

**DECISIONS OF 85TH MEETING OF MEDICAL DEVICE BOARD
HELD ON 21-03-2025**

REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S.No.	Name of Importer	<u>Manufacturers Detail</u>	Name of Medical Device	Decision
1.	Radiant Medical (Pvt) Ltd, 06 Sher Shah Block, New Garden Town, Lahore. ELI-00135 Date of R& I 01-Feb-2024 Fee Rs. 25,000/	<u>Legal Manufacturer:</u> Hill-Rom S.A.S. Z.I. du Talhouet 56330 Pluvigner - France. FSC: France. Issuance 10-02-2021 LOA validity 30-09-2026	P290 A1/ P290 A2/ P290 A3 Alternating Pressure Bed Mattress System Class-A Shelf Life: N/A Models: P290 A1/ P290 A2/ P290 A3	Approved subject to submission of Brand name.
2.	M/s Mezan International 59BR II Opp DCO House Haji Meherban Road, Bilal Town Jhelum ELI-00096 R&I Details 17-02-2025 Fee Challan No 6969682056 Dated 15-2-	<u>Legal Manufacture:</u> (ACTO GMBH Schulstrasse 8,31613 Wietzen Braunschweig Germany Tel:+49531 239 50 80 Tel:+495022 98 01 46 Email:info@actogmbh.com website:www.actogmbh.com Manufacturing Site (s): (Acto Pharma Higyen San.Tic A.S Akcaburgaz Mahallesi.3038 Sok No.1134522 Esenyurt Istanbul,Turkey Tel:+90 212 771 5622 Email: info@actopharma.com website: www.actopharma.com) LOA: Validity 24-11-2027 FSC: Country of Origin Validity: 20-10-2025 Acto gmbh FSC: FSC of Reference Country (as mentioned in rule, 67) Validity: Acto Pharma:20-10-2025 Acto gmbh : OR 2025 EC Certificate: Validity: FQA Acto phrama 27-05-2024 Acto gmbh 27-05-2024 Extension MDR Letter OR WHO PQ (verifiable from the official WHO site) ISO 13485: Validity: Acto Pharma 20-12-2025 Acto gmbh 10-03-2025	Acto Oxy Wipes Content of 100g Soaking Solution: 3,0% Hydrogen peroxide and auxiliary substances Class B Shelf life: 2 Years Codes/ Pack Sizes: Pack of 100 wipes	Approved
3.	M/s Mezan International 59BR II Opp DCO House Haji Meherban Road, Bilal Town Jhelum ELI-00096	<u>Legal Manufacture:</u> (ACTO GMBH Schulstrasse 8,31613 Wietzen Braunschweig Germany Tel:+49531 239 50 80 Tel:+495022 98 01 46 Email:info@actogmbh.com website:www.actogmbh.com Manufacturing Site (s): (Acto	Acto Oxy Foam Content of 100g Solution: 2.6% Hydrogen peroxide, ethanol and auxiliary substances Class B Shelf life: 3 Years	Approved

	R&I Details 17-02-2025 Fee Challan No 91041641 Dated 15-2-2025	Pharma Higyen San.Tic A.S Akcaburgaz Mahallesi.3038 Sok No.1134522 Esenyurt Istanbul,Turkey Tel:+90 212 771 5622 Email: info@actopharma.com website: www.actopharma.com) LOA: Validity 24-11-2027 FSC: Country of Origin Validity: 20-10-2025 Acto gmbh FSC: FSC of Reference Country (as mentioned in rule, 67) Validity: Acto Pharma:20-10-2025 Acto gmbh : OR 2025 EC Certificate: Validity: FQA Acto phrama 27-05-2024 Acto gmbh 27-05-2024 Extension MDR Letter OR WHO PQ (verifiable from the official WHO site) ISO 13485: Validity: Acto Pharma 20-12-2025 Acto gmbh 10-03-2025	Codes/Sizes Pack Sizes: 500ml,750ml,4500ml,1Liter,5 Liter	
4.	Gulfam Brothers House No.1-C, Green Villa, Zaildar Park, Ichra, Lahore, Pakistan ELI No.: ELI-00028	<u>Legal Manufacturer:</u> SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD Address: No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA FSC Valid till: 17-06-2026 EC Valid till: 31-12-2028 ISO Valid till: 19-06-2025	Undis Disposable Heat and Moisture Exchange Sizes: Codes: HME-01, HME-02 HME-03, HME-04 Class-B Shelf life: 5 Years DRAP Application Receiving Date: 24-12-2024 DRAP Fees: Rs: 31,000/- Challan No. 4961394392 Dated 20-12-2024	Approved
5.	Gulfam Brothers House No.1-C, Green Villa, Zaildar Park, Ichra, Lahore, Pakistan ELI No.: ELI-00028	<u>Legal Manufacturer:</u> SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD Address: No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA FSC Valid till: 17-06-2026 EC Valid till: 31-12-2028 ISO Valid till: 19-06-2025	Undis Disposable Nasal Oxygen Cannula Sizes: Codes: N01,N02,N03,D01, D02,S01,W01,W02 Class-B Shelf life: 5 Years DRAP Application Receiving Date: 24-12-2024	Approved

			DRAP Fees: Rs: 31,000/- Challan No. 083974337 Dated 20-12-2024	
6.	Gulfam Brothers House No.1-C, Green Villa, Zaildar Park, Ichra, Lahore, Pakistan ELI No.: ELI-00028	<u>Legal Manufacturer:</u> SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD Address: No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA FSC Valid till: 17-06-2026 EC Valid till: 31-12-2028 ISO Valid till: 19-06-2025	Undis Disposable Nebulizer Mask Sizes: Codes: WHQ-01-01 WHQ-01-02 WHQ-01-03 WHQ-01-04 Class-B Shelf life: 5 Years DRAP Application Receiving Date: 24-12-2024 DRAP Fees: Rs: 31,000/- Challan No. 06671944553 Dated 20-12-2024	Approved
7.	Gulfam Brothers House No.1-C, Green Villa, Zaildar Park, Ichra, Lahore, Pakistan ELI No.: ELI-00028	<u>Legal Manufacturer:</u> SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD Address: No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA FSC Valid till: 17-06-2026 EC Valid till: 31-12-2028 ISO Valid till: 19-06-2025	Undis Disposable Closed Suction System Sizes: Codes: CSS-A05PY CSS-A06PY CSS-A07PY CSS-A08PY CSS-A10EY CSS-A12EY CSS-A14EY CSS-A16EY CSS-A10TY CSS A12TY CSS-A14TY CSS-A16TY CSS-B05PY CSS-B06PY CSS-B07PY CSS-B08PY CSS-B10EY CSS-B12EY CSS-B14EY CSS-B16EY CSS-B10TY	Approved subject to submission of fee as per revised SRO for the System.

			CSS-B12TY CSS-B14TY CSS-B16TY Class-B Shelf life: 5 Years DRAP Application Receiving Date: 24-12-2024 DRAP Fees: Rs: 31,000/- Challan
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		LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	<table><tr><td>dS Breast 7ch 3.0T</td><td>4598017299 1X</td></tr><tr><td>dS Breast 16ch 1.5T</td><td>4598017298 8X</td></tr><tr><td>dS Breast 16ch 3.0T</td><td>4598017298 9X</td></tr></table>	dS Breast 7ch 3.0T	4598017299 1X	dS Breast 16ch 1.5T	4598017298 8X	dS Breast 16ch 3.0T	4598017298 9X	
dS Breast 7ch 3.0T	4598017299 1X									
dS Breast 16ch 1.5T	4598017298 8X									
dS Breast 16ch 3.0T	4598017298 9X									
10.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Anterior. Class-B Service Life: Model No: <table><tr><td>dS Anterior 1.5T</td><td>45980173011 X</td></tr><tr><td>dS Anterior 3.0T</td><td>45980173012 X</td></tr></table>	dS Anterior 1.5T	45980173011 X	dS Anterior 3.0T	45980173012 X	Approved		
dS Anterior 1.5T	45980173011 X									
dS Anterior 3.0T	45980173012 X									
11.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Base. Class-B Service Life: 10 years Model No: <table><tr><td>dS Base 1.5T</td><td>45980173005X</td></tr><tr><td>dS Base 3.0T</td><td>45980173006X</td></tr></table>	dS Base 1.5T	45980173005X	dS Base 3.0T	45980173006X	Approved		
dS Base 1.5T	45980173005X									
dS Base 3.0T	45980173006X									
12.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore	Philips dS HiRes Hand/Wrist. Class-B Service Life: 10 years Models: <table><tr><td>dS HiRes Hand/Wrist</td><td>4598017288 6X</td></tr></table>	dS HiRes Hand/Wrist	4598017288 6X	Approved				
dS HiRes Hand/Wrist	4598017288 6X									

		319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	<table><tr><td>16Ch 1.5T</td><td></td></tr><tr><td>dS HiRes Hand/Wrist 16CH 3.0T</td><td>4598017288 7X</td></tr></table>	16Ch 1.5T		dS HiRes Hand/Wrist 16CH 3.0T	4598017288 7X									
16Ch 1.5T																
dS HiRes Hand/Wrist 16CH 3.0T	4598017288 7X															
13.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Flex. Class-B Service Life: 10 years Models: <table><tr><td>dS Flex-L 1.5T</td><td>45980172993 X</td></tr><tr><td>dS Flex-L 3.0T</td><td>45980172994 X</td></tr><tr><td>dS Flex-M 1.5T</td><td>45980172995 X</td></tr><tr><td>dS Flex-M 3.0T</td><td>45980172996 X</td></tr><tr><td>dS Flex-S 1.5T</td><td>45980172997 X</td></tr><tr><td>dS Flex-S</td><td>45980172998 X</td></tr></table>	dS Flex-L 1.5T	45980172993 X	dS Flex-L 3.0T	45980172994 X	dS Flex-M 1.5T	45980172995 X	dS Flex-M 3.0T	45980172996 X	dS Flex-S 1.5T	45980172997 X	dS Flex-S	45980172998 X	Approved
dS Flex-L 1.5T	45980172993 X															
dS Flex-L 3.0T	45980172994 X															
dS Flex-M 1.5T	45980172995 X															
dS Flex-M 3.0T	45980172996 X															
dS Flex-S 1.5T	45980172997 X															
dS Flex-S	45980172998 X															
14.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS FootAnkle Coil. Class-B Service Life: 10 years Models: <table><tr><td>dS FootAnkle 16Ch 1.5T</td><td>4598017288 4X</td></tr><tr><td>dS FootAnkle 16CH 3.0T</td><td>4598017288 5X</td></tr><tr><td>dS FootAnkle Coil 8ch 1.5T</td><td>4598017293 5X</td></tr></table>	dS FootAnkle 16Ch 1.5T	4598017288 4X	dS FootAnkle 16CH 3.0T	4598017288 5X	dS FootAnkle Coil 8ch 1.5T	4598017293 5X	Approved						
dS FootAnkle 16Ch 1.5T	4598017288 4X															
dS FootAnkle 16CH 3.0T	4598017288 5X															
dS FootAnkle Coil 8ch 1.5T	4598017293 5X															

15.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Head Class-B Service Life: 10 years Models: <table><tr><td>dS Head 32ch 3.0T</td><td>4598017301 3X</td></tr><tr><td>dS Head 1.5T</td><td>4598017300 7X</td></tr><tr><td>dS Head 3.0T</td><td>4598017300 8X</td></tr></table>	dS Head 32ch 3.0T	4598017301 3X	dS Head 1.5T	4598017300 7X	dS Head 3.0T	4598017300 8X	Approved
dS Head 32ch 3.0T	4598017301 3X									
dS Head 1.5T	4598017300 7X									
dS Head 3.0T	4598017300 8X									
16.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS HeadNeck Class-B Service Life: 10 years Models: <table><tr><td>dS HeadNeck 1.5T</td><td>45980173009X</td></tr><tr><td>dS HeadNeck 3.0T</td><td>45980173010X</td></tr></table>	dS HeadNeck 1.5T	45980173009X	dS HeadNeck 3.0T	45980173010X	Approved		
dS HeadNeck 1.5T	45980173009X									
dS HeadNeck 3.0T	45980173010X									
17.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Knee Coil. Class-B Service Life: 10 years Models <table><tr><td>dS Knee Coil 8ch 1.5T</td><td>4598017288 8X</td></tr><tr><td>dS Knee Coil 16ch 1.5T</td><td>4598017300 2X</td></tr></table>	dS Knee Coil 8ch 1.5T	4598017288 8X	dS Knee Coil 16ch 1.5T	4598017300 2X	Approved		
dS Knee Coil 8ch 1.5T	4598017288 8X									
dS Knee Coil 16ch 1.5T	4598017300 2X									

18.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips MICROSCOPY INGENIA. Class-B Service Life: 10 years Models <table><tr><td>MICROSCOP Y 47MM, INGENIA 1.5T</td><td>45980172999X</td></tr><tr><td>MICROSCOP Y 23MM, INGENIA 1.5T</td><td>45980179504X</td></tr><tr><td>MICROSCOP Y 23MM, INGENIA 3.0T</td><td>45980173001X</td></tr><tr><td>MICROSCOP Y 47MM, INGENIA 3.0T</td><td>45980179448X</td></tr></table>	MICROSCOP Y 47MM, INGENIA 1.5T	45980172999X	MICROSCOP Y 23MM, INGENIA 1.5T	45980179504X	MICROSCOP Y 23MM, INGENIA 3.0T	45980173001X	MICROSCOP Y 47MM, INGENIA 3.0T	45980179448X	Approved
MICROSCOP Y 47MM, INGENIA 1.5T	45980172999X											
MICROSCOP Y 23MM, INGENIA 1.5T	45980179504X											
MICROSCOP Y 23MM, INGENIA 3.0T	45980173001X											
MICROSCOP Y 47MM, INGENIA 3.0T	45980179448X											
19.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Shoulder Coil. Class-B Service Life: 10 years Models <table><tr><td>dS Shoulder Coil 16Ch 1.5T</td><td>45980172883X</td></tr><tr><td>dS Shoulder Coil 16CH 3.0T</td><td>45980172883X</td></tr><tr><td>dS Shoulder Coil 8ch 1.5T</td><td>45980173004X</td></tr></table>	dS Shoulder Coil 16Ch 1.5T	45980172883X	dS Shoulder Coil 16CH 3.0T	45980172883X	dS Shoulder Coil 8ch 1.5T	45980173004X	Approved		
dS Shoulder Coil 16Ch 1.5T	45980172883X											
dS Shoulder Coil 16CH 3.0T	45980172883X											
dS Shoulder Coil 8ch 1.5T	45980173004X											
20.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road,	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best,	Philips dS Small Extremity Class-B	Approved								

	Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Service Life: 10 years Models <table><tr><td>dS Small Extremity 16Ch 1.5T</td><td>45980172879 X</td></tr><tr><td>dS Small Extremity 16CH 3.0T</td><td>45980172880 X</td></tr></table>	dS Small Extremity 16Ch 1.5T	45980172879 X	dS Small Extremity 16CH 3.0T	45980172880 X	
dS Small Extremity 16Ch 1.5T	45980172879 X							
dS Small Extremity 16CH 3.0T	45980172880 X							
21.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS T/R Knee. Class-B Service Life: 10 years Models <table><tr><td>dS T/R Knee 16CH 3.0T</td><td>45980173003 X</td></tr></table>	dS T/R Knee 16CH 3.0T	45980173003 X	Approved		
dS T/R Knee 16CH 3.0T	45980173003 X							
22.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 50,000/-	<u>Legal Manufacturer:</u> Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands <u>(Distributor)</u> Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29 th Aug 2029 Netherlands FSC valid up to April 1, 2027 ISO 13485 validity 01/02/2027	Philips dS Wrist Coil. Class-B Service Life: 10 years Models <table><tr><td>dS Wrist Coil 8CH 1.5T</td><td>45980172934 X</td></tr></table>	dS Wrist Coil 8CH 1.5T	45980172934 X	Approved		
dS Wrist Coil 8CH 1.5T	45980172934 X							
23.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V,	<u>Legal Manufacturer:</u> <u>(LEGAL MANUFACTEURER)</u> 1. Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best,	Philips Philips CT Big Bore Class-C Shelf life:	Approved				

	Lahore. 54000 Punjab, Pakistan. 62,000/-	Netherlands 2. Philips Healthcare (Suzhou) Co., Ltd Address: No.258, ZhonYuan Road Suzhou Industrial Park 215024Suzhou, Jiangsu Province PEOPLE REPUBLIC OF CHINA (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 LOA Valid till: 29th Aug 2029 Netherlands FSC valid up to 04-06- 2027 ISO 13485 validity 01/02/2027	Model: 728242	
24.	Matora Digionics Pvt Ltd 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. 62,000/-	Legal Manufacturer: Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763. LOA Valid till: 29th Aug 2029 Netherlands FSC valid up to May 26, 2025 ISO 13485 validity 01/02/2027	Philips 3D-RA Class-C Shelf life: Model No: 001102	Approved
25.	M/s Mian Enterprises Office No.UG- 400, Deans Trade Center, Peshawar Cantt 25000 Pakistan ELI-00507	Legal Manufacturer: M/s Laurus Optics Ltd. Hong Kong Unit 702, 7/F, Tower 2, Ever Gain Plaza, No.88 Container Port Road, Kwai Chung, NT, Hong Kong. LOA validity 06-02-2030 FSC issuance 17-09-2023 ISO 13485 validity 26-08-2024 CE validity 27-05-2024	LAURALENS (Hydrophilic Acrylic Intraocular Lens Hydrophilic Aspheric Acrylic Intraocular Lens) Class C Shelf Life: 5 Years Codes: HA80A Hydrophilic Aspheric Acrylic Intraocular Lens HA80R Hydrophilic Acrylic Intraocular Len	Approved subject to submission of valid ISO 13485 and Ce certificate. The firm will submit separate application and fee for HA80R Hydrophilic Acrylic Intraocular Lens

26.	M/s Chemical House situated at 6-C sikandar Malhi road Canal park Gulberg-III Lahore <u>ELI-00156.</u> R&I Details 27-01-2020 Fee Challan No. 1928856 dated 27-01-2020	Legal Manufacture: Biorad laboratories Inc. 4000 Alfred nobel drive Hercules CA, 94547, USA Manufacturing Site(s): BIO-RAD 7-rue-de madrid 67300, schiltigheim France. LOA Validity: 31/12/2027 FSC: FSC of Reference Country France) Validity: 20/09/2025 ISO 13485: Validity: 11-12-2027	D-10 Hemoglobin testing system Class B Service life: 07-years Codes/Sizes (if any) (catalogue number 12010405 (D-10 HEMOGLOBIN TESTING SYSTEM 220-0600 (D-10 Rack loader)	Approved.
27.	M/s Chemical Hose situated at 6-C sikandar Malhi road Canal park Gulberg-III Lahore ELI-00156 R&I Details 09-04-2020 Fee Challan No.2005629 dated 08-04-2020	Legal Manufacture: Biorad laboratories Inc. Manufacturing Site(s): Bio-rad laboratories Inc. 9500 jeronimo road, Irvine, CA, USA 92618. LOA Validity: 31/12/2025 FSC of USA Validity: 09/02/2025 ISO 13485: Validity: 17-05-2025	Liquichek Urine Control Class B shelf life: liquichek urine chemistry control (397, 398, 395x) - shelf life is 720-days liquichek urinalysis control (435, 436, 437) shelf life: 900-days	Approved; subject to provisions of valid FSC and original fee Challan as the attached fee slip is not legible.
28.	M/s Chemical Hose situated at 6-C sikandar Malhi road Canal park Gulberg-III Lahore ELI-00156 R&I Details 25/02/2025 Fee Challan No. 27885372 dated 08-012025	Legal Manufacture: (ABON Biopharm (Hangzhou) Co. Ltd. Address: #198 , 12th street east, Hongzhou, economic and Technological department area, 310018, Hangzhou, Republic of China Distributor name: (authorized distributor of ABON (manufacturer) products in USA) Biorad laboratories Inc. Address: 4000 Alfred Nobel drive Hercules CA, USA 94547.) Manufacturing Site(s): (ABON Biopharm (Hangzhou) Co. Ltd. Address: #198 , 12th street east, Hongzhou, economic and technological	TOX/See Drug screen test-PPX (194-5204) Class A Claimed Shelf life: 24-months	Approved.

		department area, 310018, Hangzhou, Republic of China) FSC USA Validity: 13/12/2025 LOA Validity: 31/12/2027		
29.	Taj Diagnostics Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi Email Address : (ELI-00589) Date of R&I 19-AUG-2022	<u>Legal Manufacturer:</u> INTEC PRODUCTS ,INC. 332 Xinguang Road, Xinyang Ind, Haicang, Xiamen, P.R. CHINA 361022 . <u>FSC:</u> CHINA Validity:15-JAN-2027 FSC of BELGIUM Validity: 15-JAN-2027 <u>LOA</u> Validity: 23-MARCH-2027 <u>ISO 13485</u> Validity: 30-07-2027	Brand Name: INTEC (Generic name) RAPID ANTI H. Pylori test Class B Claimed Shelf Life: 02-years Codes/Sizes: ITP10002-DS50 ITP10002-TC40 ITP10212-DS50 ITP10212-TC40	Approved.
30.	Taj Diagnostics Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi Email Address : (ELI-00589) Date of R&I 19-AUG-2022	<u>Legal Manufacturer:</u> INTEC PRODUCTS ,INC. 332 Xinguang Road, Xinyang Ind, Haicang, Xiamen, P.R. CHINA 361022 . <u>FSC:</u> CHINA Validity: 21-NOV-2026 FSC of BELGIUM Validity: 15-JAN-2027 <u>LOA</u> Validity: 23-MARCH-2027 <u>ISO 13485</u> Validity: 30-07-2027	INTEC ONE STEP Pregnancy (HCG) Test Class B Claimed Shelf Life: 02-years Codes/Sizes: ITP04002-DS50 ITP04002-TC40	Approved.
31.	Taj Diagnostics Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi Email Address : (ELI-00589) Date of R&I 19-AUG-2022	<u>Legal Manufacturer:</u> INTEC PRODUCTS ,INC. 332 Xinguang Road, Xinyang Ind, Haicang, Xiamen, P.R. CHINA 361022 . <u>FSC:</u> CHINA Validity: 21-NOV-2026 FSC of BELGIUM Validity: 15-JAN-2027 <u>LOA</u> Validity: 23-MARCH-2027 <u>ISO 13485</u> Validity: 30-07-2027	INTEC (Generic name) ONE STEP Multi-10 DOA Test Class B Claimed Shelf Life: 02-years Code: ITP-06109-DT10	Approved.
32.	M/s Pulse Surgicals Address: Suite No. 113, First	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751	Brand name: UltraCore™ Biopsy Needle	Approved; subject to provisions of valid ISO-13485 and codes.

	floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 014453765674	USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	Generic name: Biopsy needle Specification/sizes: As per FSC Class: B Claimed Shelf Life: 05-years	
33.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 14884945400	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	ProMag™ Ultra Automatic Biopsy Instrument Specification/sizes: 7675 Pro-Mag™ Ultra Automatic Biopsy Instrument Class: A Shelf life: They are reusable devices that are sold non-sterile with a manufacturing date but not a shelf life.	Approved; subject to provisions of valid ISO-13485 and differential fee for Class-B.
34.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 048656998797	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	Brand name: Pro-Mag™ Ultra Biopsy Needle Specification/sizes: As per FSC Class: B Claimed Shelf Life: 05-years	Approved; subject to provisions of valid ISO-13485 and codes.
35.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No.	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	Argon Co-Axial introducer needle Specification/sizes: MCXS1610BP MCXS1615BP MCXS1810BP MCSX1815BP MCSX1820BP Class: B Claimed Shelf Life: 05-years	Approved; subject to provisions of valid ISO-13485.

