s Anhui Sinic		
	7/8, K.C.H.S., Karachi.	Laboratory Medicine	No additive tube	
	0, 12. 0.11.0., 14.40111.	Technology Co. Ltd.	(PET/Glass)	
	(ELI-00238)	Address 01:	2ml, 3ml, 4ml, 5ml, 6ml, 7ml,	
	D.O.I: 22-10-2018	Sinic Science Park,	8ml, 9ml, 10ml.	
	2.0.1. 22 10 2010	Dongyi North Road,	, , , , , , , , , , , , , , , , , , ,	
	Dy. No.:	Tongeheng Economic	Class: A	
	Dated: 11-03-2024	Development Zone,	LOA Validity: submitted	
	Fee Challan No.:	Anhui, China.	FSC Validity: 25-05-2025	
	65756987881	Zimui, Cimiu.	Shelf life: 24 months	
	PKR: 5000/-		Storage Conditions:	
	Dated: 09-01-2024		Room temperature	
293	M/s Allied Surgicals.	Legal Manufacturer:	Siny – Single use Vacuum	Approved.
273	56/A-1, Justice	Name:	Blood Collection Tube.	ripproved.
	Inamullah Road, Block	raille.	Dioou Concenon Tube.	
	7/8, K.C.H.S., Karachi.			
<u> </u>	//0, K.C.11.5., Karacill.			

	(ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 23434841 PKR: 5000/- Dated: 09-01-2024	M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic Development Zone, Anhui, China.	Gel/sodium fluoride tube (Glass) Sizes: as per FSC Class: A LOA Validity: submitted FSC Validity: submitted Shelf life: 24 months Storage Conditions: Room temperature	
294	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 066406064 PKR: 5000/- Dated: 12-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: Sinic Science Park, Dongyi North Road, Tongeheng Economic Development Zone, Anhui, China.	Siny – Single Use Vacuum Blood Collection Tube. EDTA-K3 tube (Glass) 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: submitted FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
295	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 46691321 PKR: 5000/- Dated: 12-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: No. 02, Dongyi North Road, Economic & Technology Zone, 231400 Tongeheng, Anhui, China.	Siny Blood Collection Tube (Gel/Clot Activator) – Sizes as per FSC Class: A LOA Validity: submitted FSC Validity: submitted Shelf life: 24 months Storage Conditions: Room temperature	Approved.
296	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 3035191796 PKR: 5000/- Dated: 12-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: No. 02, Dongyi North Road, Economic & Technology Zone, 231400 Tongeheng, Anhui, China.	Siny – Single use Vacuum Blood Collection Tube. Sodium Fluoride + EDTA-K2 tube (Glass) 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: submitted FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.

297	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.:	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: No. 02, Dongyi North Road, Economic & Technology Zone, 231400	Siny- Single use Vacuum Blood Collection Tube. EDTA-K2 tube (PET/ Glass tube) 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: submitted	Approved.
	Dated: 11-03-2024 Fee Challan No.: 85155313 PKR: 5000/- Dated: 12-01-2024	Tongeheng, Anhui, China.	FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	
298	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 115143161072 PKR: 5000/- Dated: 09-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: No. 02, Dongyi North Road, Economic & Technology Zone, 231400 Tongeheng, Anhui, China.	Siny – Single use Vacuum Blood Collection Tube. Heparin Lithium Tube (Glass) 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: submitted FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
299	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 11-03-2024 Fee Challan No.: 28310553640 PKR: 5000/- Dated: 15-01-2024	Legal Manufacturer: Name: M/s Anhui Sinic Laboratory Medicine Technology Co. Ltd. Address 01: No. 02, Dongyi North Road, Economic & Technology Zone, 231400 Tongeheng, Anhui, China.	Siny – Single use Vacuum Blood Collection Tube. Sodium Fluoride / Potasium Oxalate Tube (PET) 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml & 10ml. Class: A LOA Validity: submitted FSC Validity: 25-05-2025 Shelf life: 24 months Storage Conditions: Room temperature	Approved.
300	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 01-02-2024	Legal Manufacturer: Name: M/s Guangdong Ecan Medical Co. Ltd. Address 01: Building 1, No. 222, XINDU Road, Chengjiao Street Conghua District 510920, Guangzhou city,	Maxcare Latex Foley Urethral Catheter one way, 2 ways (Pediatric, female, standard), 2 ways with tienam tip, 3 ways (Pediatric, female, standard, double balloon), 4-way t (double balloon type A and B) Sizes: 2.0mm (6Fr) – 10mm (30 Fr)	Approved.

_			D 11 G	
	Fee Challan No.:	Guangdong Province,	Balloon Capacity: 3-5ml, 5ml,	
	3936612686	China.	5-10ml, 5-15ml, 20ml, 30ml,	
	PKR: 25000/-		50ml, 30-50ml.	
	Dated: 27-10-2023			
			Class: B	
			LOA Validity: submitted	
			FSC Validity: submitted	
			Shelf life: 5 years	
			Storage Conditions:	
			Room temperature	
311	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare Silicone Foley	Approved.
	56/A-1, Justice	Name:	Catheter	
	Inamullah Road, Block	M/s Guangdong Ecan	Type:2 ways (Pediatric,	
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	female, standard), 3 ways	
	,	Address 01:	(Pediatric, female, standard)	
	(ELI-00238)	Building 1, No. 222,	Sizes: 2.0mm (6Fr) – 10mm	
	D.O.I: 22-10-2018	XINDU Road, Chengjiao	(30 Fr)	
		Street Conghua District	Balloon Capacity: 1.5ml, 3ml,	
	Dy. No.:	510920, Guangzhou city,	3-5ml, 5ml, 5-10ml, 10ml, 5-	
	Dated: 01-02-2024	Guangdong Province,	15ml, 20ml, 30ml, 50ml, 30-	
	Fee Challan No.:	China.	50ml.	
	73745906183	Cililia.	30m.	
	PKR: 25000/-		Class: B	
	Dated: 27-10-2023			
	Dateu: 27-10-2023		LOA Validity: submitted	
			FSC Validity: submitted	
			Shelf life: 5 years	
			Storage Conditions:	
212	3.5/ 4.11: 1.0	7 175	Room temperature	
312	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare Oxygen Mask	Approved.
	56/A-1, Justice	Name:	Sizes: as per FSC	
	Inamullah Road, Block	M/s Guangdong Ecan	Class: B	
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	LOA Validity: submitted	
		Address 01:	FSC Validity: submitted	
	(ELI-00238)	Building 1, No. 222,	Shelf life: 5 years	
	D.O.1: 22-10-2018		_	
			Room temperature	
	Dy. No.:			
		5 5		
		China.		
	PKR: 25000/-			
	Dated: 27-10-2023			
312	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare Endotracheal Tube	Approved.
	56/A-1, Justice	Name:	Type: Standard, oral	
	Inamullah Road, Block	M/s Guangdong Ecan	preformed, nasal preformed.	
	· ·			İ
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	Sizes: 2.0mm, 2.5mm,	
	· ·	Medical Co. Ltd. Address 01:	Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm,	
	· ·			
	7/8, K.C.H.S., Karachi.	Address 01:	3.0mm, 3.5mm, 4.0mm,	
	7/8, K.C.H.S., Karachi. (ELI-00238)	Address 01: Building 1, No. 222,	3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm,	
	7/8, K.C.H.S., Karachi. (ELI-00238)	Address 01: Building 1, No. 222, XINDU Road, Chengjiao	3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm,	
312	D.O.I: 22-10-2018 Dy. No.: Dated: 01-02-2024 Fee Challan No.: 75468924 PKR: 25000/- Dated: 27-10-2023 M/s Allied Surgicals. 56/A-1, Justice	XINDU Road, Chengjiao Street Conghua District 510920, Guangzhou city, Guangdong Province, China. Legal Manufacturer: Name:	Storage Conditions: Room temperature Maxcare Endotracheal Tube Type: Standard, oral preformed, nasal preformed.	Approved.

	Fee Challan No.:	Guangdong Province,	Class: B	
	5326374944	China.	LOA Validity: submitted	
	PKR: 25000/-	Cilina.	FSC Validity: submitted	
	Dated: 04-12-2023		Shelf life: 5 years	
	Dated: 04-12-2025		Storage Conditions:	
			Room temperature	
313	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare PVC Stomach	Approved.
	56/A-1, Justice	Name:	Tube	11
	Inamullah Road, Block	M/s Guangdong Ecan	Type & size standard without	
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	balloon (PVC) 6Fr, 8Fr, 10Fr,	
		Address 01:	12Fr, 14 Fr, 16 Fr,18 Fr, 20	
	(ELI-00238)	Building 1, No. 222,	Fr, 22 Fr	
	D.O.I: 22-10-2018	XINDU Road, Chengjiao	without balloon (silicone)	
		Street Conghua District	6Fr, 8Fr, 10Fr, 12Fr, 14 Fr, 16	
	Dy. No.:	510920, Guangzhou city,	Fr,18 Fr, 20 Fr, 22 Fr	
	Dated: 01-02-2024	Guangdong Province,	Ryle's tube: 6Fr, 8Fr, 10Fr,	
	Fee Challan No.:	China.	12Fr, 14 Fr, 16 Fr,18 Fr, 20 Fr	
	75353674630		Class: B	
	PKR: 25000/-			
	Dated: 04-12-2023		LOA Validity: submitted	
			FSC Validity: submitted	
			Shelf life: 5 years	
			Storage Conditions:	
214	100	- 115	Room temperature	
314	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare Feeding Tube	Approved.
	56/A-1, Justice	Name:	Sizes: as per FSC	
	Inamullah Road, Block	M/s Guangdong Ecan	Class: B	
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	MD group: Single.	
	(ELL 00228)	Address 01:	LOA Validity: submitted FSC Validity: submitted	
	(ELI-00238) D.O.I: 22-10-2018	Building 1, No. 222, XINDU Road, Chengjiao	Shelf life: 5 years	
	D.O.1. 22-10-2018	Street Conghua District	Storage Conditions:	
	Dy. No.:	510920, Guangzhou city,	Room temperature	
	Dated: 05-12-2023	Guangdong Province,	Room temperature	
	Fee Challan No.:	China.		
	83951691			
	PKR: 25000/-			
	Dated: 04-12-2023			
315	M/s Allied Surgicals.	Legal Manufacturer:	Maxcare Nebulizer Mask	Approved.
	56/A-1, Justice	Name:	Class: B	**
	Inamullah Road, Block	M/s Guangdong Ecan	MD group: Single.	
	7/8, K.C.H.S., Karachi.	Medical Co. Ltd.	MD group: Single.	
		Address 01:	LOA Validity: submitted	
	(ELI-00238)	Building 1, No. 222,	FSC Validity: submitted	
	D.O.I: 22-10-2018	XINDU Road, Chengjiao	Shelf life: 5 years	
		Street Conghua District	Storage Conditions:	
	Dy. No.:	510920, Guangzhou city,	Cool & dry place	
	Dated: 05-12-2023	Guangdong Province,		
	Fee Challan No.:	China.		
	66205008489			
	PKR: 25000/-			
	Dated: 04-12-2023			

316	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 26-10-2023 Fee Challan No.: 065995473 PKR: 25000/-	Legal Manufacturer: Name: M/s Tianchang Hengsheng Medical Devices Co. Ltd. Address 01: Qinlan Industrial Park, Tianchange City, Anhui Province, China.	Maxcare Sterile Surgical Gloves - Powder Free Specifications: 6.0#, 6.5#, 7.0#, 7.5#, 7.5#, 8.0#, 8.5#, 9.0#. Class: B MD group: Single. MD group: Single. LOA Validity: submitted FSC Validity: submitted Shelf life: 5 years	Approved.
	Dated: 27-10-2023		Storage Conditions: Cool & dry place	
317	M/s Allied Surgicals. 56/A-1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI-00238) D.O.I: 22-10-2018 Dy. No.: Dated: 26-10-2023 Fee Challan No.: 7877561476 PKR: 25000/- Dated: 27-10-2023	Legal Manufacturer: Name: M/s Tianchang Hengsheng Medical Devices Co. Ltd. Address 01: Qinlan Industrial Park, Tianchange City, Anhui Province, China.	Maxcare Sterile Surgical Gloves - Powdered Specifications: 6.0#, 6.5#, 7.0#, 7.5#, 7.5#, 8.0#, 8.5#, 9.0#. Class: B MD group: Single. MD group: Single. LOA Validity: submitted FSC Validity: submitted Shelf life: 5 years Storage Conditions: Cool & dry place	Approved.
318	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong, China. LOA Validity: 14-08-2029 FSC validity: 15-08-2026	Cure Sure I.V. Flow Regulator Models: Single Line Class B Shelf life: 05 Years	Approved.
319	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan.	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road,	Cure Sure Sterile Disposable Syringe with Needle Size: 1ml	Approved.

	(ELI - 01234)	Zhangdian District, Zibo 255000, Shandong, China.	Class B Shelf life: 05 Years	
		LOA Validity: 14-08-2029	Shell life. 03 Teals	
		FSC validity: 15-08-2026		
320	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong,	Cure Sure Sterile Autodisbale Syringe with Needle Size: 2ml,3ml Class B	Approved.
		China. LOA Validity: 14-08-2029 FSC validity: 15-08-2026	Shelf life: 05 Years	
321	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong, China. LOA Validity: 14-08-2029 FSC validity: 15-08-2026	Cure Sure Sterile Dispsable Syringe with needle Size:10ml Class B Shelf life: 05 Years	Approved.
322	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong, China. LOA Validity: 14-08-2029	Cure Sure Sterile Disposible Syringe with needle Sizes: 20ml, 30ml, 50ml, 60ml & 100ml Class B Shelf life: 05 Years	Approved.