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36.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 12718050	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	Traveler™ Portal Vein Access Set Generic name: Stylet/ Needle portal Vein Access Set Class: B Claimed Shelf Life: 03-years	Approved; subject to provisions of valid ISO-13485 and codes.
37.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 17129064300	Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA FSC validity: 15-05-2026 LOA validity: 23-06-2028 <u>ISO 13485</u> Validity: 08-04-2025	Scorpion Portal Vein Access Set Specification/sizes: TPS005 Sorpion Portal Vein Access Set. TPS006 Scorpion X Portal Vein Access Set Class: B Claimed Shelf Life: 03-years	Approved; subject to provisions of valid ISO-13485 and submit fee for TPS006 Scorpion X Portal Vein Access Set
38.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No:32059421480 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Singapore Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	A&M STF P T1 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10940423	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
39.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028	Brand Name: A&M STF P T3 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10940420, 10940421	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.

	R&I details 06/03/2025 Fee Challan No: 03036486 Dated: 28/02/2025	<u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025		
40.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 25162451753 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M STF XP T3 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10941683, 10941684	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
41.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 14632199563 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM P P4 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10940415, 10940414	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
42.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin	Brand Name: A&M XTM XP P4 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10941678, 10941677	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.

	06/03/2025 Fee Challan No: 2454271219 Dated: 28/02/2025	Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025		
43.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 709368750 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM CUSTOM P4 Generic Name: Hearing Instrument Customized Model Class: B Shelf Life: N/A Codes/Sizes: 10957883, 10957884, 10957887, 10957888, 10957889, 10957890, 10957893,	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
44.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 70534346 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM P P6 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10951357, 10951334	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
45.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u>	Brand Name: A&M XTM XP P6 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10941675, 10941674	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.

	Fee Challan No: 15182979 Dated: 28/02/2025	Validity: 30/11/2025		
46.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 5890940111 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM CUSTOM P6 a Generic Name: Hearing Instrument Customized Model Class: B Shelf Life: N/A Codes/Sizes: 10957882, 10957881, 10957880, 10957879, 10957876, 10957875, 10957891, N/A	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
47.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 53637943754 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM P P8 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10956382, 10956375	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
48.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 00645933403	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM XP P8 Generic Name: Hearing Instrument BTE (Behind-The-Ear) Class: B Shelf Life: N/A Codes/Sizes: 10957913, 10957912	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.

	Dated: 28/02/2025			
49.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 329544725 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM RIC P8 Generic Name: Hearing Instrument RIC (Receiver-in-Canal) Class: B Shelf Life: N/A Codes/Sizes: 10956319, 10956318	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
50.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 6967322998 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM CUSTOM P8 Generic Name: Hearing Instrument Customized Model Class: B Shelf Life: N/A Codes/Sizes: As per FSC.	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
51.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 20810397 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	Brand Name: A&M XTM IF CIC P4 Generic Name: Hearing Instrument CIC (Completely-in-the-Canal) Class: B Shelf Life: N/A Codes/Sizes: 10943604, 10943603.	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.

52.	M/s Hearing Healthcare Centre, 2-Kausar Arcade opp Hotel Sindbad Kalma Chowk, Multan Canntt ELI-01267 R&I details 06/03/2025 Fee Challan No: 8512959117 Dated: 28/02/2025	Legal Manufacturer: Sivantos GmbH, Henri-Dunant-Strasse 100, 91058 Erlangen, Germany Manufacturing Site (s): Sivantos Pte Ltd, 18 Tai Seng Street #08-08 Singapore 539775 <u>LOA:</u> Validity: 30/06/2028 <u>FSC:</u> Country of Origin Validity: 13/01/2027 <u>ISO 13485:</u> Validity: 30/11/2025	A&M XTM IF ITC P4. Generic Name: Hearing Instrument IF ITC (Ideal For First-Time-Users) Class: B Shelf Life: N/A Codes/Sizes: 10943610, 10943609	Approved; subject to provisions of valid FSC of Germany or any RRA or CE certificate.
53.	M/s. Uniprom Healthcare Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi. ELI-00286 Date of R&I 17th October 2022	<u>Legal Manufacturer:</u> M/s Amity International, U.K. Address: Libra House, West Street, Worsbrough Dale, Barnsley, S70 5PG. UK <u>FSC:</u> Country of Origin: UK Validity: 14th September 2024 <u>LOA</u> Validity: 31 December 2025 <u>ISO 13485</u> Validity: 14th September 2024	Brand Name Virusolve+™ Generic name (Didecyldimethyl ammonium chloride) Class: Class B Shelf Life: Shelf life of the product is three years from date of manufacture when stored unopened and as directed. <u>Codes/Sizes:</u> 1.Virusolve+ High Level Medical Surface Disinfectant –125 ml 2.Virusolve+ High Level Medical Surface Disinfectant –250 ml	Approved; Subject to Provisions of Valid FSC of UK and <u>ISO 13485</u> Certificate. The firm will submit separate application and fee for Virusolve+™ Lavender.
54.	M/s. Uniprom Healthcare Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi. ELI-00286 Date of R&I 17th October 2022	<u>Legal Manufacturer:</u> M/s Amity International, U.K. Address: Libra House, West Street, Worsbrough Dale, Barnsley, S70 5PG. UK <u>FSC:</u> Country of Origin: UK Validity: 14th September 2024 <u>LOA</u> Validity: 31 December 2025 <u>ISO 13485</u> Validity: 14th September 2024	Brand Name VIRUSOLVE+ EDS Generic name: (Didecyldimethyl ammonium chloride) Class : Class C Shelf Life: 3 Years Codes/Sizes: VIRUSOLVE+ EDS 125ml VIRUSOLVE+ EDS 250ml VIRUSOLVE+ EDS 1Liter	Approved; Subject to Provisions of Valid FSC of UK and <u>ISO 13485</u> Certificate.
55.	M/s Jasani Scientifics SC-45, Marium	<u>Legal Manufacturer:</u> Nidek Co. LTD, Address: 34-14	RT-3100 Refractor (Refractometer)	Approved; Subject to Provisions of Valid FSC of RRA and <u>ISO</u>

	Square, chandni Chowk, Stadium road, Karachi, 74800, ELI- 000416. R&I: 03/11/2020 Fee Slip No: 2006296 Fee Submission Date: 08/10/2020	Maehama, Hiroishi-cho, Gamagori, Aichi 4430038 Japan. FSC Validity Date: 13/09/2024 LOA Validity: 31/12/2027	Class-A Shelf life: N/A GMDN Codes: 35299 Codes and Sizes as per FSC	<u>13485.</u>
56.	M/s Muller & Phipps Pakistan (Pvt.) Limited Uzma Court Main Clifton Road, Karachi. License No. ELI- 00030	<u>Legal Manufacturer:</u> ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK, FSC Issue: 20-10-2024 LOA Validity: 28-01-2026 ISO-13485 Validity: 30-01-2026	SILESSE Advance barrier film Codes 420790 Class A Shelf Life:04-Years	Approved.
57.	M/S ORBIT DIAGNOSTIC S Address of Importer: 403, PLAZA 55, BEHRIA TOWN-IV, CIVIC CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021	SHIJIAZHUANG Hipro Bio technology Co., ltd (Manufacturing site) No. 3 Building, Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang, P.R. CHINA LOA Valid till 01-04-2026 FSC: China Validity: 24-11-2025 ISO 13485 Validity: 16 July 2026	HIPRO Automatic Immunoassay System Class B Shelf Life: 05 Years Code: 57871 Specification Model: HP-AFS/1 Analyzer	Approved; subject to provisions of valid FSC of any RRA or CE certificate.
58.	Aston Medical Pakistan 4-A, 4 TH Floor 38C Bukhari Commercial Lane 8 Phase 6 DHA Karachi ELI-00797	Manufacturer Name: Chalice Medical Ltd Address: Manton Wood Enterprise Park, Workshop Nottinghamshire S80 2RS United Kingdom. Distributed by: Aston Med UK Address: 18 St James Road, Purley, Surrey CR8 2DL UK	Paragon Oxygenators with Accessories Class B Shelf Life: 02 YEARS Codes/Sizes: XCMOPI260MN - Paragon Adult Midi Integrated Oxygenator with Micronet Filter XCMOPI260PP - Paragon Adult Midi Integrated Oxygenator	Approved.

		Date of R&I 10-02-2025 FSC: Country of Origin UK Validity: 27-04-2028 LOA Validity: 27-08-2027 ISO-13485 Validity: 09-11-2025.																				
59.	Musaji Adam & Sons Address:C-285, Block 10, Federal B Area, Karachi. Establishment License: ELI 00239. Date of R&I 29-jan-2021	Legal Manufacturer: Trek diagnostic systems, limited. Manufacturing Site: Units 17-19,Willard Way, Birches Industrial Estate, East Grinstead, RH 191 XZ, United Kingdom. FSC: Country of Origin: United Kingdom Validity: May,2025 LOA Validity:31-12-2025 ISO 13485 Validity: 06-11-2025	Sensititre™ YeastOne Product code: YO10 Class:B Shelf Life:24 Month	Approved.																		
60.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Date of submission: 18 th Oct 2023 Fee submitted: PKR 25,000/- (Challan # 8529460653) Tracking id: 87W-ZTH- YMR4	Legal Manufacture Manufacturing Site SFRI SAS Lieu-dit Berganton – 33127 Saint Jean d'lllac France LOA Expiry Date: 30 th June 2025 FSC : France Date of Issuance: 21-July-2022 ISO 13485 Expiry: 27-11-2023	Name of Medical Device Hemix 3-60 automated high quality hematology analyzer Class B Shelf Life: Codes: <table><tr><td>Nam e</td><td>Code</td><td>Shelf Life</td></tr><tr><td>Hem ix 3- 60 Anal yzer</td><td>A021 4</td><td>36 Mont hs</td></tr><tr><td>SFRI Dilu ent 3-60</td><td>HSD3 26</td><td>36 Mont hs</td></tr><tr><td>SFRI Lyse 3-60</td><td>HSL3 06</td><td>24 Mont hs</td></tr><tr><td>SFRI Clea nEZ 3-60</td><td>HSC3 06</td><td>24 Mont hs</td></tr><tr><td>SFRI Clair 3-60</td><td>HSC1 06</td><td>12 Mont hs</td></tr></table>	Nam e	Code	Shelf Life	Hem ix 3- 60 Anal yzer	A021 4	36 Mont hs	SFRI Dilu ent 3-60	HSD3 26	36 Mont hs	SFRI Lyse 3-60	HSL3 06	24 Mont hs	SFRI Clea nEZ 3-60	HSC3 06	24 Mont hs	SFRI Clair 3-60	HSC1 06	12 Mont hs	Approved; subject to provisions of valid ISO.
Nam e	Code	Shelf Life																				
Hem ix 3- 60 Anal yzer	A021 4	36 Mont hs																				
SFRI Dilu ent 3-60	HSD3 26	36 Mont hs																				
SFRI Lyse 3-60	HSL3 06	24 Mont hs																				
SFRI Clea nEZ 3-60	HSC3 06	24 Mont hs																				
SFRI Clair 3-60	HSC1 06	12 Mont hs																				
61.	Name of Firm (s)	Legal Manufacture Manufacturing Site	Name of Medical Device	Approved; subject to provisions																		

	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Date of submission: 7th Jan 2025 Fee submitted: PKR 6,000/- Challan # 15947038279 Tracking id: UYW-LPY-UPLA	Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland LOA Expiry Date: 27th January 2026 FSC Country of Origin: Finland Date of Issuance: 12-Sep-2024 FSC Reference Country: Australia Date of Issuance: 27-Feb-2023 ISO 13485 Expiry: 31-3-2027	Clinical Chemistry (Immunochemistry) Class A Shelf Life: Codes: <table><tr><td>Nam e</td><td>Cod e</td><td>She lf Lif e</td></tr><tr><td>Hea moly zing Reag ent</td><td>9816 59</td><td>18 Mo nth s</td></tr></table>	Nam e	Cod e	She lf Lif e	Hea moly zing Reag ent	9816 59	18 Mo nth s	of differential fee of class-B.						
Nam e	Cod e	She lf Lif e														
Hea moly zing Reag ent	9816 59	18 Mo nth s														
62.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Date of submission: 7th Jan 2025 Fee submitted: PKR 31,000/- Challan # 34719978117 Tracking id: 95P-5N4-G1M8	Legal Manufacture Manufacturing Site Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland LOA Expiry Date: 27th January 2026 FSC Country of Origin: Finland Date of Issuance: 12-Sep-2024 FSC Reference Country: Australia Date of Issuance: 27-Feb-2023 ISO 13485 Expiry: 31-3-2027	Name of Medical Device Clinical Chemistry (Electrolyte Electrodes) Class B Shelf Life: Codes: <table><tr><td>Name</td><td>C o d e</td><td>Shelf Life</td></tr><tr><td>Potass ium (k+) Micro Volu me Electr ode</td><td>9 8 1 5 9 3</td><td>18 Mont hs</td></tr><tr><td>Chlori de (Cl-) Micro Volu me Electr ode</td><td>9 8 1 5 9 6</td><td>Mont hs</td></tr><tr><td>Sodiu</td><td>9</td><td>Mont</td></tr></table>	Name	C o d e	Shelf Life	Potass ium (k+) Micro Volu me Electr ode	9 8 1 5 9 3	18 Mont hs	Chlori de (Cl-) Micro Volu me Electr ode	9 8 1 5 9 6	Mont hs	Sodiu	9	Mont	Approved.
Name	C o d e	Shelf Life														
Potass ium (k+) Micro Volu me Electr ode	9 8 1 5 9 3	18 Mont hs														
Chlori de (Cl-) Micro Volu me Electr ode	9 8 1 5 9 6	Mont hs														
Sodiu	9	Mont														

			m (NA+) Micro Volu me Electr ode	8 1 5 9 4	hs										
63.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrach-e-Faisal, Karachi (ELI-00015) Date of submission: 4th February 2025 Fee submitted: PKR 31,000/- Challan # 4118038628 Tracking id: 4EX-XW8-6YBW	Legal Manufacture Manufacturing Site ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hizmetleri Sanayi ve Ticaret Anonim Sirketi. Kaynarca Mh. Kadirli Sk No:10b/D Blok Pendik Turkey LOA Expiry Date: 13th August 2026 FSC Country of Origin: Turkey Validity: 22-Dec-2026 EC Certificates FQA Validity: 26-May-2025 Design Examination Validity: 26-May-2025 ISO 13485 Expiry: 8-7-2025	ODAK OBG Forward group Class B Shelf Life: Codes: <table><tr><td>Name</td><td>Co de</td><td>Shel f Life</td></tr><tr><td>ODAK OBG Forward group 1</td><td>OBG FG 1-50</td><td>13 Months</td></tr><tr><td>ODAK OBG Forward group 2</td><td>OBG FG 2-50</td><td>13 Months</td></tr></table>			Name	Co de	Shel f Life	ODAK OBG Forward group 1	OBG FG 1-50	13 Months	ODAK OBG Forward group 2	OBG FG 2-50	13 Months	Approved, subject to provisions of differential fee of class-D.
Name	Co de	Shel f Life													
ODAK OBG Forward group 1	OBG FG 1-50	13 Months													
ODAK OBG Forward group 2	OBG FG 2-50	13 Months													
64.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrach-e-Faisal, Karachi (ELI-00015) Date of submission: 4th February 2025 Fee submitted: PKR 31,000/-	Legal Manufacture Manufacturing Site ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hizmetleri Sanayi ve Ticaret Anonim Sirketi. Kaynarca Mh. Kadirli Sk No:10b/D Blok Pendik Turkey LOA Expiry Date: 13th August 2026 FSC Country of Origin: Turkey Validity: 22-Dec-2026 EC Certificates FQA Validity: 26-May-2025 Design Examination Validity: 26-May-2025	ODAK OBG Forward & Reverse group Class B Shelf Life: 13 Months Codes: OBGFRG-50			Approved, subject to provisions of differential fee of class-D.									

	Challan # 793088193072 Tracking id: Y7N-TV8- YPAH	ISO 13485 Expiry: 8-7-2025		
65.	Siemens Healthcare Private Limited; th Floor, State Life Building, 15-A, Davis Road, Lahore ELI-00146 1 R&I Details: 19 th December 2024	Legal Manufacturer: Siemens Medical Solutions USA Inc 2501 N. Barrington Road Hoffman Estates, IL, 60192, USA Manufacturing Site: Private Limited Siemens Medical Solutions USA Inc 15-A, 2501 N. Barrington Road Hoffman Estates, IL, 60192, USA Lo Validity: 30 September 2029 FSC: Country of origin: USA Validity: N/A EC Certificate: Validity: N/A ISO-13485: Validity: 05 June 2027	Symbia Evo + Excel gamma camera Class B Shelf Life: Not applicable. (Made to order) Code/Sizes: 10910500 11006983 10910501	Approved, subject to provisions of valid FSC of USA or any RRA or CE certificate.
66.	M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrahe- Quaideen, Karachi, Pakistan (ELI-00078) R & I Date: 26.05.2023 Paid Fee Challan No.: 830212308 Dt: 22.05.2023	<u>Legal Manufacturer:</u> M/s Siemens Healthcare Diagnostics Products GmbH Emil-von- Behring-Straße 76 35041 Marburg Germany FSC: Germany Issue Date: 19.01.2023 (No Expiry) LOA Validity: 13.12 2025 ISO Validity: 15.08.2027	Dade Owren's Veronal Buffer Class A Shelf Life: 24 months months Codes: OQAA33	Approved
67.	M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrahe- Quaideen, Karachi, Pakistan (ELI-00078) R & I Date: 26.05.2023 Paid Fee Challan	Legal Manufacturer: M/s Siemens Healthcare Diagnostics Products GmbH Emil- von-Behring-Straße 76 35041 Marburg Germany FSC: Germany issue Date: 19.01.2023 LOA Validity: 13.12.2025 ISO Validity: 15.08.2027	Supplementary Reagents for Coagulation Analyzers 1. Product name: Calcium Chloride Solution Product code: ORH037 Class A Shelf Life: 60 months Sizes as per FSC	Approved

	No. 115596918894 Dt: 22.05.2023																	
68.	Rech International, Karachi Address of Importer 247/B, Block 6 PECHS Shahrah-e-Faisal Karachi. Date of R& I Submission date: 6-March-2024 Fee Rs 25,000, fees challan NO; 82579984739	M/s Beijing Medkon Medical Devices Co, Ltd Floor 1 and 2 Building 1, Floor 1and 2 Building 5, 8 Yunteng Rd., Miyun Economic Development Zone, Miyun District, 101500 Beijing, P.R. China. Fsc: China (18-03-2026) LOA- Validity- 20th October 2025 ISO 13485- Validity 29-1-2027	Medkon (Pulse Lavage System) Class B Shelf Life: N/A Sizes as per FSC	Approved, subject to provisions of valid FSC of any RRA/CE certificate and codes.														
69.	Rech International, Karachi Address of Importer 247/B, Block 6 PECHS Shahrah-e-Faisal Karachi. Date of R& I Submission date: 6-March-2024 ubmission date: 17, Aug-2020 Fee Rs 5,000	(LEGAL MANUFACTEURER) Changzhou Kanghui Medical Device Innovation Co., Ltd Complete Address: No.11, north Changjiang Road, xinbei zone, Changzhou 213022, Jiangsu, P.R. China Fsc: China Nov,2024 FSC 2: Germany, Expiry Not mentioned Marketing Authorization Letter: LOA-Validity- Dec,2026 13485) ISO 13485- Validity June,2026.	Surgical Instrument Class-A Shelf Life: N/A	Deferred for provision of complete description and classes of the products mentioned, Brand name and instrumeents applied.														
70.	M.M BROTHERS shop no. 36 madina centre kutchi gali no.1 denso hall Karachi. <u>ELI-00651</u> Date of R& I 30/12/2024 Fee Rs. 31,000/ through slip no. 91694250, dated 20/12/2024	<u>Legal Manufacturer:</u> MEDPLUS INC <u>Manufacturing Site:</u> add 4 th floor, building 6 no.586 zhongshun road, zhongcun panyu district, Guangzhou china. <u>LOA:</u> Original Agency agreement Validity: MARCH, 2029 <u>FSC:</u> CHINA	Abm disposable semi-automatic biopsy Needle Class B Shelf Life: 5 YEARS Codes/Sizes: <table><tr><th>Code</th><th>Size</th></tr><tr><td>15011 4107</td><td>14G*10 CM</td></tr><tr><td>15011 4157</td><td>14G*15 CM</td></tr><tr><td>15011 4207</td><td>14G*20 CM</td></tr><tr><td>15011 6107</td><td>16G*10 CM</td></tr><tr><td>15011 6157</td><td>16G*15 CM</td></tr><tr><td>15011 6207</td><td>16G*20 CM</td></tr></table>	Code	Size	15011 4107	14G*10 CM	15011 4157	14G*15 CM	15011 4207	14G*20 CM	15011 6107	16G*10 CM	15011 6157	16G*15 CM	15011 6207	16G*20 CM	Approved subject to provision of FSC of RRA/CE and Valid ISO-13485.
Code	Size																	
15011 4107	14G*10 CM																	
15011 4157	14G*15 CM																	
15011 4207	14G*20 CM																	
15011 6107	16G*10 CM																	
15011 6157	16G*15 CM																	
15011 6207	16G*20 CM																	

			<table><tr><td>15011 6257</td><td>16G*25 CM</td></tr><tr><td>15011 8107</td><td>18G*10 CM</td></tr><tr><td>15011 8157</td><td>18G*15 CM</td></tr><tr><td>15011 8207</td><td>18G*20 CM</td></tr><tr><td>15011 8257</td><td>18G*25 CM</td></tr></table>	15011 6257	16G*25 CM	15011 8107	18G*10 CM	15011 8157	18G*15 CM	15011 8207	18G*20 CM	15011 8257	18G*25 CM	
15011 6257	16G*25 CM													
15011 8107	18G*10 CM													
15011 8157	18G*15 CM													
15011 8207	18G*20 CM													
15011 8257	18G*25 CM													
71.	M/s. Unique Visual System L-18, Block-17, Gulshan-e-Iqbal, Karachi, Pakistan ELI-00449	Legal Manufacturer: NEO VISION CO., LTD. Head Office : Heungdeokjungang-ro, Giheung-gu, Yongin-si, Gyeonggi-do 120 U-TOWER 17F, Korea Factory: 129-1, Donghwagongdan-ro, Munmak-eup, Wonjusi, Gangwon-do, Korea FSC: (EXPORT ONLY) KOREA Issued on Sep 2, 2024 VALIDTY LOA July 15, 2024 ISO 13485 VALIDITY: 25-08-2027	OPTIANO-55 Generic Name NEO CLEAN (Additional name: OPTIANO-55) Soft Contact Lens HS CODE 9001.3000 Class: B Shelf Life: 5 Years	Approved subject to provision of FSC of RRA/CE and Valid ISO-13485.										
72.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details Date: 06/02/2023 Slip no. 95489196885 Rs. 5000/-	Legal Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned issued in Oct. 2022 LOA Validity: 31/12/2025 ISO 13485 VALIDITY: 31-05-2025	KARL STORZ Retaining Systems to hold instruments. Class A Shelf Life: N/A Codes / Sizes: As per FSC.	Approved subject to provsion of instruments involved and codes.										
73.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details	Legal Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned, issued in Oct. 2022 LOA	KARL STORZ Sheaths Trocars (Sheaths, Trocars and accessories (sterile/non-sterile)) Class A Shelf Life: N/A Codes / Sizes:	Approved sheaths subject to provision of codes for sterile. Apply separately for non sterile and trocar										

	Date: 06/02/2023 Slip no. 916963722024 Rs. 5000/-	Validity: 31/12/2025 ISO 13485 VALIDITY: 31-05-2025								
74.	Musaji Adam & Sons Address:C-285, Block 10, Federal B Area, Karachi. Establishment License: ELI- 00239 Date of R&I 24 -Nov-2022	<u>Legal Manufacturer:</u> Remel Europe Limited Manufacturing Site: Remel house, Clipper boulevard west,crossways,Dartford kent,DA26PT,United Kingdom. <u>FSC:</u> Country of Origin United Kingdom Validity: 28-03-2027 <u>LOA</u> Validity:31-12-2025 <u>ISO 13485</u> Validity: 10-12-2025	Brucella Abortus Agglutinating Serum R30164801 24 Months Brucella melitensis Agglutinating Serum R30164901 24 Months	Approved. Firm submitted FSC of UK.						
75.	Musaji Adam & Sons Address:C-285, Block 10, Federal B Area, Karachi. Establishment License: ELI-00239. <u>Date of R&I</u> 29-jan-2021	<u>Legal Manufacturer:</u> M/S IMMY,Inc . <u>Manufacturing Site:</u> IMMY, Inc 2701 Corporate Centre Drive, Norman, Ok 73069 USA <u>CFG & COE:</u> Country of Origin: United States Of America Validity: 25-06-2025 <u>LOA</u> Validity:31-12-2025 <u>ISO 13485</u> Validity: 19-09-2027	Sona Aspergillus Galactomannan LateralFlow Assay (A/C to COE) Product code: AF2003 Class: B Shelf Life: 18 month Cluster: Fungal Infection Immunology CrAg Lateral Flow Assay(A/c to CFG) Product code: CR2003 Class: B Shelf Life: 18 month Size: 50 Tests Cluster: Fungal Infection Immunology Sona Cube Reader (A/c to CFG) Product code: LFARDR Class: B Shelf Life: 18 month Cluster: Fungal Infection Immunology	Approved. Firm submitted FSC of UK.						
76.	M/s. Glo-Med Technologies Address: A-21/2 B1, KDA Scheme 1 (Ext.), National Stadium Road, Karachi, Pakistan. ELI-00712 R&I details 18-04-2023	<u>Legal Manufacturer:</u> Shenzhen HugeMed Medical Technical Development Co., Ltd Address: 416-1,516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street,Longgang District, Shenzhen 518115, China <u>FSC:</u> Country of Origin: China Validity: 22-10-2025 <u>LOA</u> Validity: 31-03-2025 <u>ISO 13485</u>	HugeMed Video Laryngoscope System (Video Laryngoscope) Class A Shelf Life: N/A Codes/Sizes: <table><tr><th>Component Name</th><th>Model</th></tr><tr><td>Video Laryngoscope</td><td>VL4R</td></tr><tr><td>Open Video Laryngoscope</td><td>VL4D</td></tr></table>	Component Name	Model	Video Laryngoscope	VL4R	Open Video Laryngoscope	VL4D	Approved, subject to provisions of valid LoA.
Component Name	Model									
Video Laryngoscope	VL4R									
Open Video Laryngoscope	VL4D									

		Validity: 21-12-2025.	<table><tr><td>Video Laryngoscope</td><td>VL3S</td></tr><tr><td>Video Laryngoscope</td><td>VLRM</td></tr><tr><td>Video ope Laryngoscope</td><td>VLDM</td></tr><tr><td>Single use Laryngoscope Blade</td><td>MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5</td></tr></table>	Video Laryngoscope	VL3S	Video Laryngoscope	VLRM	Video ope Laryngoscope	VLDM	Single use Laryngoscope Blade	MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5	
Video Laryngoscope	VL3S											
Video Laryngoscope	VLRM											
Video ope Laryngoscope	VLDM											
Single use Laryngoscope Blade	MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5											
77.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) Manual Wheelchair CLASS: A SHELF LIFE: 05-YEARS	Approved.								
78.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) WALKER CLASS: A SHELF LIFE: 03 YEARS	Approved.								