		FSC validity:		
		15-08-2026		
323	Cure Connect Pakistan	Legal Manufacturer: Zibo Eastmed HealthCare	Cure Sure Sterile Infusion Set	Approved.
	Plot No. B-204, First	Product Co., Ltd.	Sizes: DM002, DM003,	
	Floor, Sector 6-F,		DM004, DM018, DM019,	
	Mehran Town, Korangi, Karachi Pakistan.	Address:	DM020, DM005	
	Karachi Pakistan.	No. 118 Huaguang Road, Zhangdian District, Zibo	Class B	
	(ELI - 01234)	255000, Shandong,	Class D	
	,	China.	Shelf life: 05 Years	
		LOA Validity:		
		14-08-2029		
		FSC validity:		
224	C C + D 1 : +	15-08-2026		A 1
324	Cure Connect Pakistan	Legal Manufacturer: Zibo Eastmed HealthCare	Cure Sure Sterile Hypodermic Needle	Approved.
	Plot No. B-204, First	Product Co., Ltd.	recuie	
	Floor, Sector 6-F,	,	Sizes: 14G, 15G, 16G, 18G,	
	Mehran Town, Korangi,	Address:	19G, 20G, 21G, 22G, 23G,	
	Karachi Pakistan.	No. 118 Huaguang Road,	24G, 25G, 26G, 27G, 28G,	
	(ELI - 01234)	Zhangdian District, Zibo 255000, Shandong,	29G, 30G, 31G	
	(ELI - 01234)	China.	Class B	
			G1 161'C 0537	
		LOA Validity: 14-08-2029	Shelf life: 05 Years	
		FSC validity: 15-08-2026		
325	Cure Connect Pakistan	Legal Manufacturer:	Cure Sure Scalp Vein Set	Approved.
		Zibo Eastmed HealthCare	(Sterile Intravenous Needle)	11
	Plot No. B-204, First	Product Co., Ltd.		
	Floor, Sector 6-F,	Addwaga.	Sizes: 27G, 26G, 25G, 24G,	
	Mehran Town, Korangi, Karachi Pakistan.	Address: No. 118 Huaguang Road,	23G, 22G, 21G, 20G	
	ixaraom i axistan.	Zhangdian District, Zibo	Class B	
	(ELI - 01234)	255000, Shandong,		
		China.	Shelf life: 05 Years	
		LOA Validity:		
		14-08-2029		
		FSC validity:		
22.5		15-08-2026		
326	Cure Connect Pakistan	Legal Manufacturer: Zibo Eastmed HealthCare	Cure Sure Infusion Set With Burette	Approved.
	Plot No. B-204, First	Product Co., Ltd.	Durelle	
	Floor, Sector 6-F,	110ddet Co., Did.	Sizes: 100ml & 150ml	
	Mehran Town, Korangi,	Address:		

	Karachi Pakistan.	No. 118 Huaguang Road,	Class B	
	(ELI - 01234)	Zhangdian District, Zibo 255000, Shandong, China.	Shelf life: 05 Years	
		LOA Validity: 14-08-2029		
		FSC validity: 15-08-2026		
327	Cure Connect Pakistan Plot No. B-204, First	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd.	Cure Sure Blood Transfusion Set	Approved.
	Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan.	Address: No. 118 Huaguang Road,	Models: DMSX-1, DMSX-2, DMSX-3, DMSX-4, DMSX-5	
	(ELI - 01234)	Zhangdian District, Zibo 255000, Shandong, China.	Class B	
		LOA Validity:	Shelf life: 05 Years	
		14-08-2029 FSC validity: 15-08-2026		
328	Cure Connect Pakistan	Legal Manufacturer:	Cure Sure Sterile Urine Bag	Approved the
	Plot No. B-204, First Floor, Sector 6-F,	Zibo Eastmed HealthCare Product Co., Ltd.	Sizes: 500ml, 1000ml, 1500ml, 2000ml	product in Class A.
	Mehran Town, Korangi, Karachi Pakistan.	Address: No. 118 Huaguang Road, Zhangdian District, Zibo	Class B	
	(ELI - 01234)	255000, Shandong, China.	Shelf life: 05 Years	
		LOA Validity: 14-08-2029		
		FSC validity: 15-08-2026		
329	Cure Connect Pakistan Plot No. B-204, First	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd.	Cure Sure Sterile Three-way Stopcock with Extension Tube	Approved.
	Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan.	Address: No. 118 Huaguang Road, Zhangdian District, Zibo	Length of extension tube: 10cm, 25cm, 50cm, 80cm,	
	(ELI - 01234)	Zhangdian District, Zibo 255000, Shandong, China.	100cm, 150mm Class B	
		LOA Validity: 14-08-2029	Shelf life: 05 Years	

		FSC validity: 15-08-2026		
330	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong, China. LOA Validity: 14-08-2029 FSC validity: 15-08-2026	Cure Sure Sterile Heparin Cap Models: Transparent Type & Yellow Type Class B Shelf life: 05 Years	Approved.
331	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Zibo Eastmed HealthCare Product Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong, China. LOA Validity: 14-08-2029 FSC validity: 15-08-2026	Cure Sure Sterile Three-way Stopcock Model: Grease Resistance Class B Shelf life: 05 Years	Approved.
332	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Heze Yinuo Medical Industry Co., Ltd. Address: Dingtao Country Economic Development Zone, Heze City, Shangdong, People's Republic of China. LOA validity: 17-06-2029 FSC Validity: 03-12-2024 Expired but valid upon submission	Cure + Disposable Syringe with needle (Luer Lock type) Size: 1 ml Class B Shelf life: 05 Years	Approved.

333	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Heze Yinuo Medical Industry Co., Ltd. Address: Dingtao Country Economic Development Zone, Heze City, Shangdong, People's Republic of China. LOA validity: 17-06-2029 FSC Validity: 03-12-2024 Expired but valid upon submission	Cure + Autodisable Syringe with needle (Luer Lock type) Sizes: 2ml,3ml Class B Shelf life: 05 Years	Approved.
334	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Heze Yinuo Medical Industry Co., Ltd. Address: Dingtao Country Economic Development Zone, Heze City, Shangdong, People's Republic of China. LOA validity: 17-06-2029 FSC Validity: 03-12-2024 Expired but valid upon submission	Cure + Autodisable Syringe with needle (Luer Lock type) Size: 5ml Class B Shelf life: 05 Years	Approved.
335	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI - 01234)	Legal Manufacturer: Heze Yinuo Medical Industry Co., Ltd. Address: Dingtao Country Economic Development Zone, Heze City, Shangdong, People's Republic of China. LOA validity: 17-06-2029	Cure + Disposable Syringe with needle (Luer Lock type) Sizes: 20ml, 30ml, 50ml & 60ml Class B Shelf life: 05 Years	Approved.

		FSC Validity:		
		03-12-2024		
		Expired but valid upon submission		
336	Cure Connect Pakistan	Legal Manufacturer:	Cure + Blood Transfusion Set	Approved.
330	Cure Connect 1 axistan	Heze Yinuo Medical	Cure Blood Transfusion Set	прриочец.
	Plot No. B-204, First	Industry Co., Ltd.	Needle size; 18G/19 G /20 G	
	Floor, Sector 6-F,	•	/21 G /22 G /23 G /24 G /25	
	Mehran Town, Korangi,	Address:	G /26 G /27 G	
	Karachi Pakistan.	Dingtao Country		
	(ELL 01224)	Economic Development	Class B	
	(ELI - 01234)	Zone, Heze City, Shangdong, People's	Shelf life: 05 Years	
		Republic of China.	Shell life. 03 Tears	
		republic of clinia.		
		LOA validity:		
		17-06-2029		
		EGGY VIV		
		FSC Validity: 03-12-2024		
		Expired but valid upon		
		submission		
337	Cure Connect Pakistan	Legal Manufacturer:	Cure + Sterile Hypodermic	Approved.
		Heze Yinuo Medical	Needle	
	Plot No. B-204, First	Industry Co., Ltd.	M. 1.1 14C 15C 16C 19C	
	Floor, Sector 6-F, Mehran Town, Korangi,	Address:	Models: 14G, 15G, 16G, 18G, 19G, 20G, 21G, 22G, 23G,	
	Karachi Pakistan.	Dingtao Country	24G, 25G, 26G, 27G, 28G,	
		Economic Development	29G, 30G, 31G	
	(ELI - 01234)	Zone, Heze City,		
		Shangdong, People's	Class B	
		Republic of China.	CI ICI'C OF W	
		LOA validity:	Shelf life: 05 Years	
		17-06-2029		
		FSC Validity:		
		03-12-2024		
		Expired but valid upon		
338	Cure Connect Pakistan	submission Legal Manufacturer:	Cure + Infusion Set For	Approved.
	2 STO COMPONE T UNIDUM	Heze Yinuo Medical	Single Use	Tippio (ou.
	Plot No. B-204, First	Industry Co., Ltd.		
	Floor, Sector 6-F,		Models: A, A-1, A-2 & A-3	
	Mehran Town, Korangi,	Address:	CI D	
	Karachi Pakistan.	Dingtao Country Economic Development	Class B	
	(ELI - 01234)	Economic Development Zone, Heze City,	Shelf life: 05 Years	
	(1234)	Shangdong, People's	Shell life. 05 Teals	
		Republic of China.		

		LOA validity: 17-06-2029 FSC Validity: 03-12-2024 Expired but valid upon submission		
339	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)	Legal Manufacturer: Name: M/s Dongguan Kewei Medial Instrument Co., Ltd Address of manufacturer: No. 1 Tongqing Road Dongcheng District Dongguan City Guangdong 523127 China	Kewei Arterial Cannula (Not wirewound) Class: D MD group: Family LOA Validity: 31-December 2024 FSC Validity: China- Date of validity 02-04-2025 Netherland- validity Oct 09 2027	Approved.
	R&I Dated: Submission date: 20-11-2024 Fee Challan No.: 0790378356 PKR: 110000/-	LOA validity: 31-12-2024 FSC validity: 02-04-2025 (China) FSC validity	Shelf life: 03 Years Codes: Cat No: IFAC-PSN-08 Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-10, Arterial Cannula, Straight Plastic tip, not Wirewound Body with	
		31-12-2027 (The Netherlands)	peel cap IFAC-PSN-12, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-14, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-16, Arterial Cannula, Straight Plastic tip,	

not Wirewound Body with peel cap IFAC-PSN-18, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-20, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-22, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-24, Arterial Cannula, Straight Plastic tip, not Wirewound Body with peel cap IFAC-PSN-SR-14, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap IFAC-PSN-SR-16, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap IFAC-PSN-SR-18, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap IFAC-PSN-SR-20, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap IFAC-PSN-SR-22, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap IFAC-PSN-SR-24, Arterial Cannula, Straight Plastic tip, not Wirewound Body with suture ring, with peel cap

			IFAC-PCN-12, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap IFAC-PCN-14, Arterial Cannula, Angled Plastic tip, not Wirewound Body with	
			peel cap IFAC-PCN-16, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap	
			IFAC-PCN-18, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap	
			IFAC-PCN-20, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap	
			IFAC-PCN-22, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap	
			IFAC-PCN-24, Arterial Cannula, Angled Plastic tip, not Wirewound Body with peel cap	
340	M/s MICROPORT	Legal Manufacturer:	Kewei Venous return cannula	Approved.
	SCIENTIFIC PAKISTAN (PRIVATE)	Name:	(Two Stage)	
	LIMITED	M/s Dongguan Kewei	Class: D	
	Address of Importer	Medial Instrument Co., Ltd	MD group: Family	
	Office No 02/3, 2nd floor Hive Gizri Road,		LOA Validity: 31-December 2024	
	Block 9, Clifton, Karachi, South, Saddar	Address of manufacturer: No. 1 Tongqing Road	FSC Validity:	
	town	Dongcheng District Dongguan City Guangdong 523127	China- Date of validity 02-04-2025	
	(ELI-01182)	China	Netherland- validity Oct 09 2027	

R&I Dated: Submission	LOA validity:	Shelf life: 03 Years
date: 20-11-2024	31-12-2024	Codes:
Fee Challan No.: 1761490728 PKR: 110000/-	FSC validity: 02-04-2025 (China)	VC-TSR-2428, Venous return cannula, Two stage, Round Lumen VC-TSR-2836, Venous return
	FSC validity 31-12-2027 (The Netherlands)	cannula, Two stage, Round Lumen VC-TSR-3038, Venous return cannula, Two stage, Round Lumen VC-TSR-3238, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3438, Venous return cannula, Two stage, Round Lumen VC-TSR-3440, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3446, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3448, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3646, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3650, Venous return cannula, Two stage, Round Lumen
		VC-TSR-3850, Venous return cannula, Two stage, Round Lumen
		VC-TSO-2428, Venous return cannula, Two stage, Ovel Lumen

			VC-TSO-2836, Venous return cannula, Two stage, Ovel Lumen VC-TSO-3038, Venous	
			return cannula, Two stage, Ovel Lumen	
			VC-TSO-3238, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3438, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3440, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3446, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3448, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3646, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3650, Venous return cannula, Two stage, Ovel Lumen	
			VC-TSO-3850 Venous return cannula, Two stage, Ovel Lumen	
341	M/s MICROPORT SCIENTIFIC	Legal Manufacturer: Name:	Kewei Suction Catheter (Suction Wand)	Approved.
	PAKISTAN (PRIVATE) LIMITED	M/s Dongguan Kewei	Class: D	
	Address of Importer	Medial Instrument Co., Ltd	MD group: Family	
	Office No 02/3, 2nd floor Hive Gizri Road,		LOA Validity: 31-December 2024	
	Block 9, Clifton, Karachi, South, Saddar	Address of manufacturer:	FSC Validity:	
	town	No. 1 Tongqing Road Dongcheng District Dongguan City	China- Date of validity 02-04- 2025	

	(ELI-01182)	Guangdong 523127 China	Netherland- validity December 31 2027 Shelf life: 03 Years	
	DOLD 1 G L 1	LOA validity:	Coes	
	R&I Dated: Submission date: 20-11-2024	31-12-2024	SCR-18, Suction wand, Rigid Suction catheter 18Fr	
	Fee Challan No.:	FSC validity:	SCR-14, Suction wand, Rigid Suction catheter 14Fr	
	0532156602 PKR: 100000/-	02-04-2025 (China)	:SCF-18, Suction wand, Flexible Suction catheter 18Fr	
		FSC validity 31-12-2027	SCF-14, Suction wand, Flexible Suction catheter 14Fr	
		(The Netherlands)		
342	M/s MICROPORT SCIENTIFIC PAKISTAN (PRIVATE)	Legal Manufacturer: Name:	Kewei Cardioplegia circuit cannula (Coronary Artery Ostial Cannula)	Approved.
	LIMITED	M/s Dongguan Kewei	Class: D	
	Address of Importer	Medial Instrument Co., Ltd	MD group: Family	
	Office No 02/3, 2nd floor Hive Gizri Road, Block 9, Clifton,	Address of manufacturer:	LOA Validity: 31-December 2024	
	Karachi, South, Saddar town	No. 1 Tongqing Road Dongcheng District	FSC Validity:	
		Dongguan City Guangdong 523127	China- Date of validity 02-04-2025	
	(ELI-01182)	China	Netherland- validity December 31 2027	
	R&I Dated: Submission	LOA validity:	Shelf life: 02 Years	
	date: 20-11-2024	31-12-2024	Codes:	
	Fee Challan No.:	ESC volidity	Coronary Artery ostial cannula,45° angle Tip, 10Fr	
	09744174446	FSC validity: 02-04-2025 (China)	Coronary Artery ostial cannula,45° angle Tip, 12Fr	
	PKR: 50000/- Paid on 25/3/2024	FSC validity	Coronary Artery ostial cannula,45° angle Tip, 14Fr	
		31-12-2027	Coronary Artery ostial cannula,90° angle Tip, 10Fr	

			Τ	T
		(The Netherlands)	Coronary Artery ostial cannula,90° angle Tip, 12Fr Coronary Artery ostial	
			cannula,90° angle Tip, 14Fr	
343	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) R&I Dated: Submission date: 20-11-2024 Fee Challan No.: 2244746172 PKR: 50000/-	Legal Manufacturer: Name: M/s Dongguan Kewei Medial Instrument Co., Ltd Address of manufacturer: No. 1 Tongqing Road Dongcheng District Dongguan City Guangdong 523127 China LOA validity: 31-12-2024 FSC validity: 02-04-2025 (China) FSC validity 31-12-2027 (The Netherlands)	Kewei Cardioplegia circuit cannula (Aortic Root Cannula) Class: D MD group: Family LOA Validity: 31-December 2024 FSC Validity: China- Date of validity 02-04-2025 Netherland- validity December 31 2027 Shelf life: 02 Years Codes Aortic root cannula, without Vent line, 15Ga(9Fr) Aortic root cannula, without Vent line, 16Ga(9Fr) Aortic root cannula, with Vent line, 15Ga(9Fr) Aortic root cannula, with Vent line, 15Ga(9Fr) Aortic root cannula, with Vent line, 16Ga(9Fr)	Approved.
344	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	IIFT: Autoimmune Encephalitis Mosaic 1 Immuno-chemistry Test Kit Class B Shelf Life: 18 months Code:- FA 112d-1005-1 Date of Submission: 22-01-2020 Fee submitted: Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	Approved.

345	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026	IIFT: Autoimmune Encephalitis Mosaic 6 Immuno-chemistry Test Kit Class B Shelf Life: 18 months Code:- FA 112d-1005-6 Date of Submission: 22-01-2020 Fee submitted: Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	Approved.
346	M/s Labserv,	FQA/CE: 26-05-2025 LOA valid till 31-12- 2024 Manufacturer:	Anti-Aquaporin-4 IIFT	Approved.
	House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	Immuno-chemistry Test Kit Class B Shelf Life: 18 months Code:- FA 1128-1005-50 Date of Submission: 22-01-2020 Fee submitted: Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	
347	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site:	Anti-Myelin-Oligidendrocyte Glycoprotein (MOG) IIFT Immuno-chemistry Test Kit Class B Shelf Life: 18 months Code:- FA 1156-1005-50	Approved.