79.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) CHAIR RAISED TOILET SEAT CLASS: A SHELF LIFE: 03 YEARS	Approved.
80.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) SHOWER CHAIR CLASS: A SHELF LIFE: 03 YEARS	Approved.
81.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) ROLLATOR CLASS: A SHELF LIFE: 05 YEARS	Approved.
82.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026	(MEDICAL BAZAR) CRUTCH CLASS: A SHELF LIFE: 03-YEARS	Approved.

	R&I: 04/09/2024	LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.		
83.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) WALKING STICK CLASS: A SHELF LIFE: 03 YEARS	Approved.
84.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) ELECTRIC WHEELCHAIR CLASS: A SHELF LIFE: 05 YEARS	Approved.
85.	M/s. Hakimi Medtech Address: Room # 4 Jason Centre BC-8, Block Clifton, Karachi Pakistan. ELI-00627 R&I: 04/09/2024	M/s. Guangdong Dayang Medical Address: Technology Co., Ltd. Xingxian Development Zone Changhongling Industrial Park (2nd Phase), Shishan Nanhai District Foshan CHINA. FSC VALIDITY: 29-05-2026 LOA VALIDITY: 05-07-2029. <u>ISO 13485</u> Validity: 24-06-2025.	(MEDICAL BAZAR) ELECTRIC HOSPITAL BED CLASS: A SHELF LIFE: 05 YEARS	Approved.
86.	MOODY Global Services Office address: Office No. 14, 2nd Floor,	Etiometry Inc., Address: 280 Summer Street, Fourth Floor Boston, MA, USA	Etiometry Platform software Generic Name; Clinical Decision Support Software Class A	Deferred; for clarification regarding the IQ, OQ and PQ of the product at the premises of Installation.

	Mujahid Plaza, Blue area, Islamabad Licence No. ELI-00926 Date of issue: 17-05-2022	FSC: UK Validity: 28-02-2028 LOA Validity: 30-06-2029 <u>ISO 13485</u> Validity: 28-02-2027.	Shelf Life: NA. Stability studies do not apply to software because software does not degrade over time like physical products. Model name and its version: (As per FSC) T3 Platform Software: DAV5.4 RAE 10.0	Further submission required that in which category of medical equipment it will be devises and what is the critical classification of the product use. Its monitoring the vitals of patient individually or whether alongwith other Software/medical devices.												
87.	Cardiac Care 848-C Shadman -1, Lahore. <u>ELI-00070</u> R&I 25-02-2021 Fee Challan No 2039280 dated 22-02-21	VYGON Address: 5 rue Adeline - 95440 Ecouen – FRANCE FSC issued date: 24/07/2023 LOA valid: 31/12/2026. <u>ISO 13485</u> Validity: 09-05-2027.	SINGLE valve For thoracic Drainage. (Pleural drainage valve) Class A Shelf Life: 05-years CODE: 669.10	Approved, subject to provision of original fee slip, because annexed slip is not legible.												
88.	M/s. Glo-Med Technologies Address: A-21/2 B1, KDA Scheme 1 (Ext.), National Stadium Road, Karachi, Pakistan. ELI-00712 R&I details 18-04-2023	<u>Legal Manufacturer:</u> Shenzhen HugeMed Medical Technical Development Co., Ltd Address: 416-1,516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street,Longgang District, Shenzhen 518115, China <u>FSC:</u> Country of Origin: China Validity: 22-10-2025 <u>LOA</u> Validity: 31-03-2025 <u>ISO 13485</u> Validity: 21-12-2025.	HugeMed Video Laryngoscope System (Video Laryngoscope) Class A Shelf Life: N/A Codes/Sizes: <table><tr><th>Component Name</th><th>Model</th></tr><tr><td>Video Laryngoscope</td><td>VL4R</td></tr><tr><td>Open Video Laryngoscope</td><td>VL4D</td></tr><tr><td>Video Laryngoscope</td><td>VL3S</td></tr><tr><td>Video Laryngoscope</td><td>VLRM</td></tr><tr><td>Video open Laryngoscope</td><td>VLDM</td></tr></table>	Component Name	Model	Video Laryngoscope	VL4R	Open Video Laryngoscope	VL4D	Video Laryngoscope	VL3S	Video Laryngoscope	VLRM	Video open Laryngoscope	VLDM	Approved, subject to provisions of valid LoA and differential fee of Class-B.
Component Name	Model															
Video Laryngoscope	VL4R															
Open Video Laryngoscope	VL4D															
Video Laryngoscope	VL3S															
Video Laryngoscope	VLRM															
Video open Laryngoscope	VLDM															

			<table><tr><td>pe</td><td></td></tr><tr><td>Single use Laryngoscope Blade</td><td>MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5</td></tr></table>	pe		Single use Laryngoscope Blade	MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5			
pe										
Single use Laryngoscope Blade	MAC1, MAC2, MAC3, MAC3 1, MAC4, MAC5, MILLE R00, MILLE R0, CMAC 3, CMAC 4, CMAC 5									
89.	MOODY Global Services Office address: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad Licence No. ELI-00926 Date of issue: 17-05-2022	Etiometry Inc., Address: 280 Summer Street, Fourth Floor Boston, MA, USA FSC: UK Validity: 28-02-2028 LOA Validity: 30-06-2029 <u>ISO 13485</u> Validity: 28-02-2027.	Etiometry Platform software Generic Name; Clinical Decision Support Software Class A Shelf Life: NA. Stability studies do not apply to software because software does not degrade over time like physical products. Model name and its version: (As per FSC) T3 Platform Software: DAV5.4 RAE 10.0	Deferred; for clarification regarding the IQ, OQ and PQ of the product at the premises of Installation. Further submission required that in which category of medical equipment it will be devised and what is the critical classification of the product use. Its monitoring the vitals of patient individually or whether alongwith other Software/ medical devices.						
90.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrach-e-Faisal, Karachi (ELI-00015) Date of submission: 7th Jan 2025	Legal Manufacture Manufacturing Site Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland LOA Expiry Date: 27th January 2026 FSC Country of Origin: Finland Date of Issuance: 12-Sep-2024 FSC Reference Country: Australia Date of Issuance: 27-Feb-2023 ISO 13485 Expiry: 31-3-2027	Name of Medical Device Clinical Chemistry (Immunochemistry) Class A Shelf Life: Codes: <table><tr><td>Nam e</td><td>Cod e</td><td>She lf Lif e</td></tr><tr><td>Hea moly zing Reag ent</td><td>9816 59</td><td>18 Mo nth s</td></tr></table>	Nam e	Cod e	She lf Lif e	Hea moly zing Reag ent	9816 59	18 Mo nth s	Approved; subject to provisions of differential fee of class-B and brand name.
Nam e	Cod e	She lf Lif e								
Hea moly zing Reag ent	9816 59	18 Mo nth s								

	Fee submitted: PKR 6,000/- Challan # 15947038279 Tracking id: UYW-LPY- UPLA															
91.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Date of submission: 7 th Jan 2025 Fee submitted: PKR 31,000/- Challan # 34719978117 Tracking id: 95P-5N4-G1M8	Legal Manufacture Manufacturing Site Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland LOA Expiry Date: 27 th January 2026 FSC Country of Origin: Finland Date of Issuance: 12-Sep-2024 FSC Reference Country: Australia Date of Issuance: 27-Feb-2023 ISO 13485 Expiry: 31-3-2027	Name of Medical Device Clinical Chemistry (Electrolyte Electrodes) Class B Shelf Life: Codes: <table><tr><td>Name</td><td>Code</td><td>Shelf Life</td></tr><tr><td>Potassium (k+) Micro Volume Electrode</td><td>981593</td><td>18 Months</td></tr><tr><td>Chloride (Cl-) Micro Volume Electrode</td><td>981596</td><td>Months</td></tr><tr><td>Sodium (NA+) Micro Volume Electrode</td><td>981594</td><td>Months</td></tr></table>	Name	Code	Shelf Life	Potassium (k+) Micro Volume Electrode	981593	18 Months	Chloride (Cl-) Micro Volume Electrode	981596	Months	Sodium (NA+) Micro Volume Electrode	981594	Months	Approved subject to Brand name
Name	Code	Shelf Life														
Potassium (k+) Micro Volume Electrode	981593	18 Months														
Chloride (Cl-) Micro Volume Electrode	981596	Months														
Sodium (NA+) Micro Volume Electrode	981594	Months														
92.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society,	Legal Manufacture Manufacturing Site ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hizmetleri Sanayi ve Ticaret Anonim Sirketi. Kaynarca Mh. Kadirli Sk No:10b/D Blok Pendik Turkey LOA	ODAK OBG Forward group Class B Shelf Life: Codes: <table><tr><td>Name</td><td>Code</td><td>Shelf</td></tr></table>	Name	Code	Shelf	Approved, subject to provisions of differential fee of class-D.									
Name	Code	Shelf														

	Shahrah-e-Faisal, Karachi (ELI-00015) Date of submission: 4th February 2025 Fee submitted: PKR 31,000/- Challan # 4118038628 Tracking id: 4EX-XW8-6YBW	Expiry Date: 13th August 2026 FSC Country of Origin: Turkey Validity: 22-Dec-2026 EC Certificates FQA Validity: 26-May-2025 Design Examination Validity: 26-May-2025 ISO 13485 Expiry: 8-7-2025	<table><tr><td></td><td></td><td>Life</td></tr><tr><td>ODA K OBG Forw ard group 1</td><td>O B G F G 1- 50</td><td>13 Mon ths</td></tr><tr><td>ODA K OBG Forw ard group 2</td><td>O B G F G 2- 50</td><td>13 Mon ths</td></tr></table>			Life	ODA K OBG Forw ard group 1	O B G F G 1- 50	13 Mon ths	ODA K OBG Forw ard group 2	O B G F G 2- 50	13 Mon ths	
		Life											
ODA K OBG Forw ard group 1	O B G F G 1- 50	13 Mon ths											
ODA K OBG Forw ard group 2	O B G F G 2- 50	13 Mon ths											
93.	Name of Firm (s) Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Date of submission: 4th February 2025 Fee submitted: PKR 31,000/- Challan # 793088193072 Tracking id: Y7N-TV8-YPAH	Legal Manufacture Manufacturing Site ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hizmetleri Sanayi ve Ticaret Anonim Sirketi. Kaynarca Mh. Kadirli Sk No:10b/D Blok Pendik Turkey LOA Expiry Date: 13th August 2026 FSC Country of Origin: Turkey Validity: 22-Dec-2026 EC Certificates FQA Validity: 26-May-2025 Design Examination Validity: 26-May-2025 ISO 13485 Expiry: 8-7-2025	ODAK OBG Forward & Reverse group Class B Shelf Life: 13 Months Codes: OBGFRG-50	Approved, subject to provisions of differential fee of class-D.									
94.	V care International 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi ELI: 00433 607-C-C	Legal Manufacturer: M/S HONSUN (NANTONG) CO LTD.NO 08 TONGXING ROAD NANTONG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT AREA, NANTONG CITY P.R.China Distributor: Microlife AG LOA: 31.12.25	Stethoscope Class-A Shelf life: ST-71 Stethoscope Combined with AG1-20 (Anerioed BP) ST-77 Sprague Rappaport Stethoscope	Approved firm will provide notarized copy of ISO 13485; Firm will provide separate fee for ST-77 Sprague Rappaport Stethoscope									

	00210982654 5000 R&I 05-10-2022	FSC Chins 11-07-2025 ISO 13485 08.03.26		
95.	V care International 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi ELI: 00433 607-C-C 84938557723 25000 R&I 05-10-2022	Legal Manufacturer: M/S HONSUN (NANTONG) CO LTD.NO 08 TONGXING ROAD NANTONG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT AREA, NANTONG CITY P.R.China Distributor: Microlife AG LOA: 31.12.25 FSC Chins 08-12-2024 ISO 13485 08.03.26	Blood Pressure Monitor Class-A Shelf life: AG1-20 Aneroid Blood Pressure meter AG1-40 Aneroid Blood Pressure meter	Approved firm will provide notarized copy of ISO 13485; & valid FSC
96.	V care International 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi ELI: 00433 607-C-C 78351880937 25000 paid 17.4.22 R&I 05-10-2022	Legal Manufacturer: M/s Shen Zhen Bi rich medical devices company LTD The 1st Building of no 10 Xinqiao Gagzai Road, Xinqiao Street Bao.An District, SHenzen City Distributor: Microlife AG Switzerland LOA: 31.12.25 FSC Chins 14-06-2024 ISO 13485 14.07.26	Compressor Nebulizer NEB210 BR-CN188 Nebulizer Class-B Shelf life: Nebulizer + optional with the following three accessory packages: 1.. NEB-210 including adjustable cup, PVC tube, nose piece, 2. mouthpiece, adult and child mask; 3. Kids including adjustable cup PVC Tube nosepiece adult mask child mask. KM-002nebulizer cup PVC tube	Deferred firm will provide valid FSC and CE certificate, LOA from Shenzhen in name of Microlife AG also required
97.	BIOSORIN (PRIVATE) LIMITED 19-Usman Block, Main Boulevard New Garden Town Lahore-Pakistan Phone No: +92-42-35940533 +92-42-35940534 Fax No: +92-42-35940535 E-Mail:	ESCO Medical Technologies UAB, Lithuania Address: Draugystes g. 19, Kaunas, Lithuania Tel.: +370 686 79269 Web: esco-medical.com LOA: Date of issue 09.1.23 FSC Lithunaia 08-12-2032 ISO 13485 01.09.25	Multi-zone ART Workstations (MAW) MAW 3D; MAW 4D; MAW 6D	Approved subject to submission of paid fee proof

	info@biosorin.com Web: https://www.biosorin.com/ 78351880937 25000 paid 17.4.22 R&I 10-06-2024			
98.	Applicant: M/s KASBN INTERNATIONAL Company Address: 41-K, Gulberg-III, Lahore 54660 - Pakistan Site Address: (ELI-00434) Track ID: LXB-VTX- QLDH Fee: 5000- Slip: 35907398273 Dated: 24.oct .22 R&I 19.12.24	(Legal Manufacturer) Name: M/S. VBM medizintech GmbH, FSC Validity: Country of Origin: Germany DOI: 05.03.2021 ISO 13485 18.02.25 LOA: Date of issue 31.12.26	Pneumatic tourniquet Digital tourniquet Resuscitator bag . Class: B	Approved subject to submission of fee as per S.R.O 1324 for 3 products as mentioned in FSC
99.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI-00029 R&I Details: Date: 07/10/2022 Slip no. 19642727178 Rs. 25,000/-	Legal Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr.- Karl-Storz StraBe 34 78532 Tuttlngen, Germany LOA Validity: 31/12/2025 FSC: Country of Origin Validity: Not mentioned, issued in Oct. 2022 FSC: FSC of Reference Country US Validity 22.05.24 OR EC Certificate	KARL STORZ Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without channel, Semiflexible Endoscopes with and without channel)) Class B Shelf Life: N/A Codes / Sizes : 1. 1001BN1 Broncho- Fiberscope 5.0 x 54 2. 11001RD1 Rhino- Laryngo-Fiberscope 3.7 x 34 3. 11001UD1 Rhino- Pharyngo-Laryngo- Fiberscope 5.2x2 4. 11002BD1 Broncho- Fiberscope 3.7 x 54 5. 11003BC3 Broncho- Fiberscope 2.8 x 54	Approved subject to justification as per MDB how different microscopes used for different purpose are clubbed as a single application or separate fee for each microscope as mentioned in FSC of country of origin as per S. R. O 1324

		Validity: 17-12-2025 ISO 13485 Validity: 31-05-2025	6. 11004BC1 Broncho-Fiberscope 6.4 x 54 7. 11009BC1 Broncho-Fiberscope 5.6 x 54 8. 11101RP2 Rhino-Laryngo-Fiberscope 3.5 mm, 30 cm 9. 11101SK2 Rhino-Laryngo-Fiberscope, 2.5 x 270 mm 10. 11101SP2 Rhino-Laryngo-Fiberscope, 2.5 x 370 mm 11. 11264BB1 Hystero-Fiberscope 3.5 mm x 24 cm 12. 11272C1 Cysto-Urethro-Fiberscope 13. 11272CIU1 Cysto-Urethro-Fiberscope, PDD 14. 11272CU1 Cysto-Urethro-Fiberscope 15. 11274AA1 Uretero-Fiberscope 16. 11278A1 Uretero-Reno-Fiberscope FLEX-X2S 17. 11278AC1 Ped. Cysto-Urethro-Fiberscope, FLEX-X 18. 11278ACU1 Ped. Cysto-Urethro-Fiberscope, FLEX-X 19. 11278AI1 Uretero-Fiberscope, FLEX-X ² 20. 11278AU1 Uretero-Reno-Fiberscope FLEX-X2S 21. 11292AD1 Choledocho-Fiberscope, 7.5 Fr.	
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			22. 11292BD1 Choledochofiberscope, 11 Fr. 23. 11292DE1 Choledochofiberscope, 15.5 Fr. 24. 11301AA1 Intubation Fiberscope 2.8 x 65 25. 11301BN1 Intubation Fiberscope 5.2 x 65 26. 11302BD2 Intubation Fiberscope 3.7 x 65 27. 11506AA Miniature Straight Forward Telescope 0° 28. 29. 29 11508AA Miniature Straight Forward Telescope 0° 30. 30 11510A Miniature Straight Forward Telescope 0° 31. 31 11510AA Miniature Straight Forward Telescope 0° 32. 32 11540AA Mini Straight Forward Telescope 0°,1.3mm 33. 33 11572A Mini Straight Forw. Telescope 0°, 0.8 mm 34. 34 11573A Mini Straight Forward Telescope 0°,1.1mm 35. 35 11574A Mini Straight Forward Telescope 0°,1.6mm 36. 36 11575A Mini Straight Forward Telescope 0°,1.3mm 37. 37 11576A Mini Straight Forward Scope 0°,0.75mm	
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			38. 38 11577A Mini Straight Forward Telescope 0°, 1 mm 39. 39 11581A Miniature Straight Forward Telescope 0° 40. 40 11582A Miniature Straight Forward Telescope 0° 41. 41 11630AA Mini Straight-Forward Telescope 0°,2 mm 42. 42 27000K Ureteroscope, 7 Fr., 6°, 34 cm 43. 43 27000L Uretero-Renoscope, 7 Fr., 6°, 43 cm 44. 44 27001GG Instrument Port, large 45. 45 27001K Ureteroscope, 8 Fr., 6°, 34 cm 46. 46 27001L Uretero-Renoscope, 8 Fr., 6°, 43 cm 47. 47 27002K Ureteroscope, 9.5 Fr., 6°, 34 cm 48. 48 27002KP Pediatric Uretero-Renoscope 7.3 Fr. 49. 49 27002L Uretero-Renoscope, 9.5 Fr., 6°, 43 cm 50. 50 27003L MICHEL Uretero-Renoscope, 9.5 Fr.,43cm 51. 51 27010K Ureteroscope, 7 Fr., 34 cm 52. 52 27010L Uretero-Renoscope, 7 Fr., 43cm	
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			53. 53 27011K Ureteroscope, 8 Fr., 6°, 34cm 54. 54 27011KA Ureteroscope, 8 Fr., 6°, 34cm 55. 55 27011L Uretero-Renoscope, 8 Fr., 6°, 43cm 56. 56 27013L GAUTIER Uretero-Renoscope, 8 Fr., 41 cm 57. 57 27035BA Universal-Cysto-Urethroscope, 17 Fr.	
100.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI-00029 R&I Details: Date: 22/04/2021 Slip no. 1964791 Rs. 25,000/-	Legal Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz StraBe 34 78532 Tuttlingen, Germany LOA Validity: 31/12/2025 FSC: Country of Origin Validity: Not mentioned, issued in 27/01/2020 EC Certificate Validity: 17-12-2025 ISO 13485 Validity: 31-05-2025	KARL STORZ Hopkins Telescopes (Endoscopes with channel and without channel with accessories) Class B Shelf Life: N/A Codes / Sizes : 1 26252BC BETTOCCHI®B.I.O.H.® Compact Hysteroscope 2 26034AAV HOPKINS® Telescope 0°, 10mm, 23cm 3 26034AA HOPKINS® Telescope 0°, 10mm, 27cm 4 26038AA HOPKINS® Telescope 0°, 10mm, 27cm 5 26092AMA HOPKINS® Telescope 6° 6 26208AMA HOPKINS® Telescope 6° 7 27092AMA HOPKINS® Telescope 6° 8 27093AA HOPKINS® Telescope 6° 9 27292AMA HOPKINS® Telescope 6° 10 27293AA HOPKINS® Telescope 6° 11 26075AA HOPKINS® Telescope 6°, 11mm, 27.5cm 12 27294AA HOPKINS® Telescope 6°, 18 Fr. 13 27295AA HOPKINS® Telescope 6°, 18 Fr. 14 27840KA Nephroscope for MIP L 15 26053CD Telescope Bridge 16 27035BA Universal-Cysto-Urethroscope, 17 Fr.	Approved subject to justification as per MDB how different microscopes with different names used for different purpose are clubbed in a single application or separate fee for each microscope as mentioned in FSC of country of origin as per S. R. O 1324

			17 27035BB Universal-Cysto- Urethroscope, 20 Fr. 18 26252BB B.I.O.H.® Compact Hysteroscope, only 19 7232BA DCI HOPKINS® Telescope 30°, 4mm, 18cm 20 10970BA DCI® HOPKINS® Telescope 30° 21 10972BA DCI® HOPKINS® Telescope 30°, 4 mm/16 cm 22 10972BWA DCI® HOPKINS® Telescope 30°, 4 mm/16 cm 23 28731AE ENDOCAMELEON® ARTHRO HOPKINS® Telescope 24 7230AE ENDOCAMELEON® ENT HOPKINS® Telescope 25 26003AE ENDOCAMELEON® HOPKINS® Telescope 26 26003AEE ENDOCAMELEON® HOPKINS® Telescope 27 26003AS ENDOCAMELEON® HOPKINS® Telescope 28 26003ASE ENDOCAMELEON® HOPKINS® Telescope 29 26003EC ENDOCAMELEON® HOPKINS® Telescope 30 49003AE ENDOCAMELEON® HOPKINS® Telescope 31 27005BGA Greenlight HOPKINS® Telescope 30°, 4 mm 32 26003ARA HOPKINS RUBINA 0°, NIR/ICG, Ø 10 mm 33 26046ARA HOPKINS RUBINA 0°, NIR/ICG, Ø 5 mm 34 26003BRA HOPKINS RUBINA 30°, NIR/ICG, Ø 10 mm 35 26046BRA HOPKINS RUBINA 30°, NIR/ICG, Ø 5 mm 36 26003FRA HOPKINS RUBINA 45°, NIR/ICG, Ø 10 mm 37 26003FREA HOPKINS RUBINA 45°, NIR/ICG, Ø 10 mm 38 26046FRA HOPKINS RUBINA 45°, NIR/ICG, Ø 5 mm 39 26120AA HOPKINS Telescope 0°, 2.9 mm, 30 cm 40 26004AA HOPKINS Telescope 0°, 3 mm, 14 cm 41 26004BA HOPKINS Telescope 30°, 3 mm, 14 cm 42 26003FCA HOPKINS Telescope 45°, NIR/ICG, Ø 10 mm 43 26003FCEA HOPKINS Telescope 45°, NIR/ICG, Ø 10 mm 44 26046FCA HOPKINS Telescope 45°, NIR/ICG, Ø 5 mm 45 28305BA HOPKINS® Forward-	
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			Oblique Telescope 30° 46 27301AA HOPKINS® Telescope 0°, 1.9 mm 47 58705AA HOPKINS® Telescope 0°, 1.9 mm, 6.5 cm 48 27017AA HOPKINS® Telescope 0°, 1.9/2.1 mm 49 10017AA HOPKINS® Telescope 0°, 1.9/2.1mm 50 7217AA HOPKINS® Telescope 0°, 1.9/2.1mm 51 26003AA HOPKINS® Telescope 0°, 10 mm, 31 cm 52 50250AA HOPKINS® Telescope 0°, 10 mm, 31 cm 53 26003AEA HOPKINS® Telescope 0°, 10 mm, 42 cm 54 8711AA HOPKINS® Telescope 0°, 10mm, 20cm 55 26008AA HOPKINS® Telescope 0°, 2 mm, 26 cm 56 7207AA HOPKINS® Telescope 0°, 2.7 mm, 11 cm 57 10018AA HOPKINS® Telescope 0°, 2.7 mm, 18 cm 58 7229AA HOPKINS® Telescope 0°, 2.7 mm, 18 cm 59 27018AA HOPKINS® Telescope 0°, 2.7mm 60 10023ABA HOPKINS® Telescope 0°, 2.8 mm, 44 cm 61 27023ABA HOPKINS® Telescope 0°, 2.8mm 62 10020ATA HOPKINS® Telescope 0°, 2.9 mm, 30 cm 63 10324AA HOPKINS® Telescope 0°, 2.9 mm, 36 cm 64 27324AA HOPKINS® Telescope 0°, 2.9 mm, 36 cm 65 27020AA HOPKINS® Telescope 0°, 2.9mm 66 7220AA HOPKINS® Telescope 0°, 3 mm, 14 cm 67 26007AA HOPKINS® Telescope 0°, 3.3 mm, 25 cm 68 7228AA HOPKINS® Telescope 0°, 4 mm, 15 cm 69 28731AWA HOPKINS® Telescope 0°, 4 mm, 18 cm 70 7230AA HOPKINS® Telescope 0°, 4 mm, 18 cm 71 7230AWA HOPKINS® Telescope 0°, 4 mm, 18 cm 72 10005AA HOPKINS® Telescope 0°, 4 mm, 30 cm 73 26105AA HOPKINS® Telescope 0°, 4 mm, 30 cm 74 27005AA HOPKINS® Telescope 0°, 4 mm, 30 cm	
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			75 10328AA HOPKINS® Telescope 0°, 4.5mm, 50cm 76 27005AR HOPKINS® Telescope 0°, 4mm 77 26011AA HOPKINS® Telescope 0°, 5 mm, 24 cm 78 26046AA HOPKINS® Telescope 0°, 5 mm, 29 cm 79 10320AA HOPKINS® Telescope 0°, 5.5 mm, 50 cm 80 26048ASA HOPKINS® Telescope 0°, 5.5 mm, 50 cm 81 12015AA HOPKINS® Telescope 0°, 5.5 mm, 53 cm 82 8710AA HOPKINS® Telescope 0°, 5.8mm, 19cm 83 7235AWA HOPKINS® Telescope 0°, 5mm, 18cm 84 8712AA HOPKINS® Telescope 0°, 5mm, 24cm 85 8713AA HOPKINS® Telescope 0°, 5mm, 29cm 86 8714AA HOPKINS® Telescope 0°, 6.5mm, 35cm 87 26003AGA HOPKINS® Telescope 0°, NIR/ICG, Ø 10 mm 88 8711AGA HOPKINS® Telescope 0°, NIR/ICG, Ø 10mm 89 8710AGA HOPKINS® Telescope 0°, NIR/ICG, Ø 5.8 mm 90 1232AA HOPKINS® Telescope 0°, Ø 1.9 mm, 10 cm 91 49003AA HOPKINS® Telescope 0°, Ø 10 mm 92 1230AA HOPKINS® Telescope 0°, Ø 2.7 mm, 11 cm 93 1216AA HOPKINS® Telescope 0°, Ø 4 mm, 11 cm 94 49011AA HOPKINS® Telescope 0°, Ø 5 mm 95 49046AA HOPKINS® Telescope 0°, Ø 5 mm 96 49031AA HOPKINS® Telescope 0°, ø 6,5 mm 97 26008FUA HOPKINS® Telescope 12°, 2 mm, 26 cm 98 26020FA HOPKINS® Telescope 12°, 2.9 mm, 30 cm 99 27020FA HOPKINS® Telescope 12°, 2.9mm 100 26105FA HOPKINS® Telescope 12°, 4 mm, 30 cm 101 27005FA HOPKINS® Telescope 12°, 4 mm, 30 cm 102 27005EA HOPKINS® Telescope 120°, 4mm 103 7230EA HOPKINS® Telescope 120°, 4mm, 18cm 104 8575AV HOPKINS®	
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		Telescope 15°, 4 mm, 17 cm 105 24941BA HOPKINS® Telescope 30° 106 26072BA HOPKINS® Telescope 30° 107 24995BA HOPKINS® Telescope 30° 4 mm, 28.5 cm 108 58705BA HOPKINS® Telescope 30°, 1.9 mm, 6.5 cm 109 7217BA HOPKINS® Telescope 30°, 1.9/2.1mm 110 27301BA HOPKINS® Telescope 30°, 1.9mm 111 26003BA HOPKINS® Telescope 30°, 10 mm, 31 cm 112 26003BEA HOPKINS® Telescope 30°, 10 mm, 42 cm 113 26008BA HOPKINS® Telescope 30°, 2 mm, 26 cm 114 26008BUA HOPKINS® Telescope 30°, 2 mm, 26 cm 115 58700BA HOPKINS® Telescope 30°, 2,4 mm, 10 cm 116 28300BA HOPKINS® Telescope 30°, 2.4 mm, 10 cm 117 28208BA HOPKINS® Telescope 30°, 2.7 mm, 11 cm 118 7207BA HOPKINS® Telescope 30°, 2.7 mm, 11 cm 119 10018BA HOPKINS® Telescope 30°, 2.7 mm, 18 cm 120 27018BA HOPKINS® Telescope 30°, 2.7 mm, 18 cm 121 28719BA HOPKINS® Telescope 30°, 2.7 mm, 18 cm 122 7229BA HOPKINS® Telescope 30°, 2.7 mm, 18 cm 123 7219BVA HOPKINS® Telescope 30°, 2.7 mm, 18 cm 124 10020BA HOPKINS® Telescope 30°, 2.9 mm, 30 cm 125 26120BA HOPKINS® Telescope 30°, 2.9 mm, 30 cm 126 10324BA HOPKINS® Telescope 30°, 2.9 mm, 36 cm 127 26120BAL HOPKINS® Telescope 30°, 2.9 mm, 36 cm 128 27020BA HOPKINS® Telescope 30°, 2.9mm 129 7209BA HOPKINS® Telescope 30°, 3 mm, 11 cm 130 7220BA HOPKINS® Telescope 30°, 3 mm, 14 cm 131 26007BA HOPKINS® Telescope 30°, 3.3 mm, 25 cm 132 27325BA HOPKINS® Telescope 30°, 3.5mm 133 7228BA HOPKINS® Telescope 30°, 4 mm, 15 cm	
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			134 26009BA HOPKINS® Telescope 30°, 4 mm, 18 cm 135 28731BWA HOPKINS® Telescope 30°, 4 mm, 18 cm 136 50230BA HOPKINS® Telescope 30°, 4 mm, 18 cm 137 7230BA HOPKINS® Telescope 30°, 4 mm, 18 cm 138 7230BVA HOPKINS® Telescope 30°, 4 mm, 18 cm 139 7230BWA HOPKINS® Telescope 30°, 4 mm, 18 cm 140 7230BRA HOPKINS® Telescope 30°, 4 mm, 18 cm 141 26105BA HOPKINS® Telescope 30°, 4 mm, 30 cm 142 27005BA HOPKINS® Telescope 30°, 4 mm, 30 cm 143 24954BA HOPKINS® Telescope 30°, 4 mm, 9.5 cm 144 10328BA HOPKINS® Telescope 30°, 4.5mm, 50cm 145 10005BA HOPKINS® Telescope 30°, 4mm 146 28721BWA HOPKINS® Telescope 30°, 4mm, 18cm 147 26011BA HOPKINS® Telescope 30°, 5 mm, 24 cm 148 50251BA HOPKINS® Telescope 30°, 5 mm, 24 cm 149 26046BA HOPKINS® Telescope 30°, 5 mm, 29 cm 150 10320BA HOPKINS® Telescope 30°, 5.5 mm, 50 cm 151 26048BSA HOPKINS® Telescope 30°, 5.5mm, 50cm 152 8712BA HOPKINS® Telescope 30°, 5mm, 24cm 153 24941BAL HOPKINS® Telescope 30°, 5mm, 28cm 154 8713BA HOPKINS® Telescope 30°, 5mm, 29cm 155 26031BA HOPKINS® Telescope 30°, 6.5mm, 35cm 156 26003BGA HOPKINS® Telescope 30°, NIR/ICG, Ø 10 mm 157 1232BA HOPKINS® Telescope 30°, Ø 1.9 mm, 10 cm 158 49003BA HOPKINS® Telescope 30°, Ø 10 mm 159 1230BA HOPKINS® Telescope 30°, Ø 2.7 mm, 11 cm 160 1216BA HOPKINS® Telescope 30°, Ø 4 mm, 11 cm 161 49011BA HOPKINS® Telescope 30°, Ø 5 mm 162 49046BA HOPKINS® Telescope 30°, Ø 5 mm 163 27017BA HOPKINS®	
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		Telescope 30°, 1.9/2.1mm, 18cm 164 26003FA HOPKINS® Telescope 45°, 10 mm, 31 cm 165 26003FEA HOPKINS® Telescope 45°, 10 mm, 42 cm 166 7229FA HOPKINS® Telescope 45°, 2.7 mm, 18 cm 167 7219FLA HOPKINS® Telescope 45°, 2.7 mm, 18 cm 168 7209FA HOPKINS® Telescope 45°, 3 mm, 11 cm 169 7220FA HOPKINS® Telescope 45°, 3 mm, 14 cm 170 7220FVA HOPKINS® Telescope 45°, 3 mm, 14 cm, up 171 7230FA HOPKINS® Telescope 45°, 4 mm, 18 cm 172 7230FLA HOPKINS® Telescope 45°, 4mm, 18cm 173 7230FVA HOPKINS® Telescope 45°, 4mm, 18cm 174 7230FWA HOPKINS® Telescope 45°, 4mm, 18cm 175 26046FA HOPKINS® Telescope 45°, 5 mm, 29 cm 176 49205FA HOPKINS® Telescope 45°, 5 mm, 29 cm 177 26048FSA HOPKINS® Telescope 45°, 5.5 mm, 50 cm 178 8713FA HOPKINS® Telescope 45°, 5mm, 35cm 179 49003FA HOPKINS® Telescope 45°, Ø 10 mm 180 49046FA HOPKINS® Telescope 45°, Ø 5 mm 181 7217CA HOPKINS® Telescope 70°, 1.9/2.1mm 182 7207CA HOPKINS® Telescope 70°, 2.7 mm, 11 cm 183 7229CA HOPKINS® Telescope 70°, 2.7 mm, 18 cm 184 7219CVA HOPKINS® Telescope 70°, 2.7 mm, 18 cm 185 27018CA HOPKINS® Telescope 70°, 2.7mm, 18cm 186 7220CA HOPKINS® Telescope 70°, 3 mm, 14 cm 187 7228CA HOPKINS® Telescope 70°, 4 mm, 15 cm 188 28731CWA HOPKINS® Telescope 70°, 4 mm, 18 cm 189 7230CA HOPKINS® Telescope 70°, 4 mm, 18 cm 190 7230CWA HOPKINS® Telescope 70°, 4 mm, 18 cm 191 10005CA HOPKINS® Telescope 70°, 4 mm, 30 cm 192 27005CA HOPKINS® Telescope 70°, 4 mm, 30 cm	
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			193 7230CVA HOPKINS® Telescope 70°, 4mm, 18cm 194 7230CRA HOPKINS® Telescope 70°, 4mm, 18cm 195 8712CA HOPKINS® Telescope 70°, 5mm, 24cm 196 1232CA HOPKINS® Telescope 70°, Ø 1.9 mm, 10 cm 197 1230CA HOPKINS® Telescope 70°, Ø 2.7 mm, 11 cm 198 1216CA HOPKINS® Telescope 70°, Ø 4 mm, 11 cm 199 7230DA HOPKINS® Telescope 90°, 4mm, 18cm 200 8700DA HOPKINS® Telescope 90°, 5.8mm,20cm 201 7230AP PDD HOPKINS® Telescope 0°, 4 mm, 18 cm 202 27005AIA PDD HOPKINS® Telescope 0°, 4mm 203 8712AP PDD HOPKINS® Telescope 0°, 5mm, 24cm 204 27005FIA PDD HOPKINS® Telescope 12°, 4mm 205 7230BP PDD HOPKINS® Telescope 30°, 4 mm, 18 cm 206 27005BIA PDD HOPKINS® Telescope 30°, 4mm 207 8712BP PDD HOPKINS® Telescope 30°, 5mm, 24cm 208 7230FP PDD HOPKINS® Telescope 45°, 4mm, 18cm 209 27005CIA PDD HOPKINS® Telescope 70°, 4mm 210 8712CP PDD HOPKINS® Telescope 70°, 5mm, 24cm 211 8707DP PDD-Tele- Laryngoscope 90° 212 8706CA Strobo-Laryngoscope 70°, 17 cm 213 8707DA Tele-Laryngo- Pharyngoscope 90°, 15 cm 214 8700DKA Tele-Laryngo- Pharyngoscope, 5.8mm 215 8700CKA Tele-Laryngoscope 70°, 5.8 mm 216 1218AA Tele-Otoscope 0°, Ø 3 mm, 6 cm 217 1218BA Tele-Otoscope 30°, Ø 3 mm, 6 cm 218 1215AA Tele-Otoscope, Telescope 0°, Ø 4 mm, 6cm 219 1215BA Tele-Otoscope, Telescope 30°, Ø 4 mm,6cm 220 1218FA Tele-Otoscope, Telescope 45°, Ø 3 mm,6cm 221 1218CA Tele-Otoscope, Telescope 70°, Ø 3 mm,6cm 222 49020AA VITOM® 25	
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			Telescope 0°, AA 25 – 75 cm 223 20916025AGA VITOM® II NIR/ICG Telescope 0° 224 20916025AIA VITOM® II PDD Telescope 0° 225 26013VDA VITOM® Scope 90° w. green filter 226 20916025DA VITOM® Tel. 90° w Integ. Illuminator 227 20916025AA VITOM® Telescope 0° w Integ. Illuminator 228 26003BCA HOPKINS® Telescope 30°, NIR/ICG, Ø 10 mm 229 26046ACA HOPKINS® Telescope 0°, ICG, Ø 5 mm 230 26046BCA HOPKINS® Telescope 30°, ICG, Ø 5 mm 231 7215AA Contact-Micro- Rhinoscope 0° 232 7215BA Contact-Micro- Rhinoscope 30° 233 26008BAC CAMPO TROPHYSCOPE® 234 26120BAC CAMPO TROPHYscope™ 235 50253BA HOPKINS® Telescope 30°, 10 mm, 31 cm 236 10320DA HOPKINS® Telescope 90°, 5.5mm, 50cm 237 27294N Adapter 238 10970DS Adaptor 239 30141TA Adaptor for 26034 AAT 240 26075V Adaptor for Instrument channel 241 26034V Adaptor, for working channel 242 28126CR Arthroscope Sheath 243 28126R Arthroscope Sheath 244 28129CR Arthroscope Sheath 245 28132CR Arthroscope Sheath 246 28133DS Arthroscope Sheath 247 28136EC Arthroscope Sheath ENDOCAMELEON® 248 28126B Arthroscope Sheath, 5.5 mm/12 cm 249 26120BHA Examination and Contact Hysteroscope 250 58706AN High Flow Arthroscope Sheath, 2,8 mm ø 251 58703BH High Flow Arthroscope Sheath, 3,2 mm ø 252 28130CR High-Flow Arthroscope Sheath 253 28130R High-Flow Arthroscope Sheath 254 28131CR High-Flow Arthroscope Sheath 255 28131R High-Flow	
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			Arthroscope Sheath 256 28135CR High-Flow Arthroscope Sheath 257 28136CR High-Flow Arthroscope Sheath 258 28136DS High-Flow Arthroscope Sheath 259 28136S High-Flow Arthroscope Sheath 260 28229S High-Flow Arthroscope Sheath 261 28303BS High-Flow Arthroscope Sheath 262 28303DS High-Flow Arthroscope Sheath 263 28306BN High-Flow Arthroscope Sheath 264 58706BN High-Flow Arthroscope Sheath 265 28229DR High-Flow Arthroscope Sheath, 6.5/12 266 10337TA Sheath for 10337T 267 12016X Sheath Insert 268 8705CKA Slimline Tele- Laryngoscope 70°, 4mm/18cm 269 27025F Telescope Bridge 270 27025G Telescope Bridge 271 27025GF Telescope Bridge 272 27025GFA Telescope Bridge 273 27027NL Telescope Bridge 274 27034G Telescope Bridge 275 10338LCI Telescope Bridge 276 26055CD Telescope Bridge 277 26069CD Telescope Bridge 278 27025GA Telescope Bridge 279 27032F Telescope Bridge 280 27033F Telescope Bridge 281 27047F Telescope Bridge 282 27068CD Telescope Bridge 283 10338RK Telescope Bridge 284 10338RL Telescope Bridge 285 10338LCD Telescope Bridge 286 10338R Telescope Bridge 287 30117JA Telescope-Adaptor 288 10434V Adaptor for catheters, LUER-lock 289 10434Z Adaptor 290 10924D Adaptor, for respirator 291 10924DL Adaptor for respirator 292 10924E Plug for Ventilation Attachment 293 10924SP Plug for Suction 294 11014L LUER Port with Stopcocks 295 11014LU Double LUER Port 296 11900ASE Connecting Hose 297 13991CD Double valve channel splitter 298 13991CLE Connector, for vent	
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			connection 299 24950F Telescope Bridge 300 26252BM Monobloc Adapter 301 27040LB Adaptor 302 27040SC Adaptor 303 497HCS Telescope Protective Sheath for 497 HC 304 1218AL Sheath f.LASER probe and 1218A/AA 305 1218BL Sheath f.LASER probe and 1218B/BA 306 10320SP Telescope Guide Sheath 307 10328SP Telescope Guide Sheath 308 10338S Guide Piece, short, for suction catheter 309 10510AA Outer Sheath 310 10970 MEDIAFIT Outer Sheath, Ø 5 mm, 21 cm 311 11272X Guiding Device 312 11510KA Examination Sheath, ø 1.3 mm, 2 pcs. 313 11510KD Operating Sheath, straight, 6.5 Fr. 314 11510KE Operating Sheath, straight, size 5.6 Fr. 315 11510KI Operating Sheath, curved, 5.6 Fr. 316 11521S Examination sheath for 11521 A 317 11522S Examination sheath for 11522 A 318 11540KA Operating Sheath, straight, size 8 Fr. 319 11540KB Operating Sheath, curved, 8 Fr. 320 11540KE Operating Sheath, curved, size 3.3 mm 321 11576KA Examination Sheath, ø 1.1 mm, 16 cm 322 11576KF Operating Sheath, 1.1/1.3 mm, 16 cm 323 11576KG Operating Sheath, 1.1/0.8 mm, 16 cm 324 11577KA Examination Sheath, ø 1.3 mm, 16 cm 325 11577KD Operating Sheath, 1.3/0.8 mm, 16 cm 326 11577KE Operating Sheath, 1.3/1.3 mm, 16 cm 327 11605F Operating Sheath, 9 Fr. 328 11605KC Examination Sheath, Ø 2.7 mm 329 11630KF Operating Sheath, 9 Fr. 330 11630KH Operating Sheath, 9 Fr. 331 11660A Outer tube	
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			332 11660C Pusher 333 23178K Outer Sheath with Needle Holder Insert 334 23400 Outer Sheath, insulated, 43 cm 335 23400AD ROTATIP™ Outer Sheath, insulated, 36 cm 336 23400UD ROTATIP™ Outer Sheath, insulated, 36 cm 337 23500CD ROTATIP™ Outer Sheath, insulated, 50 cm 338 24514S Outer Sheath only 339 24886SOW Sliding Cap 340 24910 Rectoscope Tube, 20 mm, 30 cm 341 24911 Rectoscope Tube, 20 mm, 25 cm 342 24912 Rectoscope Tube, 20 mm, 20 cm 343 24913 Rectoscope Tube, 18 mm, 30 cm 344 24914 Rectoscope Tube, 16 mm, 30 cm 345 24915 Rectoscope Tube, 18 mm, 25 cm 346 24916 Rectoscope Tube, 16 mm, 20 cm 347 24918 Rectoscope Tube, 12 mm, 20 cm 348 24919 Rectoscope Tube, 24 mm, 20 cm 349 24941TK TEO® Operating Rectoscope Tube, 7.5 cm 350 24942T TEO® Operating Rectoscope Tube 351 24942TK TEO® Operating Rectoscope Tube 352 24942TKG TEO® Operating Rectoscope Tube 353 24942TL TEO® Operating Rectoscope Tube 354 24995 Rectoscope Tube, Ø 20 mm, 25 cm 355 26008KA Operating Sheath, 10.5 Fr. 356 26152BI BETTOCCHI® Inner Sheath 357 26152BO BETTOCCHI® Outer Sheath 358 26152DA Continuous-Flow Examination Sheath 359 26152DB Continuous-Flow Operating Sheath 360 26153BI BETTOCCHI® Inner Sheath 361 26153BIL BETTOCCHI® Inner Sheath 362 26153BO BETTOCCHI® Outer Sheath	
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			363 26153BOL BETTOCCHI® Outer Sheath 364 26153CI BETTOCCHI® Inner Sheath 365 26153CO BETTOCCHI® Outer Sheath 366 26153DB Continuous-Flow Operating Sheath 367 26153DC Continuous-Flow Operating Sheath 368 26154BI BETTOCCHI® Inner Sheath 369 26154BO BETTOCCHI® Outer Sheath 370 26161CE Examination Sheath, Ø 4.1 mm 371 26161CF CF Examination Sheath, Ø 5 mm 372 26161R Continuous-Flow Outer Sheath, Ø 3.6 mm 373 26161RN Inner Sheath, Ø 2.8 mm 374 26161U Operating Sheath, 9 Fr. 375 26161UF Operating Sheath, 11.5 Fr. 376 26161VB Inner Sheath, Ø 3.8 mm 377 26161VC Outer Sheath, Ø 4.5 mm 378 26161VS Examination Sheath, ø 4.1 mm 379 26162VB Examination Sheath, Ø 3.8 mm 380 26163CS CF Operating Sheath, Ø 7 mm 381 26163HN Operating Sheath 382 26163V Examination Sheath, Ø 5.1 mm 383 26163VB Examination Sheath, diameter 5.2 mm 384 26163VC Outer Sheath, Ø 6.2 mm 385 26164VB Inner Sheath, Ø 5.2 mm 386 26167KS Handle with Outer Sheath, size 3 mm 387 26168DE Sheath 388 26168JB Outer Sheath 389 26168JQ Manipulator Sheath 390 26168ZB Manipulator Sheath 391 26176HS Outer Tube 392 26176HSX Outer Tube 393 26177HS Outer Tube 394 26182D Diagnostic Sheath, ø 3.7 mm 395 26182TG Operating Sheath, Ø 6.6 mm 396 26183MB SUPRALOOP Outer Sheath, 5 mm, 30 cm	
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			397 26184HS Outer Tube, size 3 mm 398 26184HSS Outer Tube, size 3 mm 399 26188FA Outer Sheath 400 26190AB Outer Tube for 26190 A 401 26193DA Outer Sheath for 26193D 402 26193DB Inner Sheath for 26193D 403 26252BO B.I.O.H. Outer Sheath, 4 mm 404 26596CAA Outer Tube 405 26596CAI Inner Tube 406 27023RB Sheath for Uretero-Resectoscope 407 27026A Cystoscope Sheath, 25 Fr. 408 27026AA Cystoscope Sheath, 25 Fr. 409 27026AB Cystoscope Sheath, 25 Fr. 410 27026B Cystoscope Sheath, 22 Fr. 411 27026BA Cystoscope Sheath, 22 Fr. 412 27026BB Cystoscope Sheath, 22 Fr. 413 27026C Cystoscope Sheath, 20 Fr. 414 27026CA Cystoscope Sheath, 20 Fr. 415 27026CB Cystoscope Sheath, 20 Fr. 416 27026CC Cystoscope Sheath, 20 Fr. 417 27026D Cystoscope Sheath, 19 Fr. 418 27026DA Cystoscope Sheath, 19 Fr. 419 27026DB Cystoscope Sheath, 19 Fr. 420 27026U Cystoscope Sheath, 17 Fr. 421 27026UA Cystoscope Sheath, 17 Fr. 422 27026VA Outer Sheath, 23 Fr. 423 27026VI Inner Sheath,with 7.5Fr. working channel 424 27026VIL Inner Sheath 425 27027KL Cystoscope Sheath, 22 Fr. 426 27029CN Cystoscope Sheath, 7 Fr. 427 27029DN Cystoscope Sheath, 9 Fr. 428 27031E Cystoscope Sheath, 9.5 Fr.	
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			429 27031F Cystoscope Sheath, 11 Fr. 430 27032K Cystoscope Sheath, 11 Fr. 431 27032L Cystoscope Sheath, 13 Fr. 432 27032M Cystoscope Sheath, 14.5 Fr. 433 27033C Cystoscope Sheath, 8 Fr. 434 27033CR Cystoscope Sheath, 8 Fr. 435 27033D Cystoscope Sheath, 9 Fr. 436 27033R Resectoscope Sheath, 9 Fr. 437 27034A Cystoscope Sheath, 14 Fr. 438 27034B Cystoscope Sheath, 16 Fr. 439 27820BA Operating Sheath, 8.5/9.5 Fr. 440 27820BAS Operating Sheath, for supine position 441 27820BB Operating Sheath, 11/12 Fr. 442 27820BBS Operating Sheath, for supine position 443 27820BK Operating Sheath for Children 444 27830BA Operating Sheath, 15/16 Fr. 445 27830BAS Operating Sheath for Supine Position 446 27830BB Operating Sheath, 16.5/17.5 Fr. 447 27830BBS Operating Sheath for Supine Position 448 27830BC Operating Sheath, 21/22 Fr. 449 27830BCS Operating Sheath for Supine Position 450 27830BK Operating Sheath for Children 451 27840BA Operating Sheath, 23/24 Fr. 452 27840BAS Operating Sheath for Supine Position 453 27840BB Operating Sheath, 25/26 Fr. 454 27840BBS Operating Sheath for Supine Position 455 28147BH Arthroscope Sheath 456 28147C OR Sheath, continuously slotted 457 28179GH Half Pipe, long 458 28179GK Half Pipe, short 459 28728LH Half Pipe®, long 460 28728MH Half Pipe®, small	
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			461 28728SH Half Pipe®, short 462 50200EK Telescope Sheath, beak 5 mm 463 50200LS Telescope Sheath f. 50200 L/LM/LL 464 50251LCS Telescope Sheath for 50251 LC/LD 465 50251MS Sheath 466 58000KA Examination Sheath 1.1 mm 467 58001KA Examination Sheath 1.0 mm 468 224202 Protection Tube, 28 cm 469 225150 Protection Tube, metal, 6 cm 470 553514 Metal Outer Sheath, 3.5 mm, 14 cm 471 555014 Metal Outer Sheath, 5 mm, 14 cm 472 655001 Telescope Sheath, 3.5 mm x 10.5 cm 473 655002 Telescope Sheath, 2.5 mm x 9 cm 474 655003 Telescope sheath, 5 mm x 16 cm 475 655004 Telescope sheath for dental surgery 476 655005 Telescope sheath for dental surgery 477 722010A SCHERER LASER Rhinoscope Sheath 0° 478 722010B SCHERER LASER Rhinoscope Sheath, 30° 479 26711547 Sheath oblique 12 mm ø 480 26711557 Sheath oblique 15 mm ø 481 8661P Adaptor for Suction Tubes 8661M/N 482 10316LR Adaptor, for 10316 AS-DS 483 10337TB Distance Ring for 10337T 484 23004A2 Introducer Sleeve, 13 mm 485 23004A3 Introducer 486 23005ID LUER-Lock Connector 487 23010AS Attachment ENDOCONE, for S-PORT® Seal 488 23010SA ENDOCONE® seal 489 23020S Sealing Cap 490 23030E Attachment, S-PORT, for ENDOCONE® seal 491 23030P Port ring 492 23030S Sealing Cap 493 23030X Attachment, S-PORT, for X-CONE sealing 494 23040A Adaptor for SAAD	
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			Retrieval Tube 495 24941I Insertion aid 496 24943S TEO® High-Flow Adaptor for S-PORT® Seal 497 24944S Sealing Cap for DAPRI Rectoscope Tube 498 24980A Adaptor 499 26167A Adaptor 500 26182TD Changing Rod, ø 2.9 mm 501 27022Y Insert Cone 502 27026VY LASER Cystoscope Adaptor 503 27026X NICKELL Cystoscope Adaptor 504 27050ALC Adaptor 505 27050LC Adaptor 506 27074SC Adaptor 507 27074SZ Adaptor 508 27093GM Adaptor 509 27093GN Adaptor 510 27093SC Adaptor 511 27094BY Adaptor 512 27210A Adaptor for TOOMEY Syringe 513 27213 Adaptor 514 27506 Catheter Adaptor 515 27507 Catheter Adaptor 516 27550A Sealing Cap, Ø 0.8 mm 517 27550C Sealing Cap, Ø 1.2 mm 518 27550D Sealing Cap, without drill hole 519 27618 Insertion Mandrin 520 28124BX Changing Rod, length 23 cm 521 28124BZ Changing Rod 522 28140EWK Changing Rod ENDOCAMELEON, cannulated 523 28140W Changing Rod, Ø 4.8 mm 524 28140WK Changing Rod, cannulated, 31 cm 525 28270W Changing Rod, length 35 cm 526 28302W Changing Rod 527 30120Y Spare Silicone Leaflet Seal, 5x 528 30140DA Reduction Sleeve 529 30140DB Reduction Sleeve, 11/5 mm 530 30140DD Reduction Sleeve 531 30140EB Reduction Sleeve 532 30140EE Reduction Sleeve 533 30140FB Reduction Sleeve 534 30140FE Reduction Sleeve 535 30140GB Reduction Sleeve 536 30140GE Reduction Sleeve 22/10 mm 537 30140HB Reducer 13/5 mm	
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			538 30140HE Reduction Sleeve 13/10 mm 539 30140K Guide Sleeve 540 30140KA Reduction Sleeve 541 30141AA Reducer 542 30141DB Reducer 11/5mm 543 30141HB Reducer 544 30141HE Reducer, 13/10 mm 545 30141RS Reducer 546 30142HB Double Reducer 547 30142RS Reducer 548 30143RS Reducer 549 58702W Changing Rod 550 230000 Ventilation Drainage Tube Insert, 10cm 551 469602 Guard for Forceps 469600/488038 552 27502 LUER-Lock Tube Connector 553 26208OC Obturator for 26208 AMA 554 8715AA Contact Micro Laryngoscope 0° 555 8715BA Contact-Micro- Laryngoscope 30° 556 10030AA Miniature Telescope 0°, semirigid 557 10040AA Mini Straight Forward Telescope 0°, 1.3mm 558 26003ACA HOPKINS® Telescope 0°, NIR/ICG, Ø 10 mm 559 26604BA HOPKINS Telescope 30°, 3 mm, 14 cm 560 26605AA HOPKINS® Straight Fwd Telescope 0° 561 26605BA HOPKINS® Telescope 30°, 8mm, 29cm	
101.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details Date: 30/12/2022 Slip no. 78277421 Rs. 5000	Legal Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr.- Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned, issued in Oct. 2022 LOA Validity: 31/12/2025	KARL STORZ Pumps (Pumps, Foot Switches for Pumps, Tubing Sets (sterile/non-sterile)) Class A Shelf Life: N/A Codes / Sizes S # Article No. Description 1 UP501 S-PILOT 2 030547-01 Tubing Set, Suction, EXTRALARGE LL 3 030948-01 Tubing Set, Suction, LUER 4 20300042 Silicone Tubing Set, suction 5 26331142 Silicone Tubing Set, suction 6 UP009 Tubing Set,	Approved subject to justification as per MDB how different microscopes with different names used for different purpose are clubbed in a single application or separate fee for each microscope as mentioned in FSC of country of origin as per S. R. O 1324