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		EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026	Date of Submission: 22-01-2020 Fee submitted: Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	
		FQA/CE: 26-05-2025 LOA valid till 31-12- 2024		
348	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site:	IIFT: Crithidia luciliac sensitive (anti-dsDNA) Immuno-chemistry Test Kit Class B Shelf Life: 18 months	Approved.
		EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.	Code:- FA 1572-1010-1 Date of Submission: 22-01-2020 Fee submitted:	
		FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	
349	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.	Anti-Phopholipase A2 Receptor (PLA2R) IIFT Immuno-chemistry Test Kit Class B Shelf Life: 18 months	Approved.
	Lic. No. ELI-00103	Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany.	Code:- FA 1254-1005-50 Date of Submission: 22-01-2020 Fee submitted:	
		FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	Rs. 25,000/- Storage temperature: Store at temperature 2-8°C	

350	M/s Labserv,	Manufacturer:	EUROPLUS Granulocyte	Approved.
	House No. B-165/2	EUROIMMUN	Mosaic 25	
	Block 3A Gulistan e	Medizinische	Immuno-chemistry Test Kit	
	Jauhar, Scheme 36, Karachi.	Labordiagnostika AG, Lubeck Seekamp 31,	Class B	
	Lic. No. ELI-00105	23560 Lubeck Germany.	Shelf Life: 18 months	
	Zierrior ZZI ooros	Manufacturing Site: EUROIMMUN	Code:- FA 1201-1005-25	
		Medizinische Labordiagnostika AG, Lubeck Seekamp 31,	Date of Submission: 22-01-2020	
		23560 Lubeck Germany. FSC: Germany valid till	Fee submitted: Rs. 25,000/-	
		19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	Storage temperature: Store at temperature 2-8°C	
351	M/s Labserv,	Manufacturer:	IIFT: CIBD Profile 3	Approved.
	House No. B-165/2	EUROIMMUN	Immuno-chemistry Test Kit	
	Block 3A Gulistan e Jauhar, Scheme 36,	Medizinische Labordiagnostika AG,	Class B	
	Karachi.	Lubeck Seekamp 31, 23560 Lubeck Germany.	Shelf Life: 18 months	
	Lic. No. ELI-00105	Manufacturing Site:	Code:- FA 1391-1005-4	
		EUROIMMUN Medizinische Labordiagnostika AG,	Date of Submission: 22-01-2020	
		Lubeck Seekamp 31, 23560 Lubeck Germany.	Fee submitted: Rs. 25,000/-	
		FSC: Germany valid till 19-03-2029 ISO valid till 18-05-2026 FQA/CE: 26-05-2025 LOA valid till 31-12- 2024	Storage temperature: Store at temperature 2-8°C	
352	M/s Labserv, House No. B-165/2 Block 3A Gulistan e	Manufacturer: EUROIMMUN Medizinische	IIFT: HEp-2 Immuno-chemistry Test Kit	Approved.
	Jauhar, Scheme 36,	Labordiagnostika AG,	Class B	
	Karachi.	Lubeck Seekamp 31, 23560 Lubeck Germany.	Shelf Life: 18 months	
	Lic. No. ELI-00105	Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG,	Code:- FA 1520-1005, FA 1520-1010	

		T11- C1- 21	D-4 CC-1	
		Lubeck Seekamp 31,	Date of Submission: 22-01-	
		23560 Lubeck Germany.	2020	
		FSC: Germany valid till	Fee submitted:	
		19-03-2029	Rs. 25,000/-	
		ISO valid till 18-05-2026	103. 23,000/	
		FQA/CE: 26-05-2025	Storage temperature: Store	at
		LOA valid till 31-12-	temperature 2-8°C	
		2024		
353	M/s Labserv,	Manufacturer:	IIFT: Diabetes mellitus scre	1 1
	House No. B-165/2	EUROIMMUN	Immuno-chemistry Test Kit	
	Block 3A Gulistan e	Medizinische		
	Jauhar, Scheme 36,	Labordiagnostika AG,	Class B	
	Karachi.	Lubeck Seekamp 31,	Shelf Life: 18 months	
	Lie No ELLONIOS	23560 Lubeck Germany.	<u> </u>	
	Lic. No. ELI-00105	Manufacturing Site:	Code:- FA 1020-1005-3	
		EUROIMMUN		
		Medizinische	Date of Submission: 22-01-	
		Labordiagnostika AG,	2020	
		Lubeck Seekamp 31,	Fee submitted:	
		23560 Lubeck Germany.	Rs. 25,000/-	
			KS. 23,000/-	
		FSC: Germany valid till	Storage temperature: Store	at
		19-03-2029	temperature 2-8°C	
		ISO valid till 18-05-2026	T	
		FQA/CE: 26-05-2025		
		LOA valid till 31-12- 2024		
354	ASTO Life Science Pvt.	Legal Manufacturer:	NephroHDM	Approved
	Ltd,	NEPHROCAN INC. 940 -	Hemodialysis Machine	11
	Plaza No. 1 Block	1040 West Georgia Street,	<i>J</i>	
	Orchard 1, Paragon City	Vancouver, B.C. V6E	Class-C	
	Barki Road, Lahore	4H1, Canada.		
	Cantt.		Service Life: 10 years	
	TT 1 00105	FSC: Italy	36.44	
	ELI-00103	Validity: 12-06-2023	Model:	
255	ACTO Life Cairman Part	Logal Manufacturani	010101010101 Norther DS	Ammayad
355	ASTO Life Science Pvt. Ltd,	<u>Legal Manufacturer:</u> NEPHROCAN INC. 940 -	NephroPS Polysulfone	Approved
	Plaza No. 1 Block	1040 West Georgia Street,	Hemodialyzer	
	Orchard 1, Paragon City	Vancouver, B.C. V6E	110111001a1yz01	
	Barki Road, Lahore	4H1, Canada.	Class-C	
	Cantt.	,		
		FSC: Italy	Shelf Life: 3 years	
	ELI-00103	Validity: 12-06-2023	-	
			Codes as per FSC	
356	ASTO Life Science Pvt.	Legal Manufacturer:	NephroPRO	Approved as
	Ltd,	NEPHROCAN INC. 940 -	Portable Reverse Osmosis	
	Plaza No. 1 Block	1040 West Georgia Street,	System	
	Orchard 1, Paragon City	Vancouver, B.C. V6E	C1 C	
		4H1, Canada.	Class-C	

	Barki Road, Lahore			E
	′	ESC. Italy	Shalf Life, 10 years	
	Cantt.	FSC: Italy	Shelf Life: 10 years	
		Validity: 12-06-2023		
	ELI-00103		Model:	
			4620310	
357	ASTO Life Science Pvt.	Legal Manufacturer:	NephroBag	Approved.
	Ltd,	NEPHROCAN INC. 940 -	Bicarbonate Bags	
	Plaza No. 1 Block	1040 West Georgia Street,		
	Orchard 1, Paragon City	Vancouver, B.C. V6E	Class-C	
	Barki Road, Lahore	4H1, Canada.		
	Cantt.	iiii, Canada.	Shelf life: 2 years	
	Cantt.	ECC. Italy	Shell life. 2 years	
	EL 1 00102	FSC: Italy	G 1	
	ELI-00103	Validity: 12-06-2023	Codes:	
			4315210	
			4315220 4315230	
358	ASTO Life Science Pvt.	Legal Manufacturer:	NephroLine	Approved
	Ltd,	NEPHROCAN INC. 940 -	Bloodlines, Extra	
	Plaza No. 1 Block	1040 West Georgia Street,	corporeal blood circuits	
	Orchard 1, Paragon City	Vancouver, B.C. V6E	•	
	Barki Road, Lahore	4H1, Canada.	Class-C	
	Cantt.	, Cullului.		
	Cullit.	FSC: Italy	Shelf life: 3 years	
	EL 1 00102		Shell life. 3 years	
	ELI-00103	Validity: 12-06-2023	G 1 FGG	
2.50	A GEO T : 2 G : T		Codes as per FSC	
359	ASTO Life Science Pvt.	Legal Manufacturer:	NephnroNeedle	Approved
	Ltd,	NEPHROCAN INC. 940 -	Fistula needle set	
	Plaza No. 1 Block	1040 West Georgia Street,		
	Orchard 1, Paragon City	Vancouver, B.C. V6E	Class: B	
	Barki Road, Lahore	4H1, Canada.		
	Cantt.		Shelf life: 3 years	
		FSC: Italy		
	ELI-00103	Validity: 12-06-2023	Codes as per FSC	
260	ASTO Life Science Pvt.	Legal Manufacturer:	NephroCRO	Approved
	Ltd,	NEPHROCAN INC. 940 -	Central Reverse Osmosis	
		1040 West Georgia Street,	System	
	Orchard 1, Paragon City		- System	
			Class C	
	Barki Road, Lahore	4H1, Canada.	Class-C	
	Cantt.	FGG I I	G1 101:0 10	
		FSC: Italy	Shelf life: 10 years	
	ELI-00103	Validity: 12-06-2023		
			Codes as per FSC	
361	ASTO Life Science Pvt.	Legal Manufacturer:	NephroCart	Approved
	Ltd,	NEPHROCAN INC. 940 -	Bicarbonate Cart	= *
	Plaza No. 1 Block	1040 West Georgia Street,		
	Orchard 1, Paragon City	Vancouver, B.C. V6E	Class-C	
	Barki Road, Lahore	4H1, Canada.		
	Cantt.	iiii, Canada.	Shelf life: 2 years	
	Cant.	ESC: Italy	Shell life. 2 years	
	EL L 00102	FSC: Italy	C. 1	
	ELI-00103	Validity: 12-06-2023	Codes:	
			4315310	
		İ	4315320	İ

			4315330	
362	M/s Khan Trading Agency, New Data Complex, 16-Syed Mouj Darya Rpoad, Lahore ELI-00592	M/s Pro-Lab Diagnostics Inc., 20 Mural Street, Unit # 4, Richmond Hill, ON, Canada L4B 1K3 FSC: Canada Validity	PROLEX Staph Grouping Latex Kit/ Prolex Latex Streptococca/ Microbank Class B Shelf life: 14 Months for Prolex Staph Latex kit Code:	Approved subject to provision of shelf life of Group Latex Kit
			PL.030 (Strepto) PL.081B (Staph)	
363	Ameer Din and Sons, 305-A, Upper Mall, Lahore	Legal Manufacturer	Cooper Vision ®	Approved subject to provision of notarized LoA, FSc
	ELI: 00058	Cooper Vision Manufacturing Ltd, South Point Hamble	(Biomedics Toric)	
		Southampton SO31 4RF UK	Codes & Sizes: As per FSC	
		Manufacturing Site:		
		Cooper vision Inc 711 North Road Scottsville New York 14546 USA	Class-B	
		FSC: UK	Shelf Life: 7 year	
		Date of Issue. 14.10.2020		
364	Ameer Din and Sons,	Legal Manufacturer	Cooper Vision ®	Approved subject to
	305-A, Upper Mall, Lahore	Cooper Vision	Biomedics 55 Evolution	provision of notarized LoA, FSc
	ELL 00050	Manufacturing Ltd, South Point Hamble Southampton SO31 4RF	Codes & Sizes: As per FSC	
	ELI: 00058	UK	Class-B	
		FSC: UK	Shelf Life: 7 year	
		Date of Issue. 14.10.2020		
365	Ameer Din and Sons, 305-A, Upper Mall, Lahore	Legal Manufacturer: Oculus Private Limited 10 Kaki Bukit Avenue 1#	Oculus Freshkon Methafilcon A Soft (Contact Lens)	Approved subject to provision of notarized LoA, FSc
	ELI: 00058	06-08, Singapore, 417942 Original FSC: Singapore	Codes & Sizes: As per FSC	

		Date of Issue: 10/11/2021	Class-B	
			Shelf Life: 5 years	
366	Ameer Din and Sons,	Legal Manufacturer:	CORONET	Approved subject to
	305-A, Upper Mall, Lahore	Network Medical	Corneal Trephines	provision of notarized LoA, FSc
		Products Ltd., Coronet House, Kearsely Road,	Code: As per FSC	,
	ELI: 00058	Ripon, North Yorkshire, HG4, 2SG, UK	Class-B	
		FSC: MHRA	Shelf Life: 7 years	
		Date of Issue: 03.12.2018		
367	Ameer Din and Sons, 305-A, Upper Mall,	Legal Manufacturer:	Freshkon 58	Approved subject to provision of notarized
	Lahore		(Contact Lens)	LoA, FSc
	DV 00070	M/s Oculus Private Limited 10 KAKI Bukit	Codes & Sizes: As per FSC	
	ELI: 00058	Avenue 1 # 06-08 Singapore 417942	Class-B	
		FSC Original : Singapore	Shelf Life: 5 years	
		Date of Issue: 25/07/2022		
368	Haji S. Ameer Din &	Legal Manufacturer:	Eyestar 900	Approved subject to
	Sons 305-A Upper Mall Lahore 5400 Pakistan	M/s HAAG-STREIT AG	(Biometer)	provision of notarized LoA, FSc
		Gartenstadtstrasse 10	Codes & Sizes: As per	,
	ELI-00059	3098 Koeniz, Switzerland	FSC	
		FSC Original :Switzerland	Class-B	
		Valid till: 22/11/2026	Shelf Life: N/A	
260	II.'' C. Amara Din 0		N. J. J. LONTM I	A
369	Haji S. Ameer Din & Sons 305-A Upper Mall Lahore 5400 Pakistan	Legal Manufacturer: Norlase ApS	Norlase LION TM Laser Indirect Ophthalmoscope Photocoagulator	Approved subject to provision of notarized LoA, FSc
	Lanore 3400 Pakistan	Address:	Shelf Life 3 Year	LUA, FSC
	EL 1 00050	Brydehusvej 13 DK 2750	Class C	
	ELI-00059	Ballerup Denmark. FSC: Copenhagen, Denmark.	Codes as per FSC	
		Validity: 19-04-2025.		
370	Ameer Sons,	Legal Manufacturer:	FreshKon Etafilcon A	Approved subject to
		Oculus Private Limited	Contact Lens	provision of notarized LoA, FSc

305-A Upper Mall	Address:	Shelf Life: 5 Year	
Lahore 5400 Pakistan	10 Kaki Bukit Avenue 1 # 06-08 Singapore 417942.	Class B Codes as per FSC	
	FSC: Singapore.	1	
ELI-00058	Date of Issuance: 25-07-2022.		