			suction, DS 7 UP010 Tubing Set, suction, BS 8 030748-01 Tubing Set, Suction 9 031124-10 Filter, Suction 10 20300032 Bottle Stand, for bottle 5 l 11 20300034 Bottle Cap, 1.5 and 5 l 12 20300039 Cap for Suction Bottle 20300051 13 20300050 Suction Bottle, 5 l, sterilizable 14 20300051 Suction Bottle, 0.5 l 15 20701070 Control Cable 16 27610070 Connecting Cable 17 27610072 Connecting cable, transducer/ generator 18 UP006 Control Cable	
102.	M/s. Jasani Scientifics SC- 45, Marium Square, chandni Chowk, Stadium road, Karachi. (ELI-00416) Date of R&I 13/03/2025 Fee: PKR 5000/- Slip: 9741390814 Dated: 03/04/2023	Legal Manufacturer: C.S.O. Srl, Address: Via degli Stagnacci, 12e, 50018 Scandicci Fl Italy. FSC Italy issuance date: 06-11-2017 ISO 13485 validity: 16-12-2026 LOA Validity: 31-12-2027	Brand name: SL-9900 Slit Lamp Generic: Slit Lamp Model: (SL-2000) Class: A	Approved subject to remaining fee and provision of Fsc notorized and countersigned by embassy
103.	M/s Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, ELI-000416 R&I: 13/03/2025 Fee Slip No: 2040342371 Fee Submission Date: 03/04/2023	Legal Manufacturer: C.S.O. Srl, Address: Via degli Stagnacci, 12e, 50018 Scandicci Fl Italy. FSC Italy issuance date: 12-11-2014 ISO 13485 validity: 16-12-2026 LOA Validity: 31-12-2027	Brand Name SIRIUS TOPOGRAPHER (CORNEAL TOPOGRAPHER) Class A Shelf life: N/A GMDN Codes: 18038 Codes and Sizes as per FSC	Approved subject to remaining fee
104.	M/s Jasani Scientifics	Legal Manufacturer: C.S.O. Srl,	Brand Name A-900 Applanation Tonometer	Approved subject to remaining fee

	SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, ELI-000416 R&I: 13/03/2025 Fee Slip No: 23849473549 Fee Submission Date: 03/04/2023	Address: Via degli Stagnacci, 12e, 50018 Scandicci FI Italy. FSC Italy issuance date: 12-11-2014 ISO 13485 validity: 16-12-2026 LOA Validity: 31-12-2027	(Tonometer) Class A Shelf life: N/A GMDN Codes: 16809 Codes and Sizes as per FSc	
105.	M/s. Unique Visual System L-18, Block-17, Gulshan-e-Iqbal, Karachi, Pakistan ELI-00449 R&I: 14/06/2024 Fee Submission Date: 10/06/2024 25000/-	Legal Manufacturer: M/s Jilin Realcon Optical Technology Co.,Ltd. Address: No.88, Changchun Street, Yongji Economic Development Zone, JilinCity, Jilin, CHINA https://www.realconle.com CE FQAS Validity 27 05 2024 FSC: CHINA Validity: Jan 12, 2025 LOA Validity: Issued on April 1, 2024 (LOA is valid until further notice) ISO 13485 VALIDITY: November 3, 2027	BRAND NAME: FRESHGO Generic Name Realcon Color 38 Soft Contact Lens HS CODE 9001.3000 Class B Shelf Life: 5 Years	Firm has applied same product with 2 different brand names. Approved 1 product out of Sr No. 12-13
106.	M/s. Unique Visual System L-18, Block-17, Gulshan-e-Iqbal, Karachi, Pakistan ELI-00449 R&I: 14/06/2024 Fee Submission Date: 10/06/2024 25000/-	Legal Manufacturer: M/s Jilin Realcon Optical Technology Co.,Ltd. Address: No.88, Changchun Street, Yongji Economic Development Zone, JilinCity, Jilin, CHINA https://www.realconle.com CE FQAS Validity 27 05 2024 FSC: CHINA Validity: Jan 12, 2025 LOA Validity:	BRAND NAME: MAGISTER Generic Name Realcon Color 38 Soft Contact Lens HS CODE 9001.3000 Class B Shelf Life: 5 Years	Firm has applied same product with 2 different brand names. Approved 1 product out of Sr No. 12-13

		Issued on April 1, 2024 (LOA is valid until further notice) ISO 13485 VALIDITY: November 3, 2027		
107.	M/s. LIFE CARES M-20 Mezzanine Floor, Falak naz Plaza Main Shahra -e-Faisal Karachi 75200. Tel: 021-34581903 Lifecares@hotmail.com ELI-00077 R&I 22.11.21	M/s FORTUNE MEDICAL INSTRUMENT CORP. 6F., No.29, Sec.2, Jhongjheng E., Rd., Danshuei Dist, New Taipei City 251, Taiwan. LOA: Validity Date: 24th January 2026 FSC:(Taiwan) Validity: 26-01-2027 FSC THE NETHERLANDS Validity 31-12-2028 ISO: 13485 (validity: 08-08-2025 EC FQA: (validity: 31-12-2028 MDR Confirmation letter Attached	Brand Name; FORTUNE Generic Name; AMBU BAG Manual Resuscitator Class A ShelfLife:5years Codes / Sizes 1610-0001, 1610-002, 1610-0003, 1650 0001, 1650-0002, 1650-0003, 1690-0001, 1690 0002, 1690-0003, 1611-9000, 1611-9001, 1611-9002, 1611-9003, 1611-9004, 1611 9005, 1611-9093, 1611-9094, 1611-9095, 1651-9000, 1651-9001, 1651-9002, 1651 9003, 1651-9004, 1651-9005, 1691-9000, 1691-9001, 1691-9002, 1691-9003, 1691 9004, 1691-9005, 1603-9040, 1603-9050, 1603-9060, 1603-9070, 1603-9080, 1603 9090, 1603-9100, 1603-0040, 1603-0050, 1603-0060, 1603-0070, 1603-0080, 1603 0090, 1603-0100, 1603-0110, 1601-9001, 1601-9002, 1601-9003, 1602-9001, 1602 9060, 1602-9260, 1604-9007, 1605-8001, 1605-9001, 1606-8010, 1606-8020, 1606 9010, 1606-9020, 1607-9001	approved
108.	M/s Pulse Surgical Address: Suite No. 113, First floor, Almas height, 190/1,	Name: Argon Medical Devices, Inc. Address: 1445 Flat Creek road, Athens, Texas 75751 USA	Brand name: Intara™ Generic name: Introducer sheath Specification/sizes:	Approved. Subject to The firm will submit notarized copies of ISO 13485 & Fsc

	Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 8536842690 31000 21.1.25 R&I: 21.1.25	FSC USA validity: 15-05-2026 LOA validity: DOI 23-06-2023 ISO 13485 VALIDITY: 28.4.25	ISD10040 Intara™ Introducer Sheath 10F x 41.5cm Class: B Shelf life: 3 years	
109.	M/s Pulse Surgical Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 2105322 25000 31.3.21 R&I: 6.4.21	Name: TECHNOMED EUROPE Address: Amerikalaan 71, 6199 AE Maastricht-Airport The Netherlands FSC Netherlands validity: 05-04-2028 LOA validity: Dec 2025 ISO 13485 VALIDITY: 01.3.26	Brand name: Technomed Generic name: Electromyographic Needle Electrode Specification/sizes: DISPOSABLE HYPODERMIC NEEDLE ELECTRODE TEL/LXXXX-335 Class: B Shelf life: 3 years	Approved. Subject to The firm will submit notarized copies of ISO 13485 & Fsc
110.	M/s Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, 75400 Pakistan License No. ELI-00578 Receipt No. 2105321	Name: TECHNOMED EUROPE Address: Amerikalaan 71, 6199 AE Maastricht-Airport The Netherlands FSC Netherlands validity: 05-04-2028 LOA validity: Dec 2025 ISO 13485 VALIDITY: 01.3.26	Brand name: Technomed Generic name: Electromyographic Needle Electrode Specification/sizes: DISPOSABLE CONCENTRIC NEEDLE ELECTRODE TE/B50035-XXX Class: B Shelf life: 3 years	Approved
111.	M/s importer A ONE TRADERS name with	Legal Manufacturer Name: Zhejiang Huafu	Name of Medical device SAFE+	Deferred for provision of Fsc of ref country or CE certificate and

	complete address as per Form-4. House No.45 , Street No.4 Haroon Abad ,Near Malik Tariq Awan Qilla ,Ring Road Peshawar , KPK. (ELI-00480) R&I Dated: 29-07 -2022	Medical Equipments Co. , Ltd. Add : No 688 Xinxing 1st Road , Pingua City ,Zhejiang Province , 314200 China. FSC Netherlands validity: 05-04-2028 LOA validity: 9.2.25 ISO 13485 VALIDITY: 03.2.27	URINE BAG TYES: (SIMPLES URINE BAG , URINE BAG WITH T-VALUE 1000ML, 2000 ML) Class: A Shelf Life : 5 Years MD group: SET LOA Validity: 09/02/2027 FSC Validity: 21/05/2025	notorised valid LOA and Fsc and ISO13485
112.	M/s importer A ONE TRADERS name with complete address as per Form-4. House No.45 , Street No.4 Haroon Abad ,Near Malik Tariq Awan Qilla ,Ring Road Peshawar , KPK. (ELI-00480) R&I Dated: 15-02 -2022	Legal Manufacturer Name: Zhejiang Huaifu Medical Equipments Co. , Ltd. Add : No 688 Xinxing 1st Road , Pingua City ,Zhejiang Province , 314200 China. FSC validity: 21-04-2021 LOA validity: 9.2.25 ISO 13485 VALIDITY: 03.2.27	Name of Medical device SAFE+ HEPARIN CAP (INJECTION STOPPER) TYES: (YELLOW , TRANSPARENT) Class: B Shelf Life : 5 Years MD group: SET	Deferred for provision of Fsc of ref country or CE certificate and notorised valid LOA and Fsc and ISO13485
113.	Cardiac Care 848-C Shadman -1, Lahore ELI-00070 R&I dated: 16-01-24 Challan No 133643723118 dated 08-01-24	Ningbo Greetmed Medical Instruments Co., Ltd. Add.: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA . FSC VALID: 09-11-2025 LOA VALID: 09-10-2026 ISO : 31-03-24	Nasal oxygen cannula (Oxygen delivery cannula) CLASS: B SHELF LIFE: 05 YEARS. CODE XXS,XS,S,M,L	Deferred for provision of Fsc of ref country or CE certificate and notorised LOA, brand name and Fsc

114.	Cardiac Care 848-C Shadman -1, Lahore R&I 16-01- 2024 Fee Challan No 6176555165 dated 18-12-23	Ningbo Greetmed Medical Instruments Co., Ltd. Add.: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86-574-87722370 Fax: +86-574-87722360 Website: www.chinagreetmed.com FSC VALID: 09-11-2025 LOA VALID: 09-10-2026 ISO : 31-03-24	Brand Name Description of Nebulizer Mask (Medicine administer mask) CLASS: B SHELF LIFE: 05 YEARS. ISO VALID: 31-03-24 CODE S,M,L,XL the device : Nebulizer is used for atomization inspiration treatmen by oxygen or oil free compressed air power source. Lahore ELI-00070	Deferred for provision of Fsc of ref country or CE certificate and notorised LOA and Fsc
115.	M/s Quantum, Suite No. 801, 8th Floor, Japan Plaza, M. A Jinnah Road Karachi. Godown Address:Ware House E-30, Sector 31/D, Korangi Industrial Area Karachi	BTL Industries LtD UK ISO : 08-04-27	Neutral Electrode BTL-NE-170	Rejected Application is not as per SOP
116.	M/s Quantum, Suite No. 801, 8th Floor, Japan Plaza, M. A Jinnah Road Karachi. Godown Address:Ware House E-30, Sector 31/D, Korangi Industrial Area Karachi	BTL Industries LtD UK ISO : 08-04-27	Forehead Applicator Cheek Applicator Submentum Applicator	Rejected Application is not as per SOP
117.	M/s Chemical House 6-C sikandar Malhi road Canal park Gulberg-III Lahore.	<u>Legal Manufacturer:</u> ABON Biopharm (Hangzhou) Co. Ltd. Address: #198, 12 th street east, Hongzhou, economic and technological department area, 310018, Hangzhou, Republic of China.	Brand: TOX/SEE Drug screen test (194- 5182) (Tox/see drug screen test THC COC OPI MET MTD AMP BAR BZO (25 test)) Model: 194-5182	Approved