Cast 110. 572	
Name	Ghazali Brothers, 1st Floor, Azainab Court, Campbell Street, Karachi
Address of Importer	
Detail of ELM/ELI	ELI- 00240
Name	Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119
Address of	Lajski,
Manufacturer	Poland
Brand Name	Ravimed Blood Bag Single 500ml CPDA-1
Decision	Approved subject to clarification regarding the company name on FSC Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, and LOA Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, Poland

Case No. 373

Name	Ghazali Brothers, 1st Floor, Azainab Court, Campbell Street, Karachi
Address of Importer	
Detail of ELM/ELI	ELI- 00240
Name	Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119
Address of	Lajski,
Manufacturer	Poland
Brand Name	Ravimed Blood Bag Double 500ml CPDA-1
Decision	Approved subject to clarification regarding the company name on FSC Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, and LOA Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, Poland

Name	Ghazali Brothers, 1st Floor, Azainab Court, Campbell Street, Karachi
Address of Importer	
Detail of ELM/ELI	ELI- 00240
Name	Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119
Address of	Lajski,
Manufacturer	Poland
Brand Name	Ravimed Blood Bag Single 250ml CPDA-1
Decision	Approved subject to clarification regarding the company name on FSC Zaklad produkcji sprzetu medycznego Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, and LOA Ravimed Sp. Z o.o, ul Polna 54, 05-119 Lajski, Poland

Name	Name	
Address of Importer	rter National Enterprises	
	Address of Importer	
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi	
Detail of ELM/ELI	ELI- 00043	
Name	(LEGAL MANUFACTEURER)	
Address of	Medprin Biotech GmbH	
Manufacturer	(Address of Manufacturer)	
	GutleutstraBe 163-167, 60327 Frankfurt am Main Germany	
	(Manufacturing site)	
	Medprin Regenerative Medical Technologies Co. Ltd	
	Address: 3F and 7F, Zone E, 80 Lanyue Road Science City, New High-tech	
	Industrial Park, Guangzhou 510663,P.R.China	
Brand Name	StypCel	
Generic name	Absorbable Hemostat	
Decision	Approved	

Case No. 376

Name	Name
Address of Importer National Enterprises	
	Address of Importer
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi
Detail of ELM/ELI	ELI- 00043
Name	(LEGAL MANUFACTEURER)
Address of	Medprin Biotech GmbH
Manufacturer	(Address of Manufacturer)
	GutleutstraBe 163-167, 60327 Frankfurt am Main Germany
	(Manufacturing site)
	Medprin Regenerative Medical Technologies Co. Ltd
	Address: 3F and 7F, Zone E, 80 Lanyue Road Science City, New High-tech
	Industrial Park, Guangzhou 510663,P.R.China
Brand Name	ReDura
Generic name	(Regenerative Dural Repair Patch)
Decision	Approved

Name	Name
Address of Importer	National Enterprises
	Address of Importer
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi
Detail of ELM/ELI	ELI- 00043
Name	(LEGAL MANUFACTEURER)

Address of	Medprin Biotech GmbH
Manufacturer	(Address of Manufacturer)
	GutleutstraBe 163-167, 60327 Frankfurt am Main Germany
	(Manufacturing site)
	Medprin Regenerative Medical Technologies Co. Ltd
	Address: 3F and 7F, Zone E, 80 Lanyue Road Science City, New High-tech
	Industrial Park, Guangzhou 510663,P.R.China
Brand Name	Neodura
Generic name	(Dural Repair Patch)
Decision	Deferred for the clarification Porcine source

Name	Name
Address of Importer	National Enterprises
	Address of Importer
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi
Detail of ELM/ELI	ELI- 00043
Name	(LEGAL MANUFACTEURER)
Address of	evonos GmbH & Co. KG
Manufacturer	(Address of Manufacturer)
	Stockacher Str. 134, 78532 Tuttlingen, Germany
Brand Name	evoDrill Cranial Perforators
	Cranial Perforators
Generic name	
Decsion	Approved subject to submission of the proof of submission of FSC and LOA and
	DOC

Name	Name
Address of	National Enterprises
Importer	Address of Importer
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi
Detail of ELM/ELI	ELI- 00043
Name	(LEGAL MANUFACTEURER)
Address of	evonos GmbH & Co. KG
Manufacturer	(Address of Manufacturer)
	Stockacher Str. 134, 78532 Tuttlingen, Germany
Brand Name	evoClip Raney Scalp Clips
	Scalp Clips
Generic name	
Decision	Approved all four products as per the codes subject to submission of the
	Stability studies and DOC.
	The firm will submiut the full fee for three products with application

Name	Name
Address of Importer	M/S GHAZALI BROTHERS
	Address of Importer
	1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI,
	PAKISTAN
Detail of ELM/ELI	ELI-00240
Name	(LEGAL MANUFACTEURER)
Address of	NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD
Manufacturer	(Manufacturing site)
	YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS
	ZONE, 315199, NINGBO, CHINA
Brand Name	YINGMED ABSORBABLE CHROMIC CATGUT SURGICAL SUTURE
Decision	Approved

$\frac{DEFERRED\,/\,APPROVED\,SUBJECT\,TO\,APPLICATION\,FOR\,ENLISTMENT/}{REGISTRATION\,FOR\,IMPORT}$

Case No. 01

Name	Name: B.N TRADING COMPANY
Address of Importer	Address of Importer
_	Office # 207, 2nd Floor, Makkah Tower Namak Mandi Peshawar City
Detail of ELI	ELI- 00647
Name	(LEGAL MANUFACTEURER)
Address of	Jiangsu Webest Medical Product Co., Ltd.,
Manufacturer	(Manufacturing site)
	No.5 Yingchun Road., Industrial Park., 211700 Xuyi., JiangSu, China
Brand Name	Best Life
	(I.V. Cannula) Pen Type
Decision	Approved

Cast 110.02	
Name	Name: M/s Izhar Enterprises,
Address of Importer	
	Address of Importer
	P-39 Backside hameed Palace Street No. 1, Garden Colony, Faisalabad
Detail of ELM/ELI	ELI-01236
Name	(Legal Manufacturer)
Address of	M/s Super Health Medical (Qingdao) Co., Ltd.
Manufacturer	(Manufacturing site)
	No. 236, Heyuan Road, High-Tech Zone, Qingdao 266510 Shandong P.R China
Brand Name	Prime
Generic Name	Disposable Intravenous Catheter with Stopper
Decision	Approved

Name	Name: Cardiac Care
Address of	Address of Importer:
Importer	848-C Shadman -1, Lahore
Detail of ELM/ELI	ELI-00070
Name	M/s Pacific Hospital Supply Co., Ltd.,
Address of	4F No.160, Daye Road, Beitou District 112 Taipei, Taiwan
Manufacturer	
Name of exporting	Taiwan
country	
Brand Name	Free Trachea Closed Suction Set
Decision	Approved

Case No. 4

Name	Name: Cardiac Care
Address of	Address of Importer:
Importer	848-C Shadman -1, Lahore
Detail of ELM/ELI	ELI-00070
Name	M/s HSINER Co. Ltd.,
Address of	312, Jhongshan Rd, Shengang Dist, Taichung 429, Taiwan
Manufacturer	
Name of exporting	Taiwan
country	
Brand Name	Anesthesia and Breathing Circuit
Decision	Approved

Case No. 5

Name	Name: Cardiac Care
Address of	Address of Importer: 848-C Shadman -1, Lahore
Importer	
Detail of ELM/ELI	ELI-00070
Name	M/s HSINER Co. Ltd.,
Address of	312, Jhongshan Rd, Shengang Dist, Taichung 429, Taiwan
Manufacturer	
Name of exporting	Taiwan
country	
Brand Name	Rebreathing Bag
Decision	Approved

Name	Name: Mian Scientific Corporation (PVT) Ltd
Address of Importer	Address of Importer
	534-Jinnah Colony Faisalabad, 38030, Pakistan
Detail of ELM/ELI	ELI-00442
Name	(LEGAL MANUFACTEURER)
	CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.

Address of Manufacturer	
Brand Name	Onsite
Generic Name	Typhoid IgG-IgM Rapid test
Decision	Approved

Name	Name
Address of Importer	Mian Scientific Corporation (PVT) Ltd
	Address of Importer
	534-Jinnah Colony Faisalabad, 38030, Pakistan
Detail of ELM/ELI	ELI-00442
Name	(LEGAL MANUFACTEURER)
Address of	CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.
Manufacturer	
Brand Name	Onsite
Generic Name	HAV IgG-IgM Combo Rapid Test
Decision	Approved

Case No.8

Name	Name
Address of Importer	Mian Scientific Corporation (PVT) Ltd
	Address of Importer
	534-Jinnah Colony Faisalabad, 38030, Pakistan
Detail of ELM/ELI	ELI-00442
Name	(LEGAL MANUFACTEURER)
Address of	CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.
Manufacturer	
Brand Name	Onsite
Generic Name	H. Pylori Ab Combo Rapid Test
Decision	Approved

Name	Name	
Address of Importer	Mian Scientific Corporation (PVT) Ltd	
	Address of Importer	
	534-Jinnah Colony Faisalabad, 38030, Pakistan	
Detail of ELM/ELI	ELI-00442	
Name	(LEGAL MANUFACTEURER)	
Address of	CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA.	
Manufacturer		
Brand Name	Onsite	
Generic Name	HIV ½ Ab Plus Combo Rapid Test	
Decision	Approved	

Name	Name	
Address of Importer	nporter Mian Scientific Corporation (PVT) Ltd	
	Address of Importer	
	534-Jinnah Colony Faisalabad, 38030, Pakistan	
Detail of ELM/ELI	ELI-00442	
Name	(LEGAL MANUFACTEURER)	
Address of	Wuxi BioHerm's Bio& Medical Technology CO, Ltd.	
Manufacturer	No.136 Mashan Meiliang Road, Binhu, Wuxi, Jiangsu, China	
Brand Name	BioHerm's	
Generic Name	Glycohemoglobin Test Kit	
Decision	Approved	

Case No.11

Name	Name	
Address of Importer	Mian Scientific Corporation (PVT) Ltd	
	Address of Importer	
	534-Jinnah Colony Faisalabad, 38030, Pakistan	
Detail of ELM/ELI	ELI-00442	
Name	(LEGAL MANUFACTEURER)	
Address of	ERBA Lachema s.r.o	
Manufacturer		
Brand Name	ERBA	
Generic Name	X1-200 Chemistry Analyzer	
Decision	Approved	

Case No.12

Name	Name: Mian Scientific Corporation (PVT) Ltd	
Address of Importer	Address of Importer	
	534-Jinnah Colony Faisalabad, 38030, Pakistan	
Detail of ELM/ELI	ELI-00442	
Name	(LEGAL MANUFACTEURER)	
Address of	ERBA Lachema s.r.o	
Manufacturer		
Brand Name	ERBA	
Generic Name	Chem-7 Chemistry Analyzer	
Decision	Approved	

Name Address of	Name: Mian Scientific Corporation (PVT) Ltd	
Importer	Address of Importer	
534-Jinnah Colony Faisalabad, 38030, Pakistan		
Detail of ELM/ELI	ELI-00442	
Name	(LEGAL MANUFACTEURER)	
Address of	Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	
Manufacturer		
Brand Name	Getein	
Generic Name	T4 Fast Test Kit	
Decision	Approved	

Name Address of	Name
Importer Mian Scientific Corporation (PVT) Ltd	
Address of Importer	
	534-Jinnah Colony Faisalabad, 38030, Pakistan
Detail of ELM/ELI	ELI-00442
Name	(LEGAL MANUFACTEURER)
Address of	Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.
Manufacturer	
Brand Name	Getein
Generic Name	TSH Fast Test Kit
Decision	Approved

Case No.15

Cast 110.13	
Name	Name
Address of Importer	Mian Scientific Corporation (PVT) Ltd
	Address of Importer
	534-Jinnah Colony Faisalabad, 38030, Pakistan
Detail of ELM/ELI	ELI-00442
Name	(LEGAL MANUFACTEURER)
Address of	Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.
Manufacturer	
Brand Name	Getein
Generic Name	Troponin-I Fast Test Kit
Decision	Approved

Name	Name		
Address of Importer	Mian Scientific Corporation (PVT) Ltd		
	Address of Importer		
	534-Jinnah Colony Faisalabad, 38030, Pakistan		
Detail of ELM/ELI	ELI-00442		
Name	(LEGAL MANUFACTEURER)		
Address of	Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.		
Manufacturer			
Brand Name	Getein		
Generic Name	TPSA Fast Test Kit		
Decision	Approved		

Sr.#	Importe	er Name	Manufacturer Details	Product Details	Decision
17	M/s	Chemical	Legal Manufacturer:	Liquickek Spinal Fluid	Approved
	House,			Control	
	6-C	Sikander	M/s Bio-Rad Laboratories,		
	Malhi	Road,	Inc, 9500 Jeronimo Road	(Quality Control	
	Canal	Park,	Irvine, CA 92618, U.S.A	(Immunology/Protein	
	Gulberg	II,		Controls)	

	T 1 D 1 ' 4		T	<u> </u>
	Lahore Pakistan. ELI: 00156	FSC: USA	Codes & Sizes: As per FSC	
	Evaluator: AD-II	Valid till: 16.01.2021	Class-B	
	(2249-P)		Shelf Life: 2 years	
18	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A FSC: U.S.A Valid till: 20/08/2022	Lyphochek Specialty Immunoassay Control (Multiple Clinical Chemistry Protein IVD Control) Class-B Shelf Life: 3 years	Approved
19	(3157-P) M/s Chemical	T INT C	T' 'IID'I	A 1
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (1805-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A. FSC: USA Valid till: 16.01.2021	Liquichek Diabetes Controls (Quality Control) Class-B Shelf Life: 3 years	Approved
20	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (1802-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A. FSC: USA Valid till: 16.01.2021	Liquichek Immunology/ Protein Controls (Quality Control) Class-B Shelf Life: 720 Days	Approved
21	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II,	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA.	Bioplex 2200 HSV-1 & HSV-2 1gG (Herpes simplex virus 1gG Antibody IVD kit)	Approved

	Lahore.			
		Manufacturing Site:	Codes & Sizes: As per	
	(ELI:00156)	M/s Bio-Rad Laboratories	FSC	
	Evaluator:	Inc., 14620 NE North	Class-C	
	AD-II	Woodinville Way,	Shelf Life: As per stability	
	(3067-P)	Woodinville, WA 98072, USA.	study.	
	(3007-1)	USA.		
		FSC: U.S.A		
		Valid till: 11.08.2022		
22	M/s Chemical	Legal Manufacturer:	Bioplex 2200 MMV IgM	Approved
	House , 6-C Sikander	M/s Bio-Rad Laboratories	(Measles, Mumps,	
	Malhi Road	Inc. 4000 Alfred Nobel	Varicella Zoster IgM antibody IVD kit)	
	Gulberg-II,	Drive Hercules, CA, U.S.A		
	Lahore.	Out to 1 EGG, II G A	Codes & Sizes: As per	
	(ELI:00156)	Original FSC: U.S.A	FSC	
		Valid till: 03.02.2023	Class-C	
	Evaluator:		C1. 1C1 'C . 10	
	AD-II		Shelf Life: 18 months	
	(3071-P)			
23	M/s Chemical	Legal Manufacturer:	Bioplex 2200	Approved
23	House,		Bioplex 2200 MMRV 1gG	Approved
23		Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel	_	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II,	M/s Bio-Rad Laboratories	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster	Approved
23	House, 6-C Sikander Malhi Road	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA.	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore.	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156)	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator:	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit)	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156)	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way,	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator:	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA.	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072,	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P)	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study.	Approved
23	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability	Approved
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical House,	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022 Legal Manufacturer:	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study. Bioplex 2200 ToRC IgM	
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study.	
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II,	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022 Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA 94547,	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study. Bioplex 2200 ToRC IgM (Toxoplasma IgM, Rubella IgM, CMV IgM)	
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical House, 6-C Sikander Malhi Road	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022 Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study. Bioplex 2200 ToRC IgM (Toxoplasma IgM, Rubella IgM, CMV IgM) Codes & Sizes: As per	
	House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P) M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II,	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till: 11.08.2022 Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA 94547,	MMRV 1gG (Measles, Mumps, Rubella, Varicella zoster virus IgG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study. Bioplex 2200 ToRC IgM (Toxoplasma IgM, Rubella IgM, CMV IgM)	

	Evaluator:		1	
	AD-II		Shelf Life: 15 months	
	AD-II		Sheff Life. 13 months	
	(3073-P)			
25	M/s Chemical	Legal Manufacturer:	Liquichek Immunology	Approved
	House,		Control	прриоте
	6-C Sikander	M/s Bio-Rad Laboratories,		
	Malhi Road	Inc, 9500 Jeronimo Road	(Multiple Clinical	
	Gulberg-II,	Irvine, CA 92618, U.S.A	Chemistry Analyte IVD	
	Lahore.		Control)	
		FSC: U.S.A	Í	
	(ELI:00156)	Valid till: 20/08/2022	Codes & Sizes: As per	
	, ,		FSC	
	Evaluator:			
	AD-II		Class-B	
	(3157-P)		Shelf Life: 2 years	
26	M/s Chemical	Legal Manufacturer:	Bioplex 2200 HIV Ag-Ab	Approved
	House, 6-C	M/s D: D II I	(1117/1117/2	
	Sikander Malhi	M/s Bio-Rad Laboratories	(HIV/HIV2	
	Road, Canal Park,	Inc. 4000 Alfred Nobel	antigen/antibody IVD Kit)	
	Gulberg II, Lahore Pakistan.	Drive Hercules, CA, USA.	Cadas & Simos As and	
	Lanore Pakistan.	Manufacturing Site:	Codes & Sizes: As per FSC	
	ELI: 00156	<u>Manufacturing Site:</u>	rsc	
	LLI. 00130	M/s Bio-Rad Laboratories	Class-C	
	Evaluator:	Inc., 14620 NE North	Shelf Life: As per stability	
	AD-II	Woodinville Way,	study.	
		Woodinville, WA 98072,		
	(3065-P)	USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
27	M/s Chemical	Legal Manufacturer:	Bioplex 2200 Syphilis	Approved
	House, 6-C		Total & RPR	
	Sikander Malhi	M/s Bio-Rad Laboratories	(T)	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Treponema pallidum total	
	Lahore	Drive Hercules, CA, U.S.A	antibody and reagin	
	EL 1.00156	Manage Assis - Cita	antibody IVD kit)	
	ELI:00156	Manufacturing Site:	Codes & Sizes: As per	
	Evaluator:	M/s Bio-Rad Laboratories	FSC	
	AD-II	Inc., 14620 NE North	150	
	, 1D 11	Woodinville Way,	Class-C	
	(3072-P)	Woodinville, WA 98072,	Shelf Life: 21 months	
		USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		

27	M/s Chemical House, 6-C	Legal Manufacturer:	Liquichek Elevated CRP Control	Approved
	Sikander Malhi	M/s Bio-Rad Laboratories,		
	Road Gulberg-II,	Inc. 9500 Jeronimo Road	(C-Reactive Protein (CRP)	
	Lahore	Irvine, CA 92618, USA	IVD Control)	
	ELI:00156	FSC: U.S.A	Codes & Sizes: As per FSC	
	Evaluator: AD-II	Valid till: 20/08/2022	Class-B	
	(3169-P)		Shelf Life: 1080 days	
28	M/s Chemical	Legal Manufacturer:	Liqichek Multiple	Approved
	House, 6-C	M/ B: B II I / .	Cardiac Marker IVD	
	Sikander Malhi Road, Canal Park,	M/s Bio-Rad Laboratories , Inc . 9500 Jeronimo Road	Control	
	Gulberg II,	Irvine, CA 92618, USA	(Multiple Cardiac Marker	
	Lahore Pakistan.	11 vine, 211) 2010, 2511	IVD, Control)	
		FSC: U.S.A	, ,	
	ELI: 00156		Codes & Sizes: As per	
		Valid till: 20/08/2022	FSC	
	Evaluator:		Class-B	
	AD-II		Shelf Life: 1080 days	
	(3170-P)		Shell Life. 1000 days	
29	M/s Chemical	Legal Manufacturer:	Liquid Multiqual	Approved
	House, 6-C		Clinical Chemistry	
	Sikander Malhi	M/s Bio-Rad Laboratories,		
	Road, Canal Park, Gulberg II,	Inc. 9500 Jeronimo Road	(Multiple Clinical Chemistry Analyte IVD	
	Lahore Pakistan.	Irvine, CA 92618, USA	Control)	
	Editore Taxistan.	Original FSC: U.S.A	Control)	
	ELI: 00156	5	Codes & Sizes: As per	
		Valid till: 20/08/2022	FSC	
	Evaluator:			
	AD-II		Class-B	
	(3156-P)		Shelf Life: 3 years	
30	M/s Chemical	Legal Manufacturer:	Liquichek Diabetes	Approved
	House, 6-C	M/ D' D LT L	Control	
	Sikander Malhi Road, Canal Park,	M/s Bio-Rad Laboratories , Inc . 9500 Jeronimo Road	(Glycated Hemoglobin	
	Gulberg II,	Irvine, CA 92618, USA	(HbA Ic) IVD Control)	
	Lahore Pakistan.	11,1110, 011, 2010, 0011	(110/110) 1 v D Control)	
		Original FSC: U.S.A	Codes & Sizes: As per	
	ELI: 00156	-	FSC	
		Valid till: 20/08/2022		
	Evaluator:		Class-B	
	AD-II		Shelf Life: 3 years	
	(3160-P)			

31	M/s Chemical House, 6-C	Legal Manufacturer:	Liquichek Tumor Marker Control	Approved
	Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	(Multiple Tissue-Associated Protein/Tumor Marker IVD Control) Codes & Sizes: As per FSC Class-B Shelf Life: 2 years	
32	M/s Chemical	Legal Manufacturer:	Liquichek Reticulocyte	Approved
	House, 6-C	Degai Mananetarer	Control	ripproved
	Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA	(Reticulocyte count IVD Control)	
	ELI: 00156	Original FSC: U.S.A	Codes & Sizes: As per FSC	
	Evaluator: AD-II	Valid till: 20/08/2022	Class-B	
	(3159-P)		Shelf Life: 2 years	
33	M/s Chemical	Legal Manufacturer:	Licquichek	Approved
	House, 6-C		Immunoassay Control	
	Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA	(Multiple Clinical Chemistry Protein IVD)	
	ELI: 00156	Original FSC: U.S.A	Codes & Sizes: As per FSC	
		Valid till: 20/08/2022	Class-B	
	Evaluator: AD-II (2562-P)		Shelf Life: As per stability study	
34	M/s Chemical	Legal Manufacturer:	Liquichek Urine	Approved
	House, 6-C	M/ Pr P III I	Toxicology Control	
	Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A	(Multiple Therapeutic Drug/Drugs of Abuse IVD Control)	
	ELI: 00156	Valid till: 20/08/2022	Codes & Sizes: As per FSC	
			1	Î
	Evaluator: AD-II		Class-B	

	(3172-P)			
35	M/s Chemical House, 6-C	Legal Manufacturer:	Lyphochek Urine Chemistry Control	Approved
	Sikander Malhi	M/s Bio-Rad Laboratories,	Chemistry Control	
	Road, Canal Park,	Inc. 9500 Jeronimo Road	(Multiple urine Analyte	
	Gulberg II,	Irvine, CA 92618, USA	IVD Control)	
	Lahore Pakistan.			
	EL 1 00156	Original FSC: U.S.A	Codes & Sizes: As per	
	ELI: 00156	Valid till: 20/08/2022	FSC Class-B	
	Evaluator:	valid till: 20/08/2022	Class-D	
	AD-II		Shelf Life: 36 months	
	(2564-P)			
36	M/s Chemical	Legal Manufacturer:	Liquickek Cardiac	Approved
	House, 6-C Sikander Malhi	M/s Die Dad Laboustonies	Assessment Controls	
	Road, Canal Park,	M/s Bio-Rad Laboratories , Inc . 9500 Jeronimo Road	Codes & Sizes: As per	
	Gulberg II,	Irvine, CA 92618, USA	FSC	
	Lahore Pakistan.	,,,		
		FSC: USA	Class-B	
	ELI: 00156	Valid till: 16.01.2021		
	Essalmatam			
	Evaluator: AD-II			
	AD-II			
	(2254-P)			
37	M/s Chemical	Legal Manufacturer:	Meter Trax Control	Approved
	House, 6-C	M/ B: B II I	Trilevel	
	Sikander Malhi Road, Canal Park,	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road	(Quality Control	
	Gulberg II,	Irvine, CA 92618, USA	(Diabetes/Hb Control)	
	Lahore Pakistan.	11 vine, 211 y 2010, 2511	(Blacetes) Tro Control)	
		FSC: USA	Codes & Sizes: As per	
	ELI: 00156	Valid till: 16.01.2021	FSC	
	Evaluator:		Class-B	
	AD-II			
			Shelf Life: 180 days	
	(2251-P)		-	
38	M/s Chemical	Legal Manufacturer:	Liquichek Specialty	Approved
	House, 6-C Sikander Malhi	M/a Rio Dad I abayatawisa	Immunoassay Control	
	Sikander Malhi Road, Canal Park,	M/s Bio-Rad Laboratories , Inc . 9500 Jeronimo Road	(Multiple Clinical	
	Gulberg II,	Irvine, CA 92618, USA	Chemistry Protein IVD	
	Lahore Pakistan.	,,	Control)	
		FSC: U.S.A	Codes & Sizes: As per	
	ELI: 00156	D . CI 20.00.2022	FSC	
	Evaluator:	Date of Issue: 20.08.2022	Class- B	
	AD-II		Class- D	
	(3475-P)			
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \			

			Shelf Life: As per stability	
39	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (3469-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Date of Issue: 20.08.2022	Quantify Urinalysis Control (Multiple Urine Analyte IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Approved
40	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2572-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Date of Issue: 20.08.2022	Lyphochek Serum Chemistry Controls (Multiple Clinical Chemistry Analyte IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Approved
41	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2565-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Date of Issue: 20.08.2022	Lyphochek Multiple Therapy Therapeutic Drug Monitoring (TDM) IVD Control (Multiple Therapy Therapeutic Drug Monitoring (TDM) IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Approved subject to submission of shelf life.
42	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA	Lyphochek Diabetes and Hemoglobin IVD Control (HbA 1c and HbA2 IVD Control)	Approved subject to submission of shelf life.

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		FSC: U.S.A	Codes & Sizes: As per		
	ELI: 00156		FSC		
		Date of Issue: 20.08.2022			
	Evaluator:		Class- B		
	AD-II				
			Shelf Life: As per stability		
	(2568-P)		study		
43	M/s Chemical	Legal Manufacturer:	Lyphochek Immunology	Approved	
	House, 6-C		Plus Control	subject	to
	Sikander Malhi	M/s Bio-Rad Laboratories,		submission	
	Road, Canal Park,	Inc. 9500 Jeronimo Road	(Multiple Clinical	shelf life.	O1
	Gulberg II,	Irvine, CA 92618, USA	Chemistry Analyte IVD	such file.	
	Lahore Pakistan.	11 vine, CA 92016, USA	Control)		
	Lanore Pakistan.	FSC: U.S.A	Control)		
	ELI 00156	FSC: U.S.A			
	ELI: 00156		Codes & Sizes: As per		
		Date of Issue: 20.08.2022	FSC		
	Evaluator:				
	AD-II		Class- B		
	(2563-P)		Shelf Life: As per stability		
			study		
44	M/s Chemical	Legal Manufacturer:	Liquichek Multiple	Approved	
	House, 6-C		Therapy TDM IVD	subject	to
	Sikander Malhi	M/s Bio-Rad Laboratories,	Control	submission	of
	Road, Canal Park,	Inc. 9500 Jeronimo Road		shelf life.	01
	Gulberg II,	Irvine, CA 92618, USA	(Multiple Therapy	shen me.	
	Lahore Pakistan.	11 vine, 6/1 /2010, 65/1	Therapeutic Drug		
	Lanore Taxistan.	Original FSC: U.S.A	Monitoring (TDM) IVD		
	ELI: 00156	Original FSC. U.S.A	Control)		
	ELI. 00130	Valid till: 20/08/2022	Control)		
	Evaluator:	vand tiii. 20/08/2022	Codes & Sizes As man		
			Codes & Sizes: As per		
	AD-II		FSC		
	(0.5 (1. D)				
	(2561-P)		Class- B		
			G1 10710		
			Shelf Life: As per stability		
			study		
45	M/s Chemical	Legal Manufacturer:	Lyphochek Toxicology	Approved	
	House, 6-C		Control	subject	to
	Sikander Malhi	M/s Bio-Rad Laboratories,		submission	of
	Road, Canal Park,	Inc. 9500 Jeronimo Road	(Multiple Heavy Metal	shelf life.	
	Gulberg II,	Irvine, CA 92618, USA	IVD Control)		
	Lahore Pakistan.		ĺ		
		Original FSC: U.S.A	Codes & Sizes: As per		
	ELI: 00156		FSC		
		Valid till: 20/08/2022			
	Evaluator:	20, 00, 2022	Class- B		
	AD-II				
	1317-11		Shelf Life: As per stability		
	(2571-P)		study		
16	` /	Logal Massactarda		A	
46	M/s Chemical	Legal Manufacturer:	Lyphochek Multiple	Approved	
1	House, 6-C		Coagulation Factor IVD	subject	to

47	Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2566-P) M/s Chemical House, 6-C Sikander Malhi	M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022 Legal Manufacturer: M/s Bio-Rad Laboratories,	Control (Multiple Coagulation Factor IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study Lyphochek Anemia Control	Approved subject submission	of to of
	Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II	Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	(Multiple Anemia Related Analyte, IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	shelf life.	
48	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (428-P)	Legal Manufacturer: M/s Roboscreen GmbH, Hohmannstrasse 7, 04129 Leipzig, Germany FSC: Germany Date of issue: 29.10.2020	Instant Virus RNA/DNA Kit (847-0259200602- 847-0259200603) Class-A Shelf Life: 6 months	Approved	
49	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (498-P)	Legal Manufacturer: M/s Bio-Rad, 3 Boulevard Raymond Poincare, 92430 Marnes-la-Coquette, France Manufacturing Site: M/s Bio-Rad, 7 – Rue de Madrid – Espace Europeen de I'enterprise, 67300 Schiltigheim, France	PW40 Microplate Washer (Catalogue # 85499) Codes & Sizes: Class-A	Approved	

		FSC: France		
50		Date of issue: 01.02.2018	DD 4100 D 1	A 1
50	M/ Chemical House,	Legal Manufacturer	PR4100 Reader	Approved
	6-C Sikander	M/s Bio-Rad France, 3	(94196/91587)	
	Malhi Road	Boulevard Raymond	(5.136.51267)	
	Gulberg II	Poincare 92430 Mames-la-	Class: A	
	Lahore, Pakistan	Conquette, France	C1 1CT 'C N 1' 11	
	(ELI: 00156)	FSC: France	Shelf Life: Not applicable	
	(ELI. 00150)	TSC. Plance		
	Evaluator	Date of issue:		
	AD-II			
	(2.47 D)	15.03.2019		
51	(347-P) M/s Chemical	Legal Manufacturer:	Dionlay 2200 Symbilis	Approved
31	House, 6-C	Legal Manufacturer:	Bioplex 2200 Syphilis Total & RPR	Approved
	Sikander Malhi	M/s Bio-Rad Laboratories	1000100101	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Treponema pallidum total	
	Lahore	Drive Hercules, CA, U.S.A	antibody and reagin	
	ELI:00156	Manufacturing Site:	antibody IVD kit)	
	EL1.00150	M/s Bio-Rad Laboratories	Codes & Sizes: As per	
	Evaluator:	Inc., 14620 NE North	FSC	
	AD-II	Woodinville Way,		
	(2515)	Woodinville, WA 98072,	Class-B	
	(3517)	USA.	Shelf Life: 24 months	
		Original FSC: U.S.A	Shell Life. 24 months	
		5		
		Valid till: 11.08.2022		
52	M/s Chemical House, 6-C	Legal Manufacturer:	Bioplex 2200 Instrument	Approved
	,	M/s Bio-Rad Laboratories	(Immunoassay analyzer)	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Immunoassay analyzer)	
	Lahore	Drive Hercules, CA, U.S.A	Codes &Sizes: As per	
	FI 1 001 5 6		FSC	
	ELI:00156	Manufacturing Site: M/s Leica Biosystems	Class-A	
	Evaluator:	Melbourne Pty Ltd,	Class-A	
	AD-II	495 Blackburn Road, Mount	Shelf Life: N/A	
		Waverley, Melbourne,		
	(708-P)	Victoria, Australaia 3149		
		Original FSC: U.S.A		
		Original PSC, U.S.A		
		Valid till: 11.08.2022		
53	M/s Chemical	Legal Manufacturer:	Bioplex 25-OH Vitamin	Approved
	House, 6-C	M/. D:- D-JI l	D	
	Sikander Malhi Road Gulberg-II,	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel	(Chemiluminescent	
	Noau Guideig-II,	IIIC. 4000 AIIIEU NOUEI	(Chemininiescent	