	(ELI-00156) Date of R&I: 25/02/2025 Fee Challan No.: 15851259338 PKR: 6000/- Dated: 08-01-2025	Distributor name: (in USA) Biorad laboratories Inc. Address: 4000 Alfred Nobel drive Hercules CA, USA 94547.) Manufacturing Site(s): (ABON Biopharm (Hangzhou) Co. Ltd. Address: #198, 12 th street east, Hongzhou, economic and technological department area, 310018, Hangzhou, Republic of China)	Class A Shelf Life: 02 years																			
118.	M/s. Ontech Corporation Address: B-154 Block 13-D/2 Gulshan-e-Iqbal, Karachi. (ELI-00289) Date of R&I: 31/01/2023 Fee Challan No.: 012461374105 PKR: 5000/- Dated: 20-01-2023	Legal Manufacturer: P3 Medical Ltd Address: 1 Newbridge Close Bristol, BS4 4AX, United Kingdom. Marketing Authorization Holder: M/s. CMR Surgical Ltd. Address: Evolution Business Park, Milton Rd, Cambridge, CB24 9NG, United Kingdom	Brand: Versius Drapes Generic: (Medical Equipment Drapes for Surgical Robotic System) Class A <table><tr><th>Device</th><th>Ref:</th><th>Shelf life</th></tr><tr><td>Versius Instrument Bedside Unit Drape (Standard) (Qty. 1)</td><td>20100</td><td>12 months</td></tr><tr><td>Versius Instrument Bedside Unit Drape (Long) (Qty. 1)</td><td>20300</td><td>12 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Standard) (Qty. 1)</td><td>20200</td><td>24 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Long) (Qty. 1)</td><td>20400</td><td>24 months</td></tr><tr><td>Versius Camera Head Drape (Qty. 1)</td><td>20500</td><td>36 months</td></tr></table>	Device	Ref:	Shelf life	Versius Instrument Bedside Unit Drape (Standard) (Qty. 1)	20100	12 months	Versius Instrument Bedside Unit Drape (Long) (Qty. 1)	20300	12 months	Versius Visualisation Bedside Unit Drape (Standard) (Qty. 1)	20200	24 months	Versius Visualisation Bedside Unit Drape (Long) (Qty. 1)	20400	24 months	Versius Camera Head Drape (Qty. 1)	20500	36 months	Approved
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Versius Camera Head Drape (Qty. 1)	20500	36 months																				

			<table><tr><td>Versius Camera Head Drape (Qty. 25)</td><td>20501</td><td>36 months</td></tr><tr><td>Drape Cap Insert (Qty. 1)</td><td>20900</td><td>12 months</td></tr><tr><td>Drape Cap Insert (Qty. 100)</td><td>20901</td><td>12 months</td></tr><tr><td>Versius Instrument Bedside Unit Drape (Standard) (Qty. 5)</td><td>20101</td><td>12 months</td></tr><tr><td>Versius Instrument Bedside Unit Drape (Long) (Qty. 5)</td><td>20301</td><td>12 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Standard) (Qty. 10)</td><td>20201</td><td>24 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Long) (Qty. 10)</td><td>20401</td><td>24 months</td></tr></table>	Versius Camera Head Drape (Qty. 25)	20501	36 months	Drape Cap Insert (Qty. 1)	20900	12 months	Drape Cap Insert (Qty. 100)	20901	12 months	Versius Instrument Bedside Unit Drape (Standard) (Qty. 5)	20101	12 months	Versius Instrument Bedside Unit Drape (Long) (Qty. 5)	20301	12 months	Versius Visualisation Bedside Unit Drape (Standard) (Qty. 10)	20201	24 months	Versius Visualisation Bedside Unit Drape (Long) (Qty. 10)	20401	24 months		
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119.	M/s. Ontech Corporation Address: B-154 Block 13-D/2 Gulshan-e-Iqbal, Karachi. (ELI-00289)	Legal Manufacturer: Richard Wolf GmbH Address: Pforzheimer Straße 32, 75438 Knittlingen, Germany. Marketing Authorization Holder: M/s. CMR Surgical Ltd. Address: Evolution Business Park, Milton Rd, Cambridge, CB24 9NG, United Kingdom	Brand: Versius Drapes Generic: (Medical Equipment Drapes for Surgical Robotic System) Class A <table><tr><td>Device</td><td>Ref:</td><td>Shelf life</td></tr><tr><td>Versius</td><td>2010</td><td>12</td></tr></table>	Device	Ref:	Shelf life	Versius	2010	12	Approved																
Device	Ref:	Shelf life																								
Versius	2010	12																								

	Date of R&I: 18/09/2023 Fee Challan No.: 29480863108 PKR: 5000/- Dated: 12-09-2023		<table><tr><td>Instrument Bedside Unit Drape (Standard) (Qty. 1)</td><td>0</td><td>months</td></tr><tr><td>Versius Instrument Bedside Unit Drape (Long) (Qty. 1)</td><td>20300</td><td>12 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Standard) (Qty. 1)</td><td>20200</td><td>24 months</td></tr><tr><td>Versius Visualisation Bedside Unit Drape (Long) (Qty. 1)</td><td>20400</td><td>24 months</td></tr><tr><td>Versius Camera Head Drape (Qty. 1)</td><td>20500</td><td>36 months</td></tr><tr><td>Versius Camera Head Drape (Qty. 25)</td><td>20501</td><td>36 months</td></tr><tr><td>Drape Cap Insert (Qty. 1)</td><td>20900</td><td>12 months</td></tr></table>	Instrument Bedside Unit Drape (Standard) (Qty. 1)	0	months	Versius Instrument Bedside Unit Drape (Long) (Qty. 1)	20300	12 months	Versius Visualisation Bedside Unit Drape (Standard) (Qty. 1)	20200	24 months	Versius Visualisation Bedside Unit Drape (Long) (Qty. 1)	20400	24 months	Versius Camera Head Drape (Qty. 1)	20500	36 months	Versius Camera Head Drape (Qty. 25)	20501	36 months	Drape Cap Insert (Qty. 1)	20900	12 months	
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Versius Camera Head Drape (Qty. 25)	20501	36 months																							
Drape Cap Insert (Qty. 1)	20900	12 months																							
120.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details	<u>Legal Manufacturer:</u> KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned, issued in Oct. 2022	Fiber Light Cable & Light Source (Fiber Light Cable and Light Source with Adapters) Class A Shelf Life: N/A Codes / Sizes <table><tr><th>Article No.</th><th>Description</th></tr><tr><td>5164001</td><td>Light Source</td></tr></table>	Article No.	Description	5164001	Light Source	Approved																	
Article No.	Description																								
5164001	Light Source																								

	Date: 21/12/2022 Slip no. 651044546250 Rs. 5000.	LOA Validity: 31/12/2025		<table><tr><td></td><td>LED 2.2 80W</td></tr><tr><td>806550 35</td><td>Fiber Light Cable 5MM TL 3.5M</td></tr><tr><td>8095.07</td><td>Adapter Projector Side</td></tr><tr><td>809509</td><td>Adapter Endoscope Side</td></tr></table>		LED 2.2 80W	806550 35	Fiber Light Cable 5MM TL 3.5M	8095.07	Adapter Projector Side	809509	Adapter Endoscope Side														
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121.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI-00029 R&I Details: Date: 02/11/2022 Slip no. 1509539734 Rs. 25,000/-	<u>Legal Manufacturer:</u> KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany <u>LOA</u> Validity: 31/12/2025 <u>FSC:</u> Country of Origin Validity: Not mentioned, issued in Oct. 2022 <u>FSC:</u> FSC of Reference Country US Validity: not mentioned OR <u>EC Certificate</u> Validity: 17-12-2025 <u>ISO 13485</u> Validity: 31-05-2025	KARL STORZ Lasers (Laser Devices, Foot Switches for Laser, Laser Fibers (sterile/non- sterile)) Class B Shelf Life: N/A Codes / Sizes: <table><tr><th>Article</th><th>Name</th></tr><tr><td>27840L I</td><td>LASER Hand Instrument</td></tr><tr><td>8694</td><td>LASER Application Instrument, 23 cm</td></tr><tr><td>461000</td><td>LEUNIG- GREVERS LASER Application</td></tr><tr><td>1218AL</td><td>Sheath f.LASER probe and 1218A/AA</td></tr><tr><td>1218BL</td><td>Sheath f.LASER probe and 1218B/BA</td></tr><tr><td>27040X AL</td><td>Inner Tube for 27040 SD/SL</td></tr><tr><td>27042L V</td><td>Laser working element for vaporisation</td></tr><tr><td>27042V</td><td>Laser working element for vaporisation</td></tr><tr><td>27050V L</td><td>LASER Working Insert</td></tr><tr><td>27056E</td><td>LASER</td></tr></table>	Article	Name	27840L I	LASER Hand Instrument	8694	LASER Application Instrument, 23 cm	461000	LEUNIG- GREVERS LASER Application	1218AL	Sheath f.LASER probe and 1218A/AA	1218BL	Sheath f.LASER probe and 1218B/BA	27040X AL	Inner Tube for 27040 SD/SL	27042L V	Laser working element for vaporisation	27042V	Laser working element for vaporisation	27050V L	LASER Working Insert	27056E	LASER	Deferred since multiple products applied including both sterile and non sterile.
Article	Name																									
27840L I	LASER Hand Instrument																									
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			<table><tr><td>A</td><td>Guide Probe, 0.8 mm</td></tr><tr><td>27056E B</td><td>LASER Guide Probe, 1.5 mm</td></tr><tr><td>27056E C</td><td>LASER Guide Probe, 0.8 mm</td></tr><tr><td>27056E D</td><td>LASER Guide Probe, 1.5 mm</td></tr><tr><td>27056L A</td><td>Working Element</td></tr><tr><td>27056L B</td><td>KUNTZ Working Element</td></tr><tr><td>27056L E</td><td>LASER Working Element</td></tr><tr><td>27290L A</td><td>Laser-suction tube, outer sheath</td></tr><tr><td>27290L I</td><td>Motion control device</td></tr><tr><td>722010A</td><td>SCHERER LASER Rhinoscope Sheath 0°</td></tr><tr><td>722010B</td><td>SCHERER LASER Rhinoscope Sheath, 30°</td></tr><tr><td>8597P</td><td>LASER Mirror, Epipharynx, 20 mm</td></tr></table>	A	Guide Probe, 0.8 mm	27056E B	LASER Guide Probe, 1.5 mm	27056E C	LASER Guide Probe, 0.8 mm	27056E D	LASER Guide Probe, 1.5 mm	27056L A	Working Element	27056L B	KUNTZ Working Element	27056L E	LASER Working Element	27290L A	Laser-suction tube, outer sheath	27290L I	Motion control device	722010A	SCHERER LASER Rhinoscope Sheath 0°	722010B	SCHERER LASER Rhinoscope Sheath, 30°	8597P	LASER Mirror, Epipharynx, 20 mm	
A	Guide Probe, 0.8 mm																											
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722010B	SCHERER LASER Rhinoscope Sheath, 30°																											
8597P	LASER Mirror, Epipharynx, 20 mm																											
122.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details Date: 03/01/2023 Slip no. 777237723643 Rs. 5000.	<u>Legal Manufacturer:</u> KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned, issued in Oct. 2022 LOA Validity: 31/12/2025	KARL STORZ Motors (Motor Control Unit, Handpieces/Motors, Foot Switches for Motor Control Unit, Shaver/Drills (sterile/non-sterile)) Class A Shelf Life: N/A Codes / Sizes <table><tr><th>Article</th><th>Description</th></tr><tr><td>UM100</td><td>PowerUnit</td></tr><tr><td>407120 90</td><td>Handle for DRILLCUT -X II Handpieces</td></tr><tr><td>207116</td><td>Irrigation</td></tr></table>	Article	Description	UM100	PowerUnit	407120 90	Handle for DRILLCUT -X II Handpieces	207116	Irrigation	Deferred since multiple products applied including both sterile and non sterile.																
Article	Description																											
UM100	PowerUnit																											
407120 90	Handle for DRILLCUT -X II Handpieces																											
207116	Irrigation																											

			80	rod for Unidrive ENT		
123.	M/s. RECH International Address: 247/B, BLOCK 6 P.E.C.H.S, Karachi ELI: 00257 R&I details Date: 18-01-2024 Slip no. 064446774245 PKR 5000/- Dated: 22-12-2023	<u>Legal Manufacturer:</u> M/s Beijing Libeier Bio-engineering Institute Co., Ltd. 12 Chuangxin Road, Changping Science and Technology Park, Changping Area, Beijing, P. R. China. FSC validity: 26-10-2026 LOA Validity: 31/12/2026	Brand: Soprano Posterior cervical screw rod system instrument set Generic: Orthopedic Manual Surgical Instrument Set Class A Shelf Life: N/A Models: As per FSC			Approved subject to provision of codes.
124.	M/s. RECH International Address: 247/B, BLOCK 6 P.E.C.H.S, Karachi ELI: 00257 R&I details Date: 18-01-2024 Slip no. 064446774245 PKR 5000/- Dated: 22-12-2023	<u>Legal Manufacturer:</u> M/s Beijing Libeier Bio-engineering Institute Co., Ltd. 12 Chuangxin Road, Changping Science and Technology Park, Changping Area, Beijing, P. R. China. FSC validity: 26-10-2026 LOA Validity: 31/12/2026	Brand: Soprano Posterior cervical screw rod system instrument set Generic: Orthopedic Manual Surgical Instrument Set Class A Shelf Life: N/A Models: As per FSC			Approved subject to provision of codes.
125.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 62334559588 PKR: 25000/- Dated: 26-12-	<u>Manufacturing site:</u> M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Thyroid Stimulating Hormone (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026			Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body or CE certificate.

	2022			
126.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 7186517086 PKR: 25000/- Dated: 26-12-2022	<u>Manufacturing site:</u> M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Total Triiodothyronine Kit (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body/ CE certificate
127.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 476494378 PKR: 25000/- Dated: 26-12-2022	<u>Manufacturing site:</u> M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Total Beta Human Chrionic Gonadotropin (Total β -HCG) (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
128.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 3159985437 PKR: 25000/- Dated: 26-12-2022	<u>Manufacturing site:</u> M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Testosterone (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
129.	M/s Moody Global Services. Office No 14,	<u>Manufacturing site:</u> M/s Shenzhen Lifotronic Technology Co., Ltd	Brand: Lifotronic Generic: Prolactin (e CLIA)	Approved Subject To Submission Of Legalized & valid

	2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 5305306014 PKR: 25000/- Dated: 26-12-2022	Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	free sale certificate for country of origin as well as Reference regulatory body.
130.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 402484508 PKR: 25000/- Dated: 26-12-2022	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Free Triiodothyronine Kit (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
131.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 44087136672 PKR: 25000/- Dated: 26-12-2022	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Free Thyroxine Kit (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
132.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.	Brand: Lifotronic Generic: Ferritin Kit (e CLIA) Class B Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity:	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.

	(ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 69556614557 PKR: 25000/- Dated: 26-12-2022	ISO 13485 certificate validity: 25-03-2024	31-12-2027 Shelf Life: 12 months ISO 13485 Validity: 13-12-2026	
133.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 41294489319 PKR: 25000/- Dated: 26-12-2022	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Enhanced Washing Buffer Class B Size/specification: 50mL; 2x50mL LOA validity: 31-12-2027 Shelf Life: 24 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
134.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.: 3255837633 PKR: 5000/- Dated: 26-12-2022	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: Assay Cup Class A Size/specification: 300 T 3000 T LOA validity: 31-12-2027 Shelf Life: 24 months ISO 13485 Validity: 13-12-2026	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.
135.	M/s Moody Global Services. Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad (ELI-00926) Date of R&I: 26-10-2023 Fee Challan No.:	Manufacturing site: M/s Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. ISO 13485 certificate validity: 25-03-2024	Brand: Lifotronic Generic: 25-OH Vitamin D Total (e CLIA) Class A Size/specification: 50T, 2x50T, 100T, 2x100T LOA validity: 31-12-2027 Shelf Life: 12 months	Approved Subject To Submission Of Legalized & valid free sale certificate for country of origin as well as Reference regulatory body.

	3255837633 PKR: 25000/- Dated: 26-12-2022		ISO 13485 Validity: 13-12-2026	
136.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrahe- Quaideen, Karachi. (ELI-00078) R& I Date: 23-07-2020 Fee details: Amount: PKR 25000/- Slip: 2030402 Dated: (14-07-2020)	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1-5-1 WakinohamaKaigandori, Chuo-ku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 15-08-2027 Letter of authorization: 13-12-2025 FSC Japan issued on: 25-10-2019	SYSMEX HISCL FT3 Assay Kit with Calibrator & Consumables Code: AJ-162-809 HISCL FT3 Assay Kit Class B Shelf Life: 12 months Code: 054-2411-7 HISCL FT3 Calibrator Class B Shelf Life: 12 months Code: 064-4331-9 HISCL Substrate Reagent Set Class B Shelf Life: 12 months Code: 054-2361-8 HISCL Washing Solution Class A Shelf Life: 12 months Code: CH-219-079 HISCL Washing Solution Class A Shelf Life: 12 months	Approved .
137.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrahe- Quaideen, Karachi. (ELI-00078) R& I Date: 18-08-2020 Fee details: Amount: PKR 25000/- Slip: 2030412 Dated: 04-08-2020	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1-5-1 WakinohamaKaigandori, Chuo-ku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 15-08-2027 Letter of authorization: 13-12-2025 FSC Japan issued on: 25-10-2019	SYSMEX HISCL Insulin Assay Kit with Calibrator & Consumables Code: CV-679-198 HISCL Insulin Assay Kit Class B Shelf Life: 12 months Code: BW-351-765 HISCL Insulin Calibrator Class B Shelf Life: 12 months Code: CS-617-657 HISCL Diluent Class A Shelf Life: 12 months Code: 064-4331-9 HISCL Substrate Reagent Set Class B Shelf Life: 12 months Code: 054-2361-8 HISCL Washing Solution	Approved .

			Class A Shelf Life: 12 months Code: CH-219-079 HISCL Washing Solution Class A Shelf Life: 12 months	
138.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrache-Quaideen, Karachi. (ELI-00078) R&I Date: 18-08-2020 Fee details: Amount: PKR 25000/- Slip: 2030411 Dated: 04-08-2020	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1-5-1 WakinohamaKaigandori, Chuo-ku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 15-08-2027 Letter of authorization: 13-12-2025 FSC Japan issued on: 25-10-2019	SYSMEX HISCL TSH Assay Kit with Calibrator & Consumables Code: BB-600-695 HISCL TSH Assay Kit Class B Shelf Life: 12 months Code: 054-2441-9 HISCL TSH Calibrator Class B Shelf Life: 12 months Code: CS-617-657 HISCL Diluent Class A Shelf Life: 12 months Code: 064-4331-9 HISCL Substrate Reagent Set Class B Shelf Life: 12 months Code: 054-2361-8 HISCL Washing Solution Class A Shelf Life: 12 months Code: CH-219-079 HISCL Washing Solution Class A Shelf Life: 12 months	Approved .
139.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shahrache-Quaideen, Karachi. (ELI-00078) R&I Date: 18-08-2020 Fee details: Amount: PKR 25000/- Slip: 2030416 Dated: 16-10-2020	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1-5-1 WakinohamaKaigandori, Chuo-ku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 15-08-2027 Letter of authorization: 13-12-2025 FSC Japan issued on: 25-10-2019	SYSMEX HISCL FT4 Assay Kit with Calibrator & Consumables 1Code: CB-825-811 HISCL FT4 Assay Kit Class B Shelf Life: 12 months Code: 054-2381-2 HISCL FT4 Calibrator Class B Shelf Life: 12 months Code: 064-4331-9 HISCL Substrate Reagent Set Class B Shelf Life: 12 months	Approved .

			Code: 054-2361-8 HISCL Washing Solution Class A Shelf Life: 12 months Code: CH-219-079 HISCL Washing Solution Class A Shelf Life: 12 months	
140.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shakrahe-Quaideen, Karachi. (ELI-00078) R& I Date: 23-03-2023 Fee details: Amount: PKR 5000/- Slip: 049279101703 Dated: 21-03-2023	(Legal Manufacturer) Name: M/s LABiTec LAbor BioMedical Technologies GmbH An der Strusbek 6 22926 Ahrensburg Germany. ISO 13485 Certificate validity: 09.07.2027 Letter of authorization: 01.04 2025 FSC Germany issued on: 13.09.2019	Semi-automated Blood Coagulation Analyzer CA-104 along with Accessories & Consumables Class A Shelf Life: N/A Codes: CP944871 / Sizes (if any) Accessories & Consumables: Cuvette FL Code: AG405069 Cuvette FL Code: BD900346 CA-104 Thermal Paper Code: AC845489 DIN 18 Siliconized 8 mL White Code: CE414580 Cuv CARD FOR CA1 Code: CV198522	Approved .
141.	Applicant: M/s S. Ejazuddin & Co., 237-B, Block II, PECHS, Shakrahe-Quaideen, Karachi. (ELI-00078) R& I Date: 30.03.2020 Fee details: Amount: PKR 5000/- Slip: 1945894 Dated: 18.03.2020	(Legal Manufacturer) Name: M/s LABiTec LAbor BioMedical Technologies GmbH An der Strusbek 6 22926 Ahrensburg Germany. ISO 13485 Certificate validity: 09.07.2027 Letter of authorization: 01.04 2025 FSC Germany issued on: 13.09.2019	Semi-automated Blood Coagulation Analyzer CA-101 along with Accessories & Consumables Class A Shelf Life: N/A Codes: BX533278 / Sizes (if any) Accessories & Consumables: SUL-400A Cuvette FL Complete Code: AG405069 Cuvette FL FOR CA1 Code: BD900346 CA-104 Thermal Paper Code: AC845489 DIN 18 Siliconized 8 mL White Code: CE414580	Approved .

			Cuv CARD FOR CA1 Code: CV198522	
142.	Applicant: M/s S. Ejazuddin & Co., 236-C, Block II, PECHS, Shahrahe- Quaideen, Karachi. (ELI-00078) R& I Date: 23-05-2024 Fee details: Amount: PKR 25000/- Slip: 2827736224 Dated: 16-05- 2024	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1- 5-1 Wakinohama-Kaigandori, Chuoku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 09.07.2027 Letter of authorization: 01.04 2025 FSC Germany issued on: 13.09.2019	Sysmex Controls for Sysmex Automated Hematology Analyzer XN-31 Code: AF640985 → XN CHECK L1 CV649926 → XN CHECK L2 BV166979 → XN CHECK L3 Class B Shelf Life: 12 month	Approved .
143.	Applicant: M/s S. Ejazuddin & Co., 236-C, Block II, PECHS, Shahrahe- Quaideen, Karachi. (ELI-00078) R& I Date: 06-12-2024 Fee details: Amount: PKR 31000/- Slip: 2827736224 Dated: 28-11- 2024	(Legal Manufacturer) Name: M/s SYSMEX CORPORATION 1- 5-1 Wakinohama-Kaigandori, Chuoku, Kobe 651-0073, Japan. ISO 13485 Certificate validity: 09.07.2027 Letter of authorization: 01.04 2025 FSC Germany issued on: 13.09.2019	Sysmex Reagents & Controls of Sysmex XR- Series Automated Hematology Analyzers Code: BY541589 Name: Lysercell WDF II Shelf life: 12 months Open vial: 90 days Code: 904-1141-4 Name: SULFOLYSER Shelf life: 12 months Open vial: 90 days Code: ZPPBY541589 Name: Lysercell WDF II Shelf life: 12 months Open vial: 90 days Code: 230303 Name: WRP CHECK EX Shelf life: 93 days Open vial: 05 days Class B	Approved .
144.	Applicant: M/s BIOMADICS. Gate #1, 211/B Sindhi Muslim Corporation Housing Society, Block B, Karachi	(Legal Manufacturer) Name: M/s Diagon Ltd. Manufacturer Address: No. H – 1047Budapest, Baross u, Street 48 – 52, Hungary. FSC Hungary: issued on 10.07.2020	Cellagon 03 Hematology Analyzer (g-Cell3) Code: (g-Cell3) Cellagon – 03 Hematology Analyzer Class A Letter of authorization: 30-07-2026	Approved .