	Lahore	Drive Hercules, CA, U.S.A	Immunoassay)	
	ELI:00156	Manufacturing Site: M/s Bio-Rad Laboratories	Codes & Sizes: As per FSC	
	Evaluator: AD-II	Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072,	Class-B	
	(3511-P)	USA.	Shelf Life: 24 months	
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
54	M/s Chemical	Legal Manufacturer:	Bioplex 2200 ANA	
	House , 6-C Sikander Malhi	M/s Bio-Rad Laboratories	Screen with MDSS	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Multiple antinuclear	
	Lahore	Drive Hercules, CA, U.S.A	antibody screening IVD)	
	ELI:00156	Manufacturing Site: M/s Bio-Rad Laboratories	Class-B	
	Evaluator:	Inc., 14620 NE North	Shelf Life: 24 months	
	AD-II	Woodinville Way,		
	(3512-P)	Woodinville, WA 98072, USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
55	M/s Chemical House, 6-C	Legal Manufacturer:	Bioplex 2200 APLS IgG, IgM, & IgA	Approved
	Sikander Malhi Road Gulberg-II,	M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel	(Phospholipid antibody	
	Lahore	Drive Hercules, CA, U.S.A	IVD Kit)	
	ELI:00156	Manufacturing Site: M/s Bio-Rad Laboratories	Class-B	
	Evaluator:	Inc., 14620 NE North	Shelf Life: 24 months	
	AD-II	Woodinville Way,		
	(3513-P)	Woodinville, WA 98072, USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
56	M/s Chemical House, 6-C	Legal Manufacturer:	Bioplex 2200 Anti-CCP IVD	Approved
	Sikander Malhi	M/s Bio-Rad Laboratories	(0.11.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Cyclic citrulinated	
	Lahore	Drive Hercules, CA, U.S.A	peptide antibody (Anti- CCP) IVD Kit)	
1	ELI:00156	Manufacturing Site:	Class-B	

	Evaluator:	M/s Bio-Rad Laboratories		
	AD-II	Inc., 14620 NE North	Shelf Life: 24 months	
		Woodinville Way,	Shell Elle. 2 i months	
	(3514-P)	Woodinville, WA 98072,		
		USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
57	M/s Chemical	Legal Manufacturer:	Bioplex 2200 Vaculitis	Approved
	House, 6-C			
	Sikander Malhi	M/s Bio-Rad Laboratories	(Multiple vasculitis-	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	associated antibody IVD	
	Lahore	Drive Hercules, CA, U.S.A	kit)	
	ELI:00156	Manufacturing Site:	Class-B	
		M/s Bio-Rad Laboratories		
	Evaluator:	Inc. , 14620 NE North	Shelf Life: 24 months	
	AD-II	Woodinville Way,		
		Woodinville, WA 98072,		
	(3515-P)	USA.		
		Original FSC: U.S.A		
		V-1:4 +:11, 11 08 2022		
58	M/s Chemical	Valid till: 11.08.2022	Diamles 2200 Celies InC	Ammayyad
30	House, 6-C	Legal Manufacturer:	Bioplex 2200 Celiac IgG & IgA	Approved
	Sikander Malhi	M/s Bio-Rad Laboratories	& IgA	
	Road Gulberg-II,	Inc. 4000 Alfred Nobel	(Multiple coeliac disease	
	Lahore	Drive Hercules, CA, U.S.A	associated antibody IVD	
	Lunore	Bilve Hereares, et i, e.sr	Kit)	
	ELI:00156	Manufacturing Site:	11.0)	
		M/s Bio-Rad Laboratories	Class-B	
	Evaluator:	Inc., 14620 NE North		
	AD-II	Woodinville Way,	Shelf Life: 24 months	
		Woodinville, WA 98072,		
	(3516-P)	USA.		
		Original FSC: U.S.A		
		Valid till: 11.08.2022		
59	Mediland	Legal Manufacturer:	Maquet HLM Perfusion	Approved
	Pakistan Pvt	Maquet Cardiopulmonary	Tubing Set	
	Office No. b-09,	GmbH Kehler Str. 31 76437	(Perfusion Tubing Set with	
	2nd Floor	Rastatt Germany.	oxygenator)	
	Masood Arcade	PGC C	C1	
	IJP Road near	FSC: Germany	Class-C	
	Saidpur Road,	issuance: 12/17/2021	G1 161:6 2	
	Rawalpindi.		Shelf life: 2 years	
	EI I. 00202		Codos & Cizos Az za ECC	
	ELI: 00202		Codes & Sizes: As per FSC	
	3100-P			

	24-06-2022			
60	Medical	Legal Manufacturer:	Optivantage Dual-Head	Approved
	Equipment &	1 2/	CT Delivery System	subject to
	System, 60/61,	LLC 2111 E. Galbraith Rd	(Injector System)	updated FSC
	F.C.C Syed	Cincinnati, OH, 45237,		and ISO 13485.
	Maratab Ali	U.S.A	Class-C	
	Road, Gulberg-			
	IV, Lahore	Original FSC: U.S.A	Shelf Life: 7 years	
	FI I 00554	(Original)		
	ELI: 00554	Valid till:20/10/2023	Codes & Sizes: As per FSC	
	3139-P			
60	04-07-2022 Medical	I 1 M 6 - 4	OutiStan Elita Contract	A
00		Legal Manufacturer: Liebel-Flarsheim Company,	OptiStar Elite Contrast Delivery System	Approved subject to
	Equipment & System, 60/61,	LLC 2111 E. Galbraith Rd	(Injector System)	subject to updated FSC
	F.C.C Syed	Cincinnati, OH, 45237,	(Injector System)	and ISO 13485.
	Maratab Ali	U.S.A	Class-C	and 150 15405.
	Road, Gulberg-	0.5.11	Class	
	IV, Lahore	Original FSC: U.S.A	Shelf Life: 7 years	
		(Original)		
	ELI: 00554	Valid till:20/10/2023	Codes as per FSC:	
	3235-P		1	
	04-07-2022			
60	Medical	Legal Manufacturer:	OptiOne Single-Head	Approved
	Equipment &	Liebel-Flarsheim Company,	Contrast Delivery system	subject to
	System, 60/61,	LLC 2111 E. Galbraith Rd	(Power Injector with	updated FSC
	F.C.C Syed	Cincinnati, OH, 45237,	Pedestal)	and ISO 13485.
	Maratab Ali	U.S.A		
	Road, Gulberg-	EGG H.G.A	Class-C	
	IV, Lahore	FSC: U.S.A	Cl. 161 :6- 7	
	ELI: 00554	Valid till:23/03/2023	Shelf Life: 7 years	
	3140-P		Code:	
	04-07-2022		S8474	
61	Medical	Legal Manufacturer:	Illumena Neo Contrast	Approved
01	Equipment &	Liebel-Flarsheim Company,	Delivery System	subject to
	System, 60/61,	LLC 2111 E. Galbraith Rd	(Injector System with	updated FSC
	F.C.C Syed	Cincinnati, OH, 45237,	Pedestal)	and ISO 13485.
	Maratab Ali	U.S.A	,,	
	Road, Gulberg-		Class-C	
	IV, Lahore	FSC: U.S.A		
		Valid till:23/03/2023	Shelf Life: 7 years	
	ELI: 00554			
	3141-P		Code:	
	04-07-2022		7216	
62	Chemical House,	Legal Manufacturer:	Platelia Aspergillus	Approved
	6-C Sikander	M/s Bio-Rad, 3 Boulevard	Aspergillus fumigatus 1gG	
	Malhi Road,	Raymond Poincare, 92430	Antibody IVD kit enzyme	
	Canal Park,	Marnes, Ia Conquette,	Immunoassay EIA	
	Gulberg II,	France.	C. 1 0 C: (2702	
	Lahore Pakistan.		Codes & Sizes: 62783	

63	Chemical House, 6-C Sikander Malhi Road, Canal Park,	Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28-07-2022. Notarized copy of ISO 13485 valid upto 11-12-2024 Distribution Certificate valid upto 31-12-2023 Legal Manufacturer: M/s Bio-Rad, 3 Boulevard Raymond Poincare, 92430 Marnes, Ia Conquette,	Class-C Shelf Life: 18 months Fee: 50,000/- Date of Application: 16- 02-2023 Platelia Aspergillus Ag Aspergillus species galactomannan antigen IVD Kit EIA	Approved
	Gulberg II, Lahore Pakistan. ELI: 00156	France. Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28- 07-2022. Notarized copy of ISO 13485 valid upto 11-12-2024 Distribution Certificate valid upto 31-12-2023	Codes & Sizes: 64794 Class-C Shelf Life: 12 months Fee: 50,000/- Date of Application: 16- 02-2023	
64	Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	Legal Manufacturer: M/s Bio-Rad, 3 Boulevard Raymond Poincare, 92430 Marnes, Ia Conquette, France. Site: Bio Rad, Route de Cassel-59114 Steenvoorde France. Lagalized FSC issued by CCI Paris France dated 28- 07-2022. Notarized copy of ISO 13485 valid upto 11-12-2024 Distribution Certificate valid upto 31-12-2023	Pastorex meningitis Multiple meningitis associated bacteria antigen IVD Kit agglutination. Codes & Sizes: 61607, 61608, 61610, 61611, 61613, 61614, 61616, 61618 Class-C Shelf Life: 12 months Fee: 50,000/- Date of Application: 16- 02-2023	Approved
65	M/s RHS International 1st Floor of Building	Legal Manufacturer: Jiangsu Pedo-Care Medical Equipment Co., Ltd	Certeza (Air Compressor Nebulizer)	Approved

	C(0 D24 M	NIANIMO I I I Torre		
	S60-R34 Mozang	NANMO Industrial Town	CI D CI 101:0	
	Road Opp, Total	Haian, Jiangsu China FSC:	Class-B Shelf life:	
	Petrol Pump,	China validity		
	Lahore	03-12-2021	Model:	
	Warehouse		NB-605	
	Address 2nd		NB-607	
	Floor of Building,			
	S60-R34 Mozang			
	Road, Opp,. Total			
	Petrol Pump,			
	Lahore ELI:			
	00354			
	1148-P			
	03-02-2020			
	Court case			
66	AMB HK	Legal Manufacturer:	SURE-GUARD	Approved
	Enterprises (PvT)		IV CANNULA (With	
	Ltd, 2nd Floor	M/s Jiangxi Fenglin Medical	injection valve)	
	Plaza 60,	Applicance Co., Ltd,Fulin		
	Commercia 1	Road, Fuzhou Ciity , Jiangxi	Codes & Sizes: as per FSC	
	Block-K, Phase-	Province, China		
	1, DHA, Lahore	FSC: CHINA Valid till:	Class-B	
	ELI: 00863	29/07/2025		
	Dossier# 3675-P		Shelf Life: 03 years	
	Submission date:		Storage Temperature: +5 to	
	14/02/2023		+25°c	
	1 1/ 02/ 2025		25 6	
67	M/s Tech Zone,	Legal Manufacturer:	Yashfaeen	Approved
	764 Askari 9	Jiangsu Nanfang Medical	Zinc Oxide Adhesive	11
	Zarar Shaheed	Co., Ltd	Plaster	
	Road Cantt	1 Guoxiang RD Wujin		
	Lahore, WH:	Economic Development	Class-A	
	Ground Floor,	Zone 213149 Changhzhou		
	Weal House 8	city, Jianagsu Province China	Shelf life: 3 years	
	Faiz road, Lahore	FSC China validity	Shell life. 3 years	
	ELI: 00040	19-08-2024	Codes as per FSC	
	888-C	19-08-2024	Codes as per 13C	
68	Vertex Medical	Logal Manufacturer	Stockert S5	The Board
08		Legal Manufacturer:		
	(Pvt) Ltd, 70-B-1,	LivaNova Deutschland	(Heart Lung Machine)	approved the
	Gulberg III,	GmbH Lindberghstr.25		product for M/s
	Lahore.	80939 Munich-Germany	Class-C	Vertex, Lahore.
	EL L 001.70	Tag G	G1 101:0 10	
	ELI: 00150	FSC: Germany	Shelf Life: 10 years	
	3154-P	Date of Issue: 23/02/2022		
1				
	22-07-2022		Code:	
			45-95-02	
69	Vertex Medical	Legal Manufacturer:	45-95-02 Stockert 3T Heater Cooler	The Board
69	Vertex Medical (Pvt) Ltd, 70-B-1,	LivaNova Deutschland	45-95-02 Stockert 3T Heater Cooler System	approved the
69	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III,		45-95-02 Stockert 3T Heater Cooler	approved the subject product
69	Vertex Medical (Pvt) Ltd, 70-B-1,	LivaNova Deutschland	45-95-02 Stockert 3T Heater Cooler System	approved the
69	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III,	LivaNova Deutschland GmbH Lindberghstr.25	45-95-02 Stockert 3T Heater Cooler System	approved the subject product

	_			
	ELI-00150 3153-P	FSC: Germany Date of Issue: 23/02/2022	Service Life: 10 years Model:	
			16-02-80	
70	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore ELI-00150 3152-P 22-07-2022	Legal Manufacturer: LivaNova Deutschland GmbH Lindberghstr.25 80939 Munich-Germany FSC: Germany Date of Issue: 23/02/2022	XTRA Auto Transfusion Cell Separator (XTRA Auto Transfusion Cell Separator Class-C Shelf Life: 7 years	The Board approved the subject product for M/s Vertex, Lahore.
71	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3721 Submission date: 25/01/2023 Fee submitted: 50,000/- Challan No. 8313838062	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Address: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC:USA Valid till: 20/07/2023	Codes & Sizes: As per FSC MetriQ TM Pump,RF Cardiac Ablation System (irrigation pump, roller) Codes & sizes: M00441000 Class-C Shelf Life: N/A	Approved
72	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3900 Submission date: 10/04/2023 Fee submitted: 50,000/- Challan No. 4737766993	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN, USA 55112 FSC: USA 12/10/2024	Momentum EL-ICD (Implantable cardioverter Defibrillator) Codes & sizes: models: D120, D121 Class:D Shelf Life: 2 years	Approved
73	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh,	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA	Momentum CRT-D (Cardiac Resynchronization Therapy Defibrillator) Codes & sizes: models:	Approved

	Mayyahama (I/DI/)	115 4 01752	C124	
	Nowshera (KPK), Pakistan	USA 01752	G124 G125	
	ELI: 00120	Manufacturing Site: Boston Scientific	G125 G126	
	Dossier# 3901	Corporation	Class:D	
	Submission date:	4100 Hamline Ave N Saint	Shelf Life: 2 years	
	10/04/2023	Paul, MN		
	Fee submitted:	USA 55112		
	50,000/-			
	Challan No.	FSC: USA		
	380583560	Valid till: 23/06/2024		
74	Feroszons	Legal Manufacturer:	Emblem TM S-ICD	Approved
' -	Laboratorries	Boston Scientific	System	прргочец
	Limited, P.O	Corporation	(Subcutaneous Implantable	
	· · · · · · · · · · · · · · · · · · ·			
	Ferozsons,	4100 Hamline Avenue North	Cardioverter Defibrillator	
	Amangarh,	St. Paul, MN	(S-ICD)	
	Nowshera (KPK),	55112 USA	Codes & sizes: models:	
	Pakistan	Manufacturing Sites:	Emblem S-ICD	
	ELI: 00120	1) Boston Scientific	Subcutaneous Electrode	
	Dossier# 3909	Corporation 4100 Hamline	Model:3501	
	Submission date:	Avenue North St. Paul, MN	Class-D	
	03/05/2023	55112 USA	Shelf Life: 02 Years	
	Fee submitted:	2) Boston Scientific		
	50,000/-	Corporation Cashel Road		
	Challan No.	Clonmel Tipperary, Ireland		
	25977867082Eva	3)Boston Scientific		
	luator	Corporation NO.12 RD. No.		
	Tuttoi	698 Dorado, PR USA 00646		
		Original FSC: U.S.A		
		Valid till: 29/09/2023		
75	Feroszons	Legal Manufacturer:	IntellaNav TM ST	Approved
	Laboratorries	Boston Scientific	Ablation Catheters	11
	Limited, P.O	Corporation	(Catheter, Cardiac	
	Ferozsons,	300 Boston Scientific Way	Ablation)	
	Amangarh,	Marlborough, MA	Codes & sizes:	
	Nowshera (KPK),	USA 01752	M004R5031TH0	
	` ' '		M004R5031THK20	
	Pakistan	Manufacturing Site:		
	ELI: 00120	Boston Scientific	Class-D	
	Dossier# 3910	Corporation	Shelf Life: 03 Years	
	Submission date:	302 Parkway, Global Park		
	03/05/2023	La Aurora, Heredia Costa		
	Fee submitted:	Rica		
	50,000/-	FSC: U.S.A		
	Challan No.	Valid till: 20/07/2023		
	5522830287			
7.0	Г	T 134 C /	TABLE TOM BASES OF	A 1
76	Feroszons	Legal Manufacturer:	IntellaNav TM MiFi OI	Approved
	Laboratorries	Boston Scientific	Ablation Catheters	
	Limited, P.O	Corporation	(Catheter, Cardiac	
	Ferozsons,	300 Boston Scientific Way	Ablation)	
	Amangarh,	Marlborough, MA	Codes & Sizes:	

	Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3911 Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 37973886907	Manufacturing Site: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica FSC: U.S.A Valid till: 20/07/2023	M004PMR9620K20 M004PMR9620N40 Class-D Shelf Life: 02 Years	
77	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3912 Submission date: 03/05/2023 Fee submitted: 50,000/- Challan No. 9461769669	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 Manufacturing Site: Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica Original FSC: U.S.A Valid till: 20/07/2023	IntellaTip MiFi TM Open-Irrigated Ablation Catheters (Catheter, Cardiac Ablation) Codes & Sizes: M004PM96200 M004PM9620K20 M004PM9620N40 Class-D Shelf Life: 03 Years	Approved
78	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 3720 Submission date: 16/02/2023 Fee submitted: 50,000/- Challan No. 885927282412	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA FSC: USA Valid till: 22/07/2023	LABSYSTEMTM PRO EP Recording System and CLEARSIGNTM/CLEAR SIGNTM II Amplifier (single-patient physiological monitoring system) Codes & Sizes: M00420020230 LABSYSTEMTM PRO EP Recording System, CLEARSIGN II Amplifier for LABSYSTEM PRO EP Recording System, 120 Channels. M00420012500 LABSYSTEM PRO EP Recording System 40- Channel IC Junction Box for CLEARSIGN Amplifier, 3m M00420012300 LABSYSTEM PRO EP Recording System RF	Approved

			Filter Module for	
			CLEARSIGN Amplifier	
			M00420020210	
			LABSYSTEM PRO EP	
			Recording System,	
			CLEARSIGN II Amplifier	
			for LABSYSTEM PRO EP	
			Recording System, 40	
			Channels	
			Class: C	
			Shelf life: N/A	
79	Feroszons	Legal Manufacturer:	Momentum X4 CRT-D	Approved .
	Laboratorries	Boston Scientific	(cardiac	
	Limited, P.O	Corporation	Resynchronization therapy	
	Ferozsons,	300 Boston Scientific Way	defibrillator)	
	Amangarh,	Marlborough, MA	Codes & Sizes:	
	Nowshera (KPK),	USA 01752	Models:	
	Pakistan	Manufacturing Site:	G128	
	ELI: 00120	Boston Scientific	G138	
	Dossier# 3899	Corporation	Class: D	
	Submission date:	4100 Hamline Ave N Saint	Shelf Life: 2 years	
	10/04/2023	Paul, MN		
	Fee submitted:	USA 55112		
	50,000/-	FSC: USA		
	Challan No.	Valid till: 23/06/2024		
	800711787			
80	M/s Ferozsons	Legal Manufacturer: Lake	Victory TM 14 Polymer Tip	Approved
00	Laboratories	Region Medical Limited	Guidewire with	прриочен
	Limited, P.O	Butlersland, New Ross, Co	Hydrophilic Coating	
	Ferozsons,	Wesford Ireland	(Guidewire for	
	AmangarhNowsh	Manufacturing Site:	intravascular	
	era (KPK),	Brivant Limited Parkmore	Interventional procedures)	
	Pakistan ELI:	West Business Park Galway,	1	
	00120 3270-KP	Ireland	Class-D	
		FSC: U.S FDA Valid till:	Shelf Life: 3 years	
		12/06/2023		
			Codes & Sizes: As per FSC	
		FSC: Ireland		
0.1	-	Issued On: 19-04-2022	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
81	Ferozsons	Legal Manufacturer &	Safari 2 TM	Approved
	Laboratories	manufacturing site: Lake	Guidewires	
	Limited P.O	Region Medical 340 Lake	(Cardiac catheter	
	Ferozsons,	Hazeltine Dr. CHASKA, MN	guidewire, single- use)	
	Amangarh,	USA 55318	Codes & Sizes:	
	Nowshera (KPK)	Distributor: Boston	H74939406L1	
	ELI-00120 Dossier# 2709	Scientific Corporation 300, Boston Scientific Way,	H74939406S1	
1	DOSSICI# Z/U9	Boston Scientific Way,	H74939406XS1	
		3 /	H74020407L0	
	Submission date:	Marlborough, MA 01752,	H74939407L0	
		3 /	H74939407L0 H74939407S0 H74939407XS0	

	Fee submitted: 50,000/- Challan No. 91133737024	Valid till: 13.04.2022	Class-D Shelf Life: 3 years	
82	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Xeridiem Medical Devices 4700 S Overland Dr. Tucson, AZ, USA, 85714 Manufacturing Site: Xeridiem Medical Devices 7700 S Overland Dr. Tucson, AZ, USA 85714 FSC: U.S.A Valid till: 04.01.2024	ENDOVIVE Gastrostomy Tube, Straight, with Enfit Connector (Gastrostomy Feeding Tubes) Codes & Sizes: As per FSC Class-C Shelf life: 03- years	Approved
83	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technolgy Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist.,24888 New Taipei city, Taiwan. Certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 082573 dated 13-05-2021. FQA/CE certificate, ISO13485 submitted.	Life Check Blood Glucose Monitoring System(TD-4141 Code: Class-C Shelf Life: not mentioned however in stability 25 months is mentioned Fee:50,000/-	Approved
84	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technolgy Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist.,24888 New Taipei city, Taiwan. Copy of certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 085483 dated 12-04-2022. FQA/CE certificate, ISO13485 submitted. FSC of Germany issuance date 10.05.2023	U-Check Blood Glucose Monitoring System Code: td-4252 Class-C Shelf Life: 24months Fee:50,000/-	Approved
85	M/s Maqsood Brothers, Office	Legal & Physical manufacturer:	Atom Medical Blood Glucose Monitoring	Approved

	No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	TaiDoc Technolgy Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist.,24888 New Taipei city, Taiwan. Copy of certificate issued by Mo Health & Welfare, Republic of China (Taiwan)	System td-4277(atom At-600) Code: Class-C Shelf Life: not mentioned however in stability 25 months is mentioned	
		No. 072103 dated 25-05-2018. FQA/CE certificate, ISO13485 submitted. FSC of Germany issuance date 10.05.2023	Fee:50,000/-	
86	Maqsood Brothers Address: Office- 503-B, 5 th Floor, Saima Trade Tower, I.I Chundrigar Road Karachi ELI-00282 Date of submission 12-02-2021	Legal manufacturer Huaian Poly Medical Technology Corporation Address: No. 5 West Huaqing Road 223002 Huaian, PEOPLE's REPUBLIC China Original Legalized Free Sale Certificate (FSC) dated 29-07-21 SC Germany	LIFE CATH I.V Cannula Class- B Shelf Life: 5 Years	Approved
87	M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. (ELI-00161) 4469-P 16-05-2022	Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China FSC China Date of Issuance 06-12-2021 valid for 2 years	KBM Auto-Disable Syringe Class B Shelf life: 05 Years Sizes: 3ml, 5ml	Approved subject to submission of notarized FSC
88	NEW PAKISTAN TRADERS Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.	M/s NANTONG EGENS BIOTECHNOLOGY CO., LTD ADDRESS: Block A Fifteenth Factory-building No.1692 Xinghu Avenue,Nantong Economic & Technological	Accurate pregnancy test kit CLASS: B Shelf life: 2 years	Approved

	ELI-00161	Development Zone,	Fee 25000:-	
		NANTONG, CHINA		
	R&I	,		
	16/05/2022	FSC original China valid till 05-05-24		
89	M/s. Maxitech	Legal Manufacturer:	Mini Well (Intraocular	Approved.
	Pharma PVT		Lens (IOL))	
	LTD	SIFI . S.P.A	27560CZ	
	Address: E-178	Address: via Ercole Patti	Class: C	
	SITE area Super Highway Karachi	n.36 Lavinaio Aci S. Antonia		
	Tingiiway Karaciii	CT 95025 Italy	01)	
	Establishment		Code: Ass per FSc	
	License #:	Scanned copy of FSC Italy	Claimed Shelf life:4 years	
	(ELI-00769)	issuance date 18-02-2021	Fee 50000/-	
90	Allmed	TONGLU ZHOUJI	HEMOLOCK CLIPS	Approved
	Solutions, A-21/3, KDA	MEDICAL INSTRUMENT CO. LTD., CHINA.	(POLYMER LIGATION CLIPS)	
	Scheme No.1	CO. LID., CIMVI.	CLII 5)	
	(ext) Stadium	Address No.1 Huanzhen	Article no.	
	Road, Karachi	West Road, Fengchuan	SAr	
	(ELL00020)	Town, Tonglu County,	· _{ticl} 1ype	
	(ELI-00029)	Zhejiang Province, China Apostille FSC of china valid	n e and size	
	Date of	till 25.12.2024	no.	
	submission: 26-		ZJ- ML -	
	12-2022			
			$\begin{bmatrix} 1 & 02 & 3000 \\ M & 1000 & 3000 \end{bmatrix}$	
			L size	
			ZJ- L –	
			2 16 5MM –	
			L size ZJ- XL -	
			3 04 16MM	
			XL size	
			Class C	
			Shelf life: N/A	
			Fees Rs. 50,000/- challan	
01	M/a Haanit-1	Logal Marsufactur	no. 057557678	Defermed
91	M/s Hospital Solutions , H. No.	Legal Manufacturer:	OPA Disinfectant Ortho Phthalaldehyde 0.5%	Deferred since the frim has not
	174-E Block 2,	M/s Wuhan Snow Medical	Solution 5L & 1L	submitted FSC
	P.E.C.H.S	Disinfectant Co. Ltd, No.		of reference
	Karachi.	18, Yinhu Science &	Class B	country nor Ce
		Technology Industrial Park,		certicfate

	T	1	1	
		Dongxihu District Wuhan	Shelf Life: 05 Years	provided as
	ELI No. 00250	Hubei, China 430040		required in the 54 th MDB.
		FSC China		Further
	(221-C)			clarfcation is
		Issued on		required
		28-01-2022		regarding the china FSC where
		Valid for 2 years		in it is written
		valid for 2 years		that it does not
				belongs to
				medical device
92	M/s Hospital	Legal Manufacturer:	Snow Xue Huan	Deferred since
	Solutions, H. No.		Glutaraldehyde Solution	the frim has not
	174-E Block 2,	M/s Wuhan Snow Medical	_	submitted FSC
	P.E.C.H.S	Disinfectant Co. Ltd , No.	(Glutaraldehyde 2%)	of reference
	Karachi.	18, Yinhu Science &		country nor Ce
		Technology Industrial Park,		certicfate
	ELI No. 00250	Dongxihu District Wuhan	Class D	provided as
	Evoluatou	Hubei, China 430040	Shalf I for 02 Vacus	required in the 54 th MDB.
	Evaluator AD-II	FSC China	Shelf Life: 02 Years	54 th MDB. Further
	AD-II	rsc clilla		clarfcation is
		Issued on		required
	(4811-P)	28-01-2022		regarding the
	(.011.1)			china FSC where
		Valid for 2 years		in it is written
				that it does not
				belongs to
				medical device
93	M/s Biologic	Legal Manufacturer	HUNTLEIGH	Approved
	Medical Systems	III DITI FICH	FETAL DODDLED CD2	model SR 3 as
	(BMS) 166-E, Block No. 3,	HUNTLEIGH HEALTHCARE LTD	FETAL DOPPLER SR2-	per updated Form7A, subject
	Annex B, Off	Diagnostic products	CLASS-B	to submission of
	Khalid	Division 35 Portmanmoor	CLASS-B	the apostille/
	BinWaleed Road	Road Cardiff CF24 5HN	Shelf Life: N/A	embassy attested
	P.E.C.H.S	United Kingdom		FSC of UK or
	Karachi			Sweden attested
		FSC embassy attested: UK		by relevant
	ELI: 000346	DATE OF ISSUE:		embassy in the
		28.01.2019		country of origin
		(Master Files		EPSP, DOC and
				manufacturing
				and testing method.
				The firm has not
				provided service
				life, clarify as
				required in the
				65 th MDB.
L	1	ı	ı	ı

94	M/s Biologic Medical Systems (BMS) 166-E, Block No. 3, Annex B, Off Khalid BinWaleed Road P.E.C.H.S Karachi ELI: 000346	Legal Manufacturer HUNTLEIGH HEALTHCARE LTD Diagnostic products Division 35 Portmanmoor Road Cardiff CF24 5HN United Kingdom FSC: UK DATE OF ISSUE:	HUNTLEIGH VASCULAR DOPPLER Model: DMX-DMXR Class-B Shelf Life: N/A	Approved subject to submission of the apostille/ embassy attested FSC of UK or Sweden attested by relevant embassy in the country of origin
95	M/s Biologic Medical Systems, Karachi. ELI-00346	28.01.2019 Legal Manufacturer & Site: Huntleigh Healthcare Ltd. 35 Portmanmoor road, Cardiff CF24 5HN, UNITED kingdom. Copy of FSC issued by MHRA dated 28-01-2019. Copy of ISO 13485 valid upto 30-04-2022	Huntleigh Sonicaid Team 3 Fetal Monitor Codes & Sizes: TEAM 3A & TEAM 3I. Class-C Shelf Life: NA Fee: 50,000/- Date of Application: 27- 02-2020	Approved subject confirmation of brand name
		Copy of EC/FQA Certificate valid upto 30-09-2020. LOA valid upto 11-02-2021		
96	Ali sons room no 37, 2nd floor Luxmi Building M.A Jinnah Road, Karachi (ELI-00711) Godown: KPT plot no 30, West Wharf, Karachi. Dossier# 4368 Submission date: 22/04/2022 Fee submitted: 50,000/- Challan No. 02645472630	Legal Manufacturer: NRS Global Partners Sdn Bhd no.30, Jalan Tasik selatan, 57000, Kuala Lampur, Malaysia. FSC: Malaysia. (Original) Valid till: 16-11-2023	Ectasy Latex Condoms (Male Prophylactic Condoms) Codes& sizes: Length: min. 180mm Packing: 3s, 6s,12s Design: Reservoir ended Type: contoured super dotted Class-C Shelf Life: 5 Years	Deferred for clarifcaition since the product is not available on free sale in malysia and also clarify the barn name sinc another prodct extasy regsitred
97	M/s Kain Medical, Ali Bhai Center 3 rd Floor Office # 35 Main	Legal Manufacture M/s TEKIA, Inc., 17 Hammond, Suite 414 Irvine, California 92618, USA	Tek Lens II (Intraocular Lens)	Approved