	(ELI-00432) Fee details: Amount: PKR 5000/- Slip: 20637661382 Dated: 26-01-2023			
145.	Applicant: M/s BIOMADICS. Gate #1, 211/B Sindhi Muslim Corporation Housing Society, Block B, Karachi (ELI-00432) Fee details: Amount: PKR 5000/- Slip: 973264749228 Dated: 26-01-2023	(Legal Manufacturer) Name: M/s Biocytech Corporation sdn. bhd Manufacturer Address: No.820, Simpang Empat, Jalan Lahat, 31450 Menglembu, Ipoh, Perak, Malaysia. FSC Hungary: issued on 18-09.2020 Letter of authorization: 30-07-2026	Cellagon 03 Hematology Analyzer Reagents Model: 1. Cellaton – D (h73101) 2. Cellalyse (h73102) 3. CellaClean (h73136) 4. D-Check D 2.5 Low (DDC-18T2,5 L) 5. D-Check D 2.5 Normal (DDC-18T2,5 N) 6. D-Check D 2.5 High (DDC-18T2,5 H) 7. D-Cal D (DCALD3,0) Class A Shelf life: 02 years	Approved .
146.	Applicant: M/s BIOMADICS. Gate #1, 211/B Sindhi Muslim Corporation Housing Society, Block B, Karachi (ELI-00432) Fee details: Amount: PKR 5000/- Slip: 0916890539 Dated: 30-07-2021	(Legal Manufacturer) Name: M/s Biocytech Corporation sdn. bhd Manufacturer Address: No.820, Simpang Empat, Jalan Lahat, 31450 Menglembu, Ipoh, Perak, Malaysia. FSC Hungary: issued on 18-09.2020 Letter of authorization: 30-07-2026	PATHTEZT PAP SMEAR COLLECTION TEST KIT (PAP SMEAR TEST INSTRUMENT) Model: 1. Preserve Cell Solution 20ML (PCS-200920) 2. Non-Gyn Preserve Cell Solution 20ML (NGPCS-200920) 3. Preserve Cell Solution 926ML (PCS-926) 4. Cytolysis Solution 926ML (CTLS-9260604) 5. Filter-Slide Test (FST-36100) 6. Non-Gyn Filter-Slide Test (NFST-5100) 7. Gyn Filter (GF-0825100) 8. Non-Gyn Filter (NGF-0525100) 9. Urine Cell Filter (UCF-0813100) 10. Cyto Slide (CS-36100) 11. Pretreatment Kit (Pre-Filter) (PS-250)	Approved .

			Class A Shelf life: 02 years	
147.	Applicant: M/s : TRI TECH INTERNATIO NAL 10 C 6 SUNSET COMM LINE PHASE II DEFENCE HOUSING AUTHORITY KARACHI (ELI-00247) Fee details: Amount: PKR 25000/- Slip: 2006272 Dated: 09-07- 2020	(Legal Manufacturer) Name: M/s Bistos, 7th Floor, A Bldg, Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon- gu, Sunngnam-si, Gyeonggi-do, Korea. FSC Korea: issued on 30-01-2020 Letter of authorization: 26-06-2028	Fetal Doppler System Model: BT-250 Class B Shelf life: 05 years EC Certificate: expired ISO 13485 Certificate validity: expired	Deferred for submission of documents from legal manufacturer i.e. valid and legalized free sale certificate, EC certificate, ISO 13485 certificate along with declaration of conformity.
148.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Stomach Tube Sizes: FR 6, FR 8, FR 10, FR 12, FR 14, FR 16, FR 18, FR 20, FR 22 Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31- 07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
149.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Feeding Tube Sizes: FR 4, FR 5, FR 6, FR 8, FR 10, FR 12, FR 14, FR 16, FR 18, FR 20 Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31- 07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC

150.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Suction Catheter Sizes: Mucus Extractor type: Sizes: FR 6, FR 8, FR 10, FR 12, FR 14, FR 16, FR 18, FR 20 Normal: Sizes: FR 5, FR 6, FR 8, FR 10, FR 12, FR 14, FR 16, FR 18, FR 20, FR 22 Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31- 07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
151.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Yankauer Suction Set Sizes: Yankauer Suction handle eith suction connecting tube Sizes: 9/32", 1/4", 3/16" Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31- 07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
152.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Nasal Oxygen Cannula Sizes: Yankauer Suction handle eith suction connecting tube Sizes: 9/32", 1/4", 3/16" Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31- 07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
153.	Applicant: M/S MEDICHEM ENTERPRISES	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD.	Promed Nebulizer with Aerosol Mask Sizes: Adult standard, Pediatric	Approved subject to fee verification and valid FSC

	Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Standard, Adult elongated, Pediatric elongated, Infant Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
154.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Non-Rebreathing Mask Sizes: Adult standard, Pediatric Standard, Adult elongated, Pediatric elongated, Infant Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
155.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Oxygen Mask Sizes: Adult standard, Pediatric Standard, Adult elongated, Pediatric elongated, Infant Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
156.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China:	Promed Standard Endotracheal Tube - Cuffed Sizes: 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0 mm, 6.5 mm, 7.0mm, 7.5mm, 8.0 mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years	Approved subject to fee verification and valid FSC

	23-12-2024 Fee details:	Validity: 24-10-2025 FSC (RRA) UK Submitted	EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
157.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Standard Endotracheal Tube - Uncuffed Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0 mm, 6.5 mm, 7.0mm, 7.5mm, 8.0 mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
158.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Oral Preformed Endotracheal Tube – Cuffed Sizes: 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5 mm, 7.0mm, 7.5mm, 8.0 mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
159.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China:	Promed Nasal Preformed Endotracheal Tube – Cuffed Sizes: 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5 mm, 7.0mm, 7.5mm, 8.0 mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years	Approved subject to fee verification and valid FSC

	23-12-2024 Fee details:	Validity: 24-10-2025 FSC (RRA) UK Submitted	EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
160.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Reinforced Endotracheal Tube - Cuffed Sizes: 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5 mm, 7.0mm, 7.5mm, 8.0 mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
161.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/s BONREE MEDICAL CO. LTD. 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, Peoples's Republic of China FSC China: Validity: 24-10-2025 FSC (RRA) UK Submitted	Promed Endotracheal Tube Introducer (Bougie) / Intubating Stylet Sizes: 1. Endotracheal Tube Introducer (Bougie): A. Hollow Type: Sizes: FR 10, FR 15 B. Solid Type: Sizes: FR 6, FR 10, FR 15 2. Intubating Stylet: Sizes: FR 6, FR 10, FR 12, FR 14 Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
162.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society,	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong	Promed Endobronchial Tube Type: 1. Standard Right Sided 2. Standard Left Sided Sizes Available: 26Fr, 28 Fr, 32 Fr, 35Fr, 37Fr, 39Fr, 41Fr, 42Fr	Approved subject to fee verification and valid FSC

	Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
163.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Promed Tracheostomy Tube Type: 1. Standard Cuffed 2. Standard Uncuffed Sizes available: 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
164.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Promed Laryngeal Mask Device Type: 1. Standard Grilled 2. Standard Ungrilled 3. Reinforced Grilled 4. Reinforced Ungrilled Sizes Available: 1#, 1.5#, 2#, 2.5#, 3#, 4#, 5# Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
165.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society,	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong	Promed 2-Way Latex Foley Catheter Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Class B Shelf life: 05 years	Approved subject to fee verification and valid FSC

	Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
166.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Promed 3-Way Latex Foley Catheter Sizes: 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
167.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Promed 2-Way Silicon Foley Catheter Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
168.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD. Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	Promed 3-Way Silicon Foley Catheter Sizes: 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
169.	Applicant: M/S MEDICHEM ENTERPRISES	(Legal Manufacturer) Name: M/S GUANGDONG ECAN MEDICAL CO., LTD.	Promed 3-Way Silicon Urethral Catheter Sizes: 14Fr, 16Fr, 18Fr, 20Fr, 22Fr,	Approved subject to fee verification and valid FSC

	Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 23-12-2024 Fee details:	Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China FSC China: Validity: 21-10-2026 FSC (RRA) UK Validity: 30-06-2029	24Fr, 26Fr, 28Fr, 30Fr Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 31-07-2025 Letter of authorization: 26-06-2028	
170.	Applicant: M/S MEDICHEM ENTERPRISES Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi (ELI-00252) Date of R&I: 30-12-2024 Fee details:	(Legal Manufacturer) Name: M/S NINGBO LUKE MEDICAL CO., LTD. Gujiayan, Yangming Road 315400 Yuyao City, Zhejiang Province, People's Republic of China FSC China: Validity: 16-08-2026 FSC (RRA) Germany submitted	Promed Drainage Tube Sizes: 100% Silicon Round Perforated Drainage Tube: Sizes: 10Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr 100% Silicon Flat Perforated Drainage Tube: Sizes: • 7mm × 15 Fr, (3/4th part perforated) • 10mm × 15 Fr, (3/4th part perforated) • 4mm × 10 Fr, (Full perforated) • 7mm × 15 Fr, (Full perforated) • 10mm × 15 Fr, (Full perforated) • 13mm × 15 Fr (Full perforated) Class B Shelf life: 05 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 03-10-2026 Letter of authorization: 26-06-2028	Approved subject to fee verification and valid FSC
171.	Applicant: M/s MH Pharma Flat No. 1118, 11th Floor, Eden Heights, 6 Main Gulberg, Jail Road, Lahore (ELI-00720) Date of R&I: 24/01/2024 Fee details:	(Legal Manufacturer) Name: M/S Guilin Zizhu Latex Co., Ltd.. Address: No.6 Wushan Road, Guilin, China. FSC China: Validity: 19-01-2025	GOBON SINGLE-USE STERILE RUBBER SURGICAL GLOVES Sizes, S,M,L XL Class B Shelf life: 04 years EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 03-10-2026 Letter of authorization: 23-10-2026	Approved

	PKR 25000/- Slip# 9524409940 Dated 16/11/2023			
172.	Applicant: M/s Moon Enterprises 5/6 Rabani Road , Old Anarkali Lahore (ELI-00356) Date of R&I: 07/06/2023 Fee details: PKR 5000/- Slip# 06807696761 Dated: 25-05-2023	(Legal Manufacturer) Name: M/S AYSET TIBBİ ÜRÜNLER VE PLASTİK ELEKTRONİK GIDA TEMİZLİK MADDELERİ SAN. A.Ş Sarıhamzalı Mah. 47007 Sk No:36/A Seyhan Turkey. FSC China: submitted	Ayset® PET EDTA (K2, K3) (Vacuum Blood Collection Tube) Class A Shelf life: 02 years Letter of authorization: 16/Oct/2027	Approved
173.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Challan No.: 61173237210 PKR: 25000/- Dated: 03-05-2024	Legal Manufacturer: Name: M/s HUNTLEIGH HEALTH CARE Ltd. located at Address: 35 Portman moor Road, Cardiff CF24 5HN United Kingdom FSC Validity <i>(country of origin):UK</i> 18-06-2024 ISO 13485 Certificate validity: 16-12-2027 EC Certificate validity: 10-01-2026 LOA Validity: 30-05-2028	HUNTLEIGH Vascular Doppler - DMX Class: B MD group: Kit Shelf life: For assay: 5 Years Storage condition: 2 – 43°C	Approved
174.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Challan No.:	Legal Manufacturer: Name: M/s HUNTLEIGH HEALTH CARE Ltd. located at Address: 35 Portman moor Road, Cardiff CF24 5HN United Kingdom FSC Validity <i>(country of origin):UK</i> 18-06-2024 ISO 13485 Certificate validity: 16-12-2027	HUNTLEIGH Fetal Doppler SR-3 Class: B MD group: Kit Shelf life: For assay: 5 Years Storage condition: 2 – 43°C	Approved

	61173237210 PKR: 25000/- Dated: 03-05-2024	EC Certificate validity: 10-01-2026 LOA Validity: 30-05-2028		
175.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Challan No.: PKR: 25000/- Dated: 03-05-2024	Legal Manufacturer: Name: M/s HUNTLEIGH HEALTH CARE Ltd. located at Address: 35 Portman moor Road, Cardiff CF24 5HN United Kingdom FSC Validity (country of origin):UK 18-06-2024 ISO 13485 Certificate validity: 16-12-2027 EC Certificate validity: 10-01-2026 LOA Validity: 30-05-2028	HUNTLEIGH TEAM3A FETAL Monitor NSB Class: B MD group: Kit Shelf life: For assay: 5 Year Storage condition: 2 – 43°C	Approved
176.	M/s Biologic Medical Systems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Chillan No.: 61173237210 PKR: 25000/- Dated: 02-05-2024	Legal Manufacturer: Medi-Care Solutions S R L Legal office VIA della Zecca Nr. 1 40121 Bologna BO Facility (Production Site and offices) Via P.Nenni NR.3 40026 Imola BO Italy Name: M/s EuroClinic Medi-Care Solutions S.r.l, Italy LOA Validity: 31-12-2025 Until further notice. FSC Validity (country of origin): 09-02-2023 EC Certificate validity: 12-07-2022 ISO 13485 Certificate validity: 15-11-2026	OTOCOMPACT PROFESSIONAL TYPE 11 Class: B MD group: System Shelf life: For assay: 7 Years For controls: 7 Years Storage condition: 2 – 43°C	Approved
177.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-	Legal Manufacturer: Medi-Care Solutions S R L Legal office VIA della Zecca Nr. 1 40121 Bologna BO Facility (Production Site and offices) Via P.Nenni NR.3 40026 Imola BO Italy Name: M/s EuroClinic Medi-Care Solutions S.r.l, Italy LOA Validity:	OTOCOMPACT STEEL TYPE 11 Class: B MD group: System Shelf life: For assay: 7 Years For controls: 7 Years Storage condition: 2 – 43°C	Approved

	2024 Fee Challan No.: 0740001208 PKR: 25000/- Dated: 03-05-2024	31-12-2025 Until further notice. FSC Validity <i>(country of origin):</i> 09-02-2023 EC Certificate validity: 12-07-2022 ISO 13485 Certificate validity: 15-11-2026		
178.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Challan No.: 394185381 PKR: 25000/ Dated: 03-05-2024	Legal Manufacturer: Name: M/s Shanghai Seegen Photoelectric Technology Co.,Ltd.,China Manufacturer Address: Floor 3,Building 1,No 4299 jindu Road Minghang Dist., China. LOA issued on: 29-03-2023 FSC Validity (country of origin): 21-01-2022 EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 05-03-2026	SEEGEN DISPOSABLE ELECTRONIC FXIBLE CHOLEDOCHOSCOPE TYPE 11 Class: B MD group: Kit Shelf life: For assay: 24 months For controls: 24 months Storage condition: 2 – 40°	Approved subject to submission of valid and legalized free sale certificate.
179.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated: 03-05-2024 Fee Challan No.: 394185381 PKR: 25000/ Dated: 03-05-2024	Legal Manufacturer: Name: M/s Shanghai Seegen Photoelectric Technology Co.,Ltd.,China Manufacturer Address: Floor 3,Building 1,No 4299 jindu Road Minghang Dist., China. LOA issued on: 29-03-2023 FSC Validity (country of origin): 21-01-2022 EC Certificate validity: 26-05-2024 ISO 13485	SEEGEN IMAGING PROCESSOR (INCLUDING LIGTH SOURCE)TYPE 11 Class: B MD group: Kit Shelf life: For assay: 24 months For controls: 24 months Storage condition: 2 – 40	Approved subject to submission of valid and legalized free sale certificate.

		Certificate validity: 05-03-2026		
180.	M/s Biologic Medical Sytems Karachi. (ELI-00346) D.O.I: 04-05-2024 Dy. No.: DRAP (R&I) Dated:03-05-2024 Fee Challan No.: 394185381 PKR:25000/ Dated:03-05-2024	Legal Manufacturer: Name: M/s Shanghai Seegen Photoelectric Technology Co.,Ltd.,China Manufacturer Address: Floor 3,Building 1,No 4299 jindu Road Minghang Dist., China. LOA issued on: 29-03-2023 FSC Validity (country of origin): 21-01-2022 EC Certificate validity: 26-05-2024 ISO 13485 Certificate validity: 05-03-2026	SeeGen Disposable Electronic Flexible CystoUreteroscope System Class: B MD group: Kit Shelf life: For assay: 24 months For controls: 24 months Storage condition: 2 – 40°	Approved subject to submission of valid and legalized free sale certificate.
181.	Applicant Name: M/s. Muller & Phipps, Uzma Court, Main Clifton Road Karachi. ELI-00030 R&I Details 19/06/2020 Fee Details. Fee Challan No. 0808821. Paid Fee. 5000 dated 03-06-2020 Tracking ID 2X5-SR2-8DPH	Name of Manufacturer: M/s. ConvaTec Limited. First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK. Manufacturing Site(s): ConvaTec Dominican RePublic, Inc. Carretera Sanchez, Km. 18.5, Parque Industrial Itabo, S.A. Dominican Republic. FSC Validity: N/A LOA Validity: 28/01/202.	Brand Name: Surfit Plus Stomahesive Wafer Class A Shelf life: 5 years Codes/Sizes (if any): 38MM- 125143 45MM-125144 57MM-125145 70MM-400949	Approved.
182.	Applicant Name: M/s. Radiant Medical Private Limited.	Name of Manufacturer: M/s. Gimmi GmbH Address: Gimmi GmbH Carl-Zeiss-Str. 6	Brand Name: Gimmi Surgical Instruments Class B Shelf life:	Approved subject to submission of shelf life, codes and instruments involved/applied.

	Address : 06-Sher Shah Block New Garden Town Lahore, Pakistan ELI-000135 R&I Details 10/05/2024 Fee Details. Fee Challan No. 358853565105 Paid Fee. 25000 dated 03-04-2024 Tracking ID VY9-NDU-XQ67	78532 Tuttlingen Germany Tel: +49 (7461) 96590 0 Fax: +49 (7461) 9659033 www.gimmi.de FSC: Germany, Valid FSC Marketing Authorization Letter (LOA): Valid till: 31/12/2025 Production Quality Management System Certificate (ISO 13485) TUV DAkkS ISO 13485 certificate Valid till 31/05/2027 EU Quality Management System Certificate (MDR): TÜV SÜD Product Service GmbH valid along with extension letter valid 31 December 2028																																															
183.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790298 Dated:11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid From:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 12.03.2021 <u>Expiry Date:</u> 27.07.2022	Brand Name: Holding Micropipettes Generic Name: Holding Micropipettes <table><tr><th>Ref no.</th><th>Product Description</th><th></th></tr><tr><td>HP-80-0°</td><td>Haltepipette-OD:80µm,</td><td>BA:0°</td></tr><tr><td>HP-80-20°</td><td>Haltepipette-OD:80µm,</td><td>BA:20°</td></tr><tr><td>HP-80-30°</td><td>Haltepipette-OD:80µm,</td><td>BA:30°</td></tr><tr><td>HP-80-35°</td><td>Haltepipette-OD:80µm,</td><td>BA:35°</td></tr><tr><td>HP-80-40°</td><td>Haltepipette-OD:80µm,</td><td>BA:40°</td></tr><tr><td>HP-100-0°</td><td>Haltepipette-OD:100µm,</td><td>BA:0°</td></tr><tr><td>HP-100-20°</td><td>Haltepipette-OD:100µm,</td><td>BA:20°</td></tr><tr><td>HP-100-30°</td><td>Haltepipette-OD:100µm,</td><td>BA:30°</td></tr><tr><td>HP-100-35°</td><td>Haltepipette-OD:100µm,</td><td>BA:35°</td></tr><tr><td>HP-100-40°</td><td>Haltepipette-OD:100µm,</td><td>BA:40°</td></tr><tr><td>HP-110-30°</td><td>Haltepipette-OD:110µm,</td><td>BA:30°</td></tr><tr><td>HP-110-35°</td><td>Haltepipette-OD:110µm,</td><td>BA:35°</td></tr><tr><td>HP-120-0°</td><td>Haltepipette-OD:120µm,</td><td>BA:0°</td></tr><tr><td>HP-</td><td>Haltepipette-OD:120µm,</td><td>BA:20°</td></tr></table>	Ref no.	Product Description		HP-80-0°	Haltepipette-OD:80µm,	BA:0°	HP-80-20°	Haltepipette-OD:80µm,	BA:20°	HP-80-30°	Haltepipette-OD:80µm,	BA:30°	HP-80-35°	Haltepipette-OD:80µm,	BA:35°	HP-80-40°	Haltepipette-OD:80µm,	BA:40°	HP-100-0°	Haltepipette-OD:100µm,	BA:0°	HP-100-20°	Haltepipette-OD:100µm,	BA:20°	HP-100-30°	Haltepipette-OD:100µm,	BA:30°	HP-100-35°	Haltepipette-OD:100µm,	BA:35°	HP-100-40°	Haltepipette-OD:100µm,	BA:40°	HP-110-30°	Haltepipette-OD:110µm,	BA:30°	HP-110-35°	Haltepipette-OD:110µm,	BA:35°	HP-120-0°	Haltepipette-OD:120µm,	BA:0°	HP-	Haltepipette-OD:120µm,	BA:20°	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.
Ref no.	Product Description																																																
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HP-100-40°	Haltepipette-OD:100µm,	BA:40°																																															
HP-110-30°	Haltepipette-OD:110µm,	BA:30°																																															
HP-110-35°	Haltepipette-OD:110µm,	BA:35°																																															
HP-120-0°	Haltepipette-OD:120µm,	BA:0°																																															
HP-	Haltepipette-OD:120µm,	BA:20°																																															