	Shahrah-e-Qauideen, Karachi (ELI-00506) Date of submission 24.01.2022	Sterilization Process: M/s Pro-Tech Design & Manufacturing Inc. 14561 Marquardt Avenue Santa Fe Springs, CA 90670, USA Us Embassy attes FSC France issuance date: 15-10-2020	Shelf Life: 03 Years Codes & Sizes as per FSC 811, 811Y Fee 50000/-	
98	Bone Solution Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A., Karachi. ELI-00517	Manufacturer: Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic. A.S. Universiteler Mahallesi 1596. Cadde Safir Bloklari E Blok ofis No. 02-03 Zemin Kat Kapl No. 6 Beytepe- Cankaya-Anarka, Turkey Copy of FSC issued by Turkey Dated 08-04-2022 FQA/CE valid till 13-12-2023	Desu Hydrocephalus External Neurological Drainage Sysytem Code: 61796 Class D Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Approved subject to submission of valid Desighn exanmination , FQA and ISO 13485 certfcaite
99	Bone Solution Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A., Karachi. ELI-00517	Manufacturer: Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic. A.S. Universiteler Mahallesi 1596. Cadde Safir Bloklari E Blok ofis No. 02-03 Zemin Kat Kapl No. 6 Beytepe- Cankaya-Anarka, Turkey Copy of FSC issued by Turkey Dated 08-04-2022	Desu Hydrocephalus Shunt Systems Code: 45694 Class D Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Approved subject to submission of valid Desighn exanmination , FQA and ISO 13485 certfcaite

		FQA/CE valid till 13-12- 2023		
100	M/s Labserv, House No. B- 165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI- 00105	Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08- 2027 (embassy attested Submitted in Optilite® Freelite® Kappa Free Kit)	Optilite® Freelite® Lambda Free Kit Class C Shelf Life: 18 months Code:- LK018.OPT Date of Submission: 31- 05-2023 Fee submitted: Rs. 50,000/- Storage temperature: Store at temperature 2-8°C	Deferred for clarifcaiton of the FQA to provide details of regulation for the claim.
101	M/s Labserv, House No. B- 165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI- 00105	Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08- 2027 (embassy attested Submitted	Optilite® Freelite® Kappa Free Kit Class C Shelf Life: 18 months Code:- LK016.OPT Date of Submission: 31- 05-2023 Fee submitted: Rs. 50,000/- Storage temperature: Store at temperature 2-8°C	Deferred for clarifcaiton of the FQA to provide details of regulation for the claim.
102	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI- 00081	GUANGDONG HAIOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIOU DISPOSAL BREATHING CIRCUIT (HO-HO1, HO-HO2, HO-HO3 & HO-HO4) Class – B Shelf Life 5 Years	Approved with shelf life 24 months
103	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS,	GUANGDONG HAIOU MEDICAL APPARATUS CO., LTD	HAIOU BACTERIUM / VIRUS FILTER (HO6020, HO6130, HO7010)	Approved with bacteria filter with shelf life 24 months

	Karachi – 75400, PAKISTAN Lic. No.ELI-	Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province,	Class – B Shelf Life 5 Years	
	00081	China. ISO Valid Till (17-10-2019) FSC Valid Till (0-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)		
104	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI- 00081	GUANGDONG HAIOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (02-12-2020) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIOU DISPOSABLE INFUSION SET WITH NEEDLE (Type Al, B3 Size: 0.45x13, 0.5x19,0.55x25, 0.6x25, 0.7x25, 0.8x25, 0.9x25 and 1.2x25)" Class – B Shelf Life 3 Years	Approved with shelf life 24 months
105	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI- 00081	GUANGDONG HAIOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (02-12-2020) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIOU DISPOSABLE NASAL OXYGEN CANNULA (I TYPE & II TYPE) Class – B Shelf Life 5 Years	Approved Shelf life 02 years
106	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI- 00081	GUANGDONG HAIOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIOU DISPOSABLE PERCISION INFUSION SET WITH NEEDEL (THE PORE SIZE OF FILTER MEMBRANE B3; 5um, 3um, 2um) Class – B Shelf Life 3 Years	Approved Shelf life 02 years

107	HOCDITAL	CHANCDONG HAIOH	HAJOH DICDOCADI E	A
107	HOSPITAL	GUANGDONG HAIOU MEDICAL APPARATUS	HAIOU DISPOSABLE	Approved 1ml Shelf life 02
	SERVICES & SALES	CO., LTD	STERILE SYRINGE AND INJECTION	
	13-C Annex,	Nanyuan Industrial Area,	NEEDLE	years
	Block 6, PECHS,	North Liusha, Puning City,	(1ml, 2.5ml, 5ml, 10ml,	
	Karachi – 75400,	Guangdong Province,	20ml, 30ml, and 50ml)	
	PAKISTAN	China.	201111, 301111, and 301111)	
	Lic. No.ELI-	Cililia.	Class – B	
	00081	ISO Valid Till (17-10-2019)	Class B	
	00001	FSC Valid Till (01-12-2019)		
		EC Certificate Valid Till	Shelf Life 5 Years	
		(25-12-2021)		
		DoC Valid Till (25-10-2021)		
			Shelf life 02 years	
108	HOSPITAL	GUANGDONG HAIOU	HAIOU DISPOSABLE	Approved
	SERVICES &	MEDICAL APPARATUS	SUCTION CTHETER	02 years shelf
	SALES	CO., LTD	(6Fr, 8Fr, 10Fr, 12Fr, 14Fr,	life
	13-C Annex,	Nanyuan Industrial Area,	16Fr and 18Fr)	
	Block 6, PECHS,	North Liusha, Puning City,		
	Karachi – 75400,	Guangdong Province,	Class – B	
	PAKISTAN	China.		
	Lic. No.ELI- 00081	ISO V-1:4 T:11 (17, 10, 2010)		
	00081	ISO Valid Till (17-10-2019) FSC Valid Till (02-12-2020)	Shelf Life 5 Years	
		EC Certificate Valid Till	Shell Life 3 Tears	
		(25-12-2021)		
		DoC Valid Till (25-10-2021)		
109	HOSPITAL	GUANGDONG HAIOU	HAIOU DISPOSABLE	Approved 02
	SERVICES &	MEDICAL APPARATUS	ANESTHESIA CIRCUIT	years shelf life
	SALES	CO., LTD	(HO-M01, HO-M02, HO-	
	13-C Annex,	Nanyuan Industrial Area,	M03, HO-M04, HO-M05,	
	Block 6, PECHS,	North Liusha, Puning City,	HO-M06, HO-M07, HO-	
	Karachi – 75400,	Guangdong Province,	M08)	
	PAKISTAN	China.	CI D	
	Lic. No.ELI-	IGO V 1: 1 T: 11 (17, 10, 2010)	Class – B	
	00081	ISO Valid Till (17-10-2019)		
		FSC china Valid Till (01-12-		
		2019) EC Certificate Valid Till	Shelf Life 5 Years	
		(25-12-2021)	Shell Life J Teals	
		DoC Valid Till (25-10-2021)		
110	Johnson &	Legal Manufacturer:	Cable Implants	Deferred for
	Johnson Pakistan	Synthes GmbH	•	further
	(Pvt) Ltd., Office	3 Eimattstrasse, 4436	Class C	clarifcaiton
	No.506, 5th	Oberdorf, CH		regarding the
	Floor, Horizon		D C	system/ family
	Tower, Block 3,	FSC # 00015771 valid until	Desc Sh	of all these
	Scheme 5,	29-Sep-2025	ripti elf	accesoriss in
	Clifton, Karachi	FSC # 00015773 valid until	ons - lif	one. The firm
	(ELL00154)	24-Oct-2025	Cod e	shall provide
	(ELI-00154)	(submitted in Response to	es cou	clarifcaion with
	[2966]	48 th MDB Decision Letter)		

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			Fee Deposited: PKR 50,000/- Submission Date: 25-
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111	National	Legal Manufacturer:	Primado2 Approved with
	Enterprises,	M/S Nakanishi Inc.,	(Total Surgical System) out shelf life/NA

	409, 4th Floor, Al-Sehat Centre Annexe Reagent Plaza, Sharah-e-Faisal Karachi (ELI-00043) Dossier# 662c-F7/A Date:10-01-23 Submitted Fee: 50,000/-PKR Challan No.: 19008571657	700 Shimohinata, Kanumashi, Tochigi, 322-8666, Japan FSC: Japan Issued on: 24/03/2021	Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	
112	National Enterprises, 409, 4th Floor, Al-Sehat Centre Annexe Reagent Plaza, Sharah-e- Faisal Karachi (ELI-00043) Dossier#1238c- 7A Date:28-02-23 Submitted Fee: 25,000/-PKR Challan No.: 4265344687	Legal Manufacturer: M/S Nakanishi Inc., 700 Shimohinata, Kanumashi, Tochigi, 322-8666, Japan FSC: Japan Issued on: 24/03/2021	Primado2 (Total Surgical System cutting Accessories sterile drills, sterile Burs, Saw blades, Resps & files) Codes & Sizes: As per FSC Class-C Shelf Life burs: 05 years	Deferred for further clarification regarding the system under the MDR 2017 and shelf life.
113	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755)	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trulene (Polypropylene (Non-absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life claimed: 5 years Shelf life studies provided for: 03 years	Approved subject to provision of valid FSC and CE certificate.

114	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore.	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China	Trusilk (Silk (Black Braided Nonabsorbable Suture) Codes & Sizes: As per FSC Class-C	Approved subject to provision of valid FSC and Ce certificate.
	(ELI-00314) (2755)	FSC: China Valid till: 09.04.2023	Shelf Life claimed: 5 years Shelf life studies provided for: 03 years	
115	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314)	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China	Trulon Nylon (Non-Absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life claimed: 5 years	Approved subject to provision of valid FSC and CE certificate.
	(2755) Evaluator:	FSC: China Valid till: 09.04.2023	Shelf life studies provided for: 03 years	
		Valid till: 09.04.2023	for: 03 years	

REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE

Sr.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
No.			
1	Sethi Health Pvt Ltd.	SurgiAid High Absorb Gauze Roll	Approved subject
	Sialkot Road, 7km Off GT Road,		to submission of
	Wazirabad Sohdara / Nizam Cotton	Class: A	prescribed fee by
	Industries Pvt Ltd Wazirabad	Shelf Life: 3 years	M/s Sethi Health
	(ELM-00076)	Fee: 6,000/-	Pvt Ltd.
		Fee Slip No. 4158875763	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
2	Sethi Health Pvt Ltd.	Orthodoc Pain Relief Patch	Approved subject
	Sialkot Road, 7km Off GT Road,	Class: A	to submission of
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	prescribed fee by
		Fee: 6,000/-	

	Industries Pvt Ltd Wazirabad		M/s Sethi Health
		Eas Clin No. 775221265014	Pvt Ltd.
	(ELM-00076)	Fee Slip No. 775321365814	PVI LIU.
		Fee Paid in respect of M/s Nizam Cottton	
	C d'II d D d d	Industries	A 1 1
3	Sethi Health Pvt Ltd.	SurgiAid Absorbent Cotton Wool	Approved subject
	Sialkot Road, 7km Off GT Road,		to submission of
	Wazirabad Sohdara / Nizam Cotton	Class: A	prescribed fee by
	Industries Pvt Ltd Wazirabad	Shelf Life: 3 years	M/s Sethi Health
	(ELM-00076)	Fee: 6,000/-	Pvt Ltd.
		E 01, M 004400040	
		Fee Slip No. 607499276	
		Fee Paid in respect of M/s Nizam Cottton	
	C dir. Id D . T. I	Industries	
4	Sethi Health Pvt Ltd.	Orthodoc-Hot	Approved subject
	Sialkot Road, 7km Off GT Road,	Capsicum as Capsicin 0.025%	to submission of
	Wazirabad Sohdara / Nizam Cotton		prescribed fee by
	Industries Pvt Ltd Wazirabad	Class: A	M/s Sethi Health
	(ELM-00076)	Shelf Life: 3 years	Pvt Ltd.
		Fee: 6,000/-	
		F. GI. M. 001400450500	
		Fee Slip No. 091408452582	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
5	Sethi Health Pvt Ltd.	Surgipas Pain Plaster	Approved subject
	Sialkot Road, 7km Off GT Road,	Capsicum 0.2%	to submission of
	Wazirabad Sohdara / Nizam Cotton	Class: A	prescribed fee by
	Industries Pvt Ltd Wazirabad	Shelf Life: 3 years	M/s Sethi Health
	(ELM-00076)	Fee: 6,000/-	Pvt Ltd.
		E. Gl. N. 92072527	
		Fee Slip No. 83073537	
		Fee Paid in respect of M/s Nizam Cottton	
	C d'II d D d d	Industries	A 1 1
6	Sethi Health Pvt Ltd.	Surgi-Bella Pain Plaster	Approved subject
	Sialkot Road, 7km Off GT Road,	Belladona pain relief Plaster with	to submission of
	Wazirabad Sohdara / Nizam Cotton	_	prescribed fee by M/s Sethi Health
	Industries Pvt Ltd Wazirabad	Class: A	
	(ELM-00076)	Shelf Life: 3 years	Pvt Ltd.
		Fee: 5,000/-	
		Fee Slip No. 55525490364	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
7	Sethi Health Pvt Ltd.	Super Plast First Aid Bandage	Approved subject
'	Sialkot Road, 7km Off GT Road,	0.2% Acrflavin	to submission of
	Wazirabad Sohdara / Nizam Cotton	Class: A	prescribed fee by
	Industries Pvt Ltd Wazirabad	Shelf Life: Not Mentioned	M/s Sethi Health
			Pvt Ltd.
	(ELM-00076)	Fee: 6,000/-	rvi Lia.
		Fee Slip No. 94452535360	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
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8	Sethi Health Pvt Ltd.	Super Tape zinc Oxide Plaster	Approved subject
	Sialkot Road, 7km Off GT Road,	Class: A	to submission of
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	prescribed fee by
	Industries Pvt Ltd Wazirabad	Fee: 5,000/-	M/s Sethi Health
	(ELM-00076)		Pvt Ltd.
		Fee Slip No. 62304816060	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
9	Sethi Health Pvt Ltd.	Super aid Elastic Crepe Bandage	Approved subject
	Sialkot Road, 7km Off GT Road,	Class: A	to submission of
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	prescribed fee by
	Industries Pvt Ltd Wazirabad	Fee: 5,000/-	M/s Sethi Health
	(ELM-00076)		Pvt Ltd.
		Fee Slip No. 08805634557	
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
10	Sethi Health Pvt Ltd.	OrthoDoc Diclofenac Pain Relief Patch	Disposed of the
	Sialkot Road, 7km Off GT Road,	Class: A	application as the
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	said formulation
	Industries Pvt Ltd Wazirabad	Fee: 6,000/-	is drug and may
	(ELM-00076)		be applied in
		Fee Slip No. 044849799	PE&R division
		Fee Paid in respect of M/s Nizam Cottton	DRAP
		Industries	
11	Sethi Health Pvt Ltd.	Sethi Lion Plaster	Approved subject
	Sialkot Road, 7km Off GT Road,	Class: A	to submission of
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	prescribed fee by
	Industries Pvt Ltd Wazirabad	Fee: 6,000/-	M/s Sethi Health
	(ELM-00076)	F 01' N 15(10(50(2)	Pvt Ltd.
		Fee Slip No. 1561967963	
		Fee Paid in respect of M/s Nizam Cottton	
10	G 41' H 44 D 4 L 4	Industries	A 1 1 .
12	Sethi Health Pvt Ltd.	SurgiAid Hi-Absorb Guaze Swabs ns	Approved subject
	Sialkot Road, 7km Off GT Road,	Class: A	to submission of
	Wazirabad Sohdara / Nizam Cotton	Shelf Life: 3 years	prescribed fee by
	Industries Pvt Ltd Wazirabad	Fee: 6,000/-	M/s Sethi Health Pvt Ltd.
	(ELM-00076)	Fee Slip No. 9786355522	rvi Lia.
		Fee Paid in respect of M/s Nizam Cottton	
		Industries	
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