			<table><tr><td>120-20°</td><td></td><td></td></tr><tr><td>HP-120-30°</td><td>Haltepipette-OD:110µm, BA:30°</td><td></td></tr><tr><td>HP-120-35°</td><td>Haltepipette-OD:120µm, BA:35°</td><td></td></tr><tr><td>HP-120-40°</td><td>Haltepipette-OD:120µm, BA:40°</td><td></td></tr></table> Code: 001 MD Group: Single Class: B Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Shelf Life: 3 Years Storage Condition: Store at room temperature below 30°C	120-20°			HP-120-30°	Haltepipette-OD:110µm, BA:30°		HP-120-35°	Haltepipette-OD:120µm, BA:35°		HP-120-40°	Haltepipette-OD:120µm, BA:40°																																									
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184.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date:18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790339 Dated:11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid From:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 12.03.2021 <u>Expiry Date:</u> 27.07.2022	Brand Name: DENU – Tips Generic Name: DENU – Tips <table><tr><td>Article no.</td><td>Product list</td><td>Firm shall submit the differential fee for Class B, as per DPEP fee schedule notified in SRO-1334 Dated 30th August 2024.</td></tr><tr><td>GY-080/1</td><td>Denu-Tip 80µm; 10 tips per vial</td><td></td></tr><tr><td>GY-100/1</td><td>Denu-Tip 100µm; 10 tips per vial</td><td></td></tr><tr><td>GY-125/1</td><td>Denu-Tip 125µm; 10 tips per vial</td><td></td></tr><tr><td>GY-130/1</td><td>Denu-Tip 130µm; 10 tips per vial</td><td></td></tr><tr><td>GY-135/1</td><td>Denu-Tip 135µm; 10 tips per vial</td><td></td></tr><tr><td>GY-140/1</td><td>Denu-Tip 140µm; 10 tips per vial</td><td></td></tr><tr><td>GY-145/1</td><td>Denu-Tip 145µm; 10 tips per vial</td><td></td></tr><tr><td>GY-150/1</td><td>Denu-Tip 150µm; 10 tips per vial</td><td></td></tr><tr><td>GY-155/1</td><td>Denu-Tip 155µm; 10 tips per vial</td><td></td></tr><tr><td>GY-165/1</td><td>Denu-Tip 165µm; 10 tips per vial</td><td></td></tr><tr><td>GY-170/1</td><td>Denu-Tip 170µm; 10 tips per vial</td><td></td></tr><tr><td>GY-175/1</td><td>Denu-Tip 175µm; 10 tips per vial</td><td></td></tr><tr><td>GY-200/1</td><td>Denu-Tip 200µm; 10 tips per vial</td><td></td></tr><tr><td>GY-275/1</td><td>Denu-Tip 275µm; 10 tips per vial</td><td></td></tr><tr><td>GY-300/1</td><td>Denu-Tip 300µm; 10 tips per vial</td><td></td></tr><tr><td>GY-550/1</td><td>Denu-Tip 550µm; 10 tips per vial</td><td></td></tr></table>	Article no.	Product list	Firm shall submit the differential fee for Class B, as per DPEP fee schedule notified in SRO-1334 Dated 30th August 2024.	GY-080/1	Denu-Tip 80µm; 10 tips per vial		GY-100/1	Denu-Tip 100µm; 10 tips per vial		GY-125/1	Denu-Tip 125µm; 10 tips per vial		GY-130/1	Denu-Tip 130µm; 10 tips per vial		GY-135/1	Denu-Tip 135µm; 10 tips per vial		GY-140/1	Denu-Tip 140µm; 10 tips per vial		GY-145/1	Denu-Tip 145µm; 10 tips per vial		GY-150/1	Denu-Tip 150µm; 10 tips per vial		GY-155/1	Denu-Tip 155µm; 10 tips per vial		GY-165/1	Denu-Tip 165µm; 10 tips per vial		GY-170/1	Denu-Tip 170µm; 10 tips per vial		GY-175/1	Denu-Tip 175µm; 10 tips per vial		GY-200/1	Denu-Tip 200µm; 10 tips per vial		GY-275/1	Denu-Tip 275µm; 10 tips per vial		GY-300/1	Denu-Tip 300µm; 10 tips per vial		GY-550/1	Denu-Tip 550µm; 10 tips per vial		Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.
Article no.	Product list	Firm shall submit the differential fee for Class B, as per DPEP fee schedule notified in SRO-1334 Dated 30th August 2024.																																																					
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			GY-080/20	Denu-Tip 80µm; 20 tips per vial	
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			GY-130/20	Denu-Tip 130µm; 20 tips per vial	
			GY-135/20	Denu-Tip 135µm; 20 tips per vial	
			GY-140/20	Denu-Tip 140µm; 20 tips per vial	
			GY-145/20	Denu-Tip 145µm; 20 tips per vial	
			GY-150/20	Denu-Tip 150µm; 20 tips per vial	
			GY-155/20	Denu-Tip 155µm; 20 tips per vial	
			GY-165/20	Denu-Tip 165µm; 20 tips per vial	
			GY-170/20	Denu-Tip 170µm; 20 tips per vial	
			GY-175/20	Denu-Tip 175µm; 20 tips per vial	
			GY-200/20	Denu-Tip 200µm; 20 tips per vial	
			GY-275/20	Denu-Tip 275µm; 20 tips per vial	
			GY-300/20	Denu-Tip 300µm; 20 tips per vial	
			GY-550/20	Denu-Tip 550µm; 20 tips per vial	
			GY-080/5	Denu-Tip 80µm; 5 tips per vial	
			GY-100/5	Denu-Tip 100µm; 5 tips per vial	
			GY-125/5	Denu-Tip 125µm; 5 tips per vial	
			GY-130/5	Denu-Tip 130µm; 5 tips per vial	
			GY-135/5	Denu-Tip 135µm; 5 tips per vial	
			GY-140/5	Denu-Tip 140µm; 5 tips per vial	
			GY-145/5	Denu-Tip 145µm; 5 tips per vial	
			GY-150/5	Denu-Tip 150µm; 5 tips per vial	
			GY-155/5	Denu-Tip 155µm; 5 tips per vial	
			GY-165/5	Denu-Tip 165µm; 5 tips per vial	
			GY-170/5	Denu-Tip 170µm; 5 tips per vial	
			GY-175/5	Denu-Tip 175µm; 5 tips per vial	
			GY-200/5	Denu-Tip 200µm; 5 tips per vial	
			GY-275/5	Denu-Tip 275µm; 5 tips per vial	
			GY-300/5	Denu-Tip 300µm; 5 tips per vial	
			GY-550/5	Denu-Tip 550µm; 5 tips per vial	
			Code: GY MD Group: Single Class: B Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Shelf Life: 3 Years		

			Storage Condition: Store at room temperature below 30°C																																					
185.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790338 Dated:11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid From:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 12.03.2021 <u>Expiry Date:</u> 27.07.2022	Brand Name: Denuding Micropipettes Generic Name: Denuding Micropipettes Code: 005 MD Group: Single Class: B Shelf Life: 3 years Storage Condition: Store at room temperature below 30°C	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.																																				
186.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790337 Dated:11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid From:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 2021.03.12 <u>Expiry Date:</u> 2022.07.27	Brand Name: Biopsy Pipettes Generic Name: Biopsy Pipettes <table><tr><th>Ref No.</th><th>Product description</th><th>Pipette-ID</th></tr><tr><td>BP-10-0°-bl</td><td>Blastomere Biopsie-Pipette 10 µm, BA:0°, blunt</td><td>10</td></tr><tr><td>BP-10-0°-be</td><td>Blastomere Biopsie-Pipette 10 µm, BA:0°, bevelled</td><td>10</td></tr><tr><td>BP-10-30°-bl</td><td>Blastomere Biopsie-Pipette 10 µm, BA:30°, blunt</td><td>10</td></tr><tr><td>BP-10-30°-be</td><td>Blastomere Biopsie-Pipette 10 µm, BA:30°, bevelled</td><td>10</td></tr><tr><td>BP-10-35°-bl</td><td>Blastomere Biopsie-Pipette 10 µm, BA:35°, blunt</td><td>10</td></tr><tr><td>BP-10-35°-be</td><td>Blastomere Biopsie-Pipette 10 µm, BA:35°, bevelled</td><td>10</td></tr><tr><td>BP-15-0°-bl</td><td>Blastomere Biopsie-Pipette 15 µm, BA:0°, blunt</td><td>15</td></tr><tr><td>BP-15-0°-be</td><td>Blastomere Biopsie-Pipette 15 µm, BA:0°, bevelled</td><td>15</td></tr><tr><td>BP-15-30°-bl</td><td>Blastomere Biopsie-Pipette 15 µm, BA:30°, blunt</td><td>15</td></tr><tr><td>BP-15-30°-be</td><td>Blastomere Biopsie-Pipette 15 µm, BA:30°, bevelled</td><td>15</td></tr><tr><td>BP-15-35°-bl</td><td>Blastomere Biopsie-Pipette 15 µm, BA:35°, blunt</td><td>15</td></tr></table>	Ref No.	Product description	Pipette-ID	BP-10-0°-bl	Blastomere Biopsie-Pipette 10 µm, BA:0°, blunt	10	BP-10-0°-be	Blastomere Biopsie-Pipette 10 µm, BA:0°, bevelled	10	BP-10-30°-bl	Blastomere Biopsie-Pipette 10 µm, BA:30°, blunt	10	BP-10-30°-be	Blastomere Biopsie-Pipette 10 µm, BA:30°, bevelled	10	BP-10-35°-bl	Blastomere Biopsie-Pipette 10 µm, BA:35°, blunt	10	BP-10-35°-be	Blastomere Biopsie-Pipette 10 µm, BA:35°, bevelled	10	BP-15-0°-bl	Blastomere Biopsie-Pipette 15 µm, BA:0°, blunt	15	BP-15-0°-be	Blastomere Biopsie-Pipette 15 µm, BA:0°, bevelled	15	BP-15-30°-bl	Blastomere Biopsie-Pipette 15 µm, BA:30°, blunt	15	BP-15-30°-be	Blastomere Biopsie-Pipette 15 µm, BA:30°, bevelled	15	BP-15-35°-bl	Blastomere Biopsie-Pipette 15 µm, BA:35°, blunt	15	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.
Ref No.	Product description	Pipette-ID																																						
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BP-10-30°-bl	Blastomere Biopsie-Pipette 10 µm, BA:30°, blunt	10																																						
BP-10-30°-be	Blastomere Biopsie-Pipette 10 µm, BA:30°, bevelled	10																																						
BP-10-35°-bl	Blastomere Biopsie-Pipette 10 µm, BA:35°, blunt	10																																						
BP-10-35°-be	Blastomere Biopsie-Pipette 10 µm, BA:35°, bevelled	10																																						
BP-15-0°-bl	Blastomere Biopsie-Pipette 15 µm, BA:0°, blunt	15																																						
BP-15-0°-be	Blastomere Biopsie-Pipette 15 µm, BA:0°, bevelled	15																																						
BP-15-30°-bl	Blastomere Biopsie-Pipette 15 µm, BA:30°, blunt	15																																						
BP-15-30°-be	Blastomere Biopsie-Pipette 15 µm, BA:30°, bevelled	15																																						
BP-15-35°-bl	Blastomere Biopsie-Pipette 15 µm, BA:35°, blunt	15																																						

			BP-15-35 ⁰ -be	Blastomere Biopsie-Pipette-ID:15 μm, BA:35°, bevelled	
			BP-20-0 ⁰ -bl	Blastomere Biopsie-Pipette-ID:20 μm, BA:0°, blunt	
			BP-20-0 ⁰ -be	Blastomere Biopsie-Pipette-ID:20 μm, BA:0°, bevelled	
			BP-20-30 ⁰ -bl	Blastomere Biopsie-Pipette-ID:20 μm, BA:30°, blunt	
			BP-20-30 ⁰ -be	Blastomere Biopsie-Pipette-ID:20 μm, BA:30°, bevelled	
			BP-20-35 ⁰ -bl	Blastomere Biopsie-Pipette-ID:20 μm, BA:35°, blunt	
			BP-20-35 ⁰ -be	Blastomere Biopsie-Pipette-ID:20 μm, BA:35°, bevelled	
			BP-25-0 ⁰ -bl	Blastomere Biopsie-Pipette-ID:25 μm, BA:0°, blunt	
			BP-25-0 ⁰ -be	Blastomere Biopsie-Pipette-ID:25 μm, BA:0°, bevelled	
			BP-25-30 ⁰ -bl	Blastomere Biopsie-Pipette-ID:25 μm, BA:30°, blunt	
			BP-25-30 ⁰ -be	Blastomere Biopsie-Pipette-ID:25 μm, BA:30°, bevelled	
			BP-30-0 ⁰ -bl	Blastomere Biopsie-Pipette-ID:30 μm, BA:0°, blunt	
			BP-30-0 ⁰ -be	Blastomere Biopsie-Pipette-ID:30 μm, BA:0°, bevelled	
			BP-30-30 ⁰ -bl	Blastomere Biopsie-Pipette-ID:30 μm, BA:30°, blunt	
			BP-30-30 ⁰ -be	Blastomere Biopsie-Pipette-ID:30 μm, BA:30°, bevelled	
			BP-30-35 ⁰ -bl	Blastomere Biopsie-Pipette-ID:30 μm, BA:35°, blunt	
			BP-30-35 ⁰ -be	Blastomere Biopsie-Pipette-ID:30 μm, BA:35°, bevelled	
			BP-35-0 ⁰ -bl	Blastomere Biopsie-Pipette-ID:35 μm, BA:0°, blunt	
			BP-35-0 ⁰ -be	Blastomere Biopsie-Pipette-ID:35 μm, BA:0°, bevelled	
			BP-35-30 ⁰ -bl	Blastomere Biopsie-Pipette-ID:35 μm, BA:30°, blunt	
			BP-35-30 ⁰ -be	Blastomere Biopsie-Pipette-ID:35 μm, BA:30°, bevelled	
			BP-35-35 ⁰ -bl	Blastomere Biopsie-Pipette-ID:35 μm, BA:35°, blunt	
			BP-35-35 ⁰ -be	Blastomere Biopsie-Pipette-ID:35 μm, BA:35°, bevelled	
			Code: 004 MD Group: Single Class: B Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Shelf Life: 3 Years Storage Condition: Store at room temperature below 30°C		

187.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790293 Dated: 11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid from:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 2021.03.12 <u>Expiry Date:</u> 2022.07.27	Brand Name: Culture Generic Name: 1. GM501 Mineral Oil 4 MO 0100 - 1 x 100 m 4 MO 0500 - 1 x 500 ml Code: GM501 MG Group: Cluster Class: B Models: •GM501 Mineral oil Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Shelf Life: •GM501 Mineral oil – 18 Months Storage Condition: GM501 Mineral oil – Store at 15 – 25° C.	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.																																										
188.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790299 Dated: 11.02.2020	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid from:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 2021.03.12 <u>Expiry Date:</u> 2022.07.27	Brand Name: Injection Micropipettes Generic Name: Injection Micropipettes <table><tr><th>Ref No.</th><th>Product description</th><th>Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.</th></tr><tr><td>IC-5-0° - be</td><td>ICSI-Pipette – ID: 5µm, Bevelled</td><td></td></tr><tr><td>IC-5-0° -s</td><td>ICSI-Pipette – ID: 5µm, with spike</td><td></td></tr><tr><td>IC-5-20° - be</td><td>ICSI-Pipette – ID: 5µm, Bevelled</td><td></td></tr><tr><td>IC-5-20° -s</td><td>ICSI-Pipette – ID: 5µm, BA: 20°, with spike</td><td></td></tr><tr><td>IC-5-30° - be</td><td>ICSI-Pipette – ID: 5µm, BA: 30°, Bevelled</td><td></td></tr><tr><td>IC-5-30° -s</td><td>ICSI-Pipette – ID: 5µm, BA: 30°, with spike</td><td></td></tr><tr><td>IC-5-35° - be</td><td>ICSI-Pipette – ID: 5µm, BA: 35°, Bevelled</td><td></td></tr><tr><td>IC-5-35° -s</td><td>ICSI-Pipette – ID: 5µm, BA: 35°, with spike</td><td></td></tr><tr><td>IC-5-40° - be</td><td>ICSI-Pipette – ID: 5µm, BA: 40°, Bevelled</td><td></td></tr><tr><td>IC-5-40° -s</td><td>ICSI-Pipette – ID: 5µm, BA: 40°, with spike</td><td></td></tr><tr><td>IC-7-0° - be</td><td>ICSI-Pipette – ID: 7µm, BA: 0°, Bevelled</td><td></td></tr><tr><td>IC-7-0° -s</td><td>ICSI-Pipette – ID: 7µm, BA: 0°, with spike</td><td></td></tr><tr><td>IC-7-20° -</td><td>ICSI-Pipette – ID: 7µm, BA: 20°,</td><td></td></tr></table>	Ref No.	Product description	Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.	IC-5-0° - be	ICSI-Pipette – ID: 5µm, Bevelled		IC-5-0° -s	ICSI-Pipette – ID: 5µm, with spike		IC-5-20° - be	ICSI-Pipette – ID: 5µm, Bevelled		IC-5-20° -s	ICSI-Pipette – ID: 5µm, BA: 20°, with spike		IC-5-30° - be	ICSI-Pipette – ID: 5µm, BA: 30°, Bevelled		IC-5-30° -s	ICSI-Pipette – ID: 5µm, BA: 30°, with spike		IC-5-35° - be	ICSI-Pipette – ID: 5µm, BA: 35°, Bevelled		IC-5-35° -s	ICSI-Pipette – ID: 5µm, BA: 35°, with spike		IC-5-40° - be	ICSI-Pipette – ID: 5µm, BA: 40°, Bevelled		IC-5-40° -s	ICSI-Pipette – ID: 5µm, BA: 40°, with spike		IC-7-0° - be	ICSI-Pipette – ID: 7µm, BA: 0°, Bevelled		IC-7-0° -s	ICSI-Pipette – ID: 7µm, BA: 0°, with spike		IC-7-20° -	ICSI-Pipette – ID: 7µm, BA: 20°,		Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.
Ref No.	Product description	Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.																																												
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			<table><tr><td>be</td><td>Bevelled</td><td></td></tr><tr><td>IC-7-20° - s</td><td>ICSI-Pipette – ID: 5µm, BA: 20⁰, with spike</td><td></td></tr><tr><td>IC-7-30° - be</td><td>ICSI-Pipette – ID: 7µm, BA: 30⁰, Bevelled</td><td></td></tr><tr><td>IC-7-30° - s</td><td>ICSI-Pipette – ID: 7µm, BA: 30⁰, with spike</td><td></td></tr><tr><td>IC-7-35° - be</td><td>ICSI-Pipette – ID: 7µm, BA: 35⁰, Bevelled</td><td></td></tr><tr><td>IC-7-35° - s</td><td>ICSI-Pipette – ID: 7µm, BA: 35⁰, with spike</td><td></td></tr><tr><td>IC-7-40° - be</td><td>ICSI-Pipette – ID: 7µm, BA: 40⁰, Bevelled</td><td></td></tr><tr><td>IC-7-40° - s</td><td>ICSI-Pipette – ID: 7µm, BA: 40⁰, with spike</td><td></td></tr><tr><td>IC-SL-4.6-30°-s</td><td>ICSI-Pipette 30° mit Spike, ID: 4.6 µm thin line</td><td></td></tr><tr><td>IC-SL-4.6-35°-s</td><td>ICSI-Pipette 35° mit Spike, ID: 4.6 µm thin line</td><td></td></tr></table> Code: 002 MD Group: Single Class: B Shelf Life: 3 Years Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Storage Condition: Store at room temperature below 30°C	be	Bevelled		IC-7-20° - s	ICSI-Pipette – ID: 5µm, BA: 20 ⁰ , with spike		IC-7-30° - be	ICSI-Pipette – ID: 7µm, BA: 30 ⁰ , Bevelled		IC-7-30° - s	ICSI-Pipette – ID: 7µm, BA: 30 ⁰ , with spike		IC-7-35° - be	ICSI-Pipette – ID: 7µm, BA: 35 ⁰ , Bevelled		IC-7-35° - s	ICSI-Pipette – ID: 7µm, BA: 35 ⁰ , with spike		IC-7-40° - be	ICSI-Pipette – ID: 7µm, BA: 40 ⁰ , Bevelled		IC-7-40° - s	ICSI-Pipette – ID: 7µm, BA: 40 ⁰ , with spike		IC-SL-4.6-30°-s	ICSI-Pipette 30° mit Spike, ID: 4.6 µm thin line		IC-SL-4.6-35°-s	ICSI-Pipette 35° mit Spike, ID: 4.6 µm thin line		
be	Bevelled																																	
IC-7-20° - s	ICSI-Pipette – ID: 5µm, BA: 20 ⁰ , with spike																																	
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IC-SL-4.6-35°-s	ICSI-Pipette 35° mit Spike, ID: 4.6 µm thin line																																	
189.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 18.02.2020 Fee details: Amount Paid: 5,000/- Challan no. 0790300 Dated:	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany <u>Dated:</u> 24.02.2021 EC Certificate: <u>Valid from:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 2021.03.12 <u>Expiry Date:</u> 2022.07.27	Brand Name: Hatching Micropipettes Generic Name: Hatching Micropipettes Model Code: <table><tr><td>Code</td><td>Angle</td><td>Types</td></tr><tr><td>003</td><td>20°, 30°, 35° or straight</td><td>Class B, as per schedule notified in SRO-1324, Dated 30th August 2024.</td></tr><tr><td>003</td><td>20°, 30°, 35° or straight</td><td>Longist</td></tr></table> MD Group: Single Class: B Shelf Life: 3 Years Storage Condition: Store at room temperature below 30°C	Code	Angle	Types	003	20°, 30°, 35° or straight	Class B, as per schedule notified in SRO-1324, Dated 30th August 2024.	003	20°, 30°, 35° or straight	Longist	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate. Firm shall submit the differential fee for Class B, as per schedule notified in SRO-1324, Dated 30th August 2024.																					
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	11.02.2020			
190.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 22.02.2021 Fee details: Amount Paid: 5,000/- Challan no. 1979355	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany Dated: 05.08.2019 EC Certificate: Effective Date: 28.07.2019 Expiry Date: 27.05.2024 Letter of Authorization: Dated: 24.10.2019 ISO Certificate: Effective Date: 2021.03.12 Expiry Date: 2022.07.27	Brand Name: GM501 SpermMobil Generic Name: GM501 SpermMobil Code: 1. GM501 SpermMobil 4 GM 501SMOBIL5 - 1 x 5 ml 4 GM 501SMOBIL5-S - 1 x 1 ml MD Group: Cluster Class: A Declaration of Conformity Issuance date: 15.03.2021 Shelf Life: 6 Months Storage Condition: Store at 2-8°C.	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.
191.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) R&I Date: 22.02.2021 Fee details: Amount Paid: 5,000/- Challan no. 1979355	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany. FSC: Germany Dated: 05.08.2019 EC Certificate: Valid from: 28.07.2019 Valid till: 27.05.2024 Letter of Authorization: Dated: 24.10.2019 ISO Certificate: Effective Date: 2021.03.12 Expiry Date: 2022.07.27	Brand Name: GM508 CultActive Generic Name: GM508 CultActive Model Code: 4 GM 508CULT-active1 1 x 1ml MD Group: Cluster Class: A Declaration of Conformity Issuance date: 15.03.2021 Shelf Life: 6 Months Storage Condition: Store at 2-8°C.	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.
192.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd.	Name of Manufacturer: Gynemed GmbH & Co. KG Address: Lubecker Str. 9 23738 Lensahn Germany.	Brand Name: Oocyte Aspiration Needles Generic Name: Oocyte Aspiration Needles	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.

Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (License No. ELI-00402) • GY-711724LF R&I Date: 15.03.2021 Fee Details: Amount Paid: 5,000/- Challan no. 2072927 Dated: 11.03.2021 • GY-711724LF-A R&I Date: 15.03.2021 Fee details: Amount Paid: 5,000/- Challan no. 2072928 Dated: 11.03.2021 • GY-711824LF R&I Date: 15.03.2021 Fee details: Amount Paid: 5,000/- Challan no. 2072926 Dated: 11.03.2021 • GY-721724LF R&I date: 15.03.2021 Fee details: Amount Paid: 5,000/- Challan no. 2072925	FSC: Germany <u>Dated:</u> 05.08.2019 EC Certificate: <u>Valid from:</u> 28.07.2019 <u>Valid till:</u> 27.05.2024 Letter of Authorization: <u>Dated:</u> 24.10.2019 ISO Certificate: <u>Effective Date:</u> 2021.03.12 <u>Expiry Date:</u> 2022.07.27	Class: B MD Group: Cluster Model code and specification: • GY-711724LF single lumen, without flushing, 17-gauge needle, length of the needle 32 cm, back cut bevel, echo mark micro blasting, length of aspiration tubing 100 cm, length of vacuum tubing 100 cm, luer female • GY-711724LF-A single lumen, without flushing, 17-gauge needle, length of the needle 35 cm, back cut bevel, echo mark micro blasting, length of aspiration tubing 100 cm, length of vacuum tubing 100 cm, luer female • GY-711824LF single lumen, without flushing, 18-gauge needle, length of the needle 32 cm, back cut bevel, echo mark micro blasting, length of aspiration tubing 100 cm, length of vacuum tubing 100 cm, luer female • GY-721724LF single lumen, with flushing, 17-gauge needle, length of the needle 32 cm, back cut bevel, echo mark micro blasting, length of aspiration tubing 100 cm, length of vacuum tubing 100 cm, luer female • GY-931627LF-A double lumen, with flushing, outer diameter 16-gauge needle, length of the needle 35 cm, back cut bevel, echo mark dots up to the end of the tips, length of aspiration tubing 100 cm, length of vacuum tubing 100 cm, luer female. Declaration of Conformity <u>Issuance date:</u> 15.03.2021 Shelf Life: 3 Years Storage Condition: Store at room temperature below 30°C	Firm shall submit the differential fee for Class B, as per DRAP fee schedule notified in SRO-1324, Dated 30th August 2024.
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	Dated: 11.03.2021 • GY-931627LF-A R&I Date: 15.03.2021 Fee details: Amount Paid: 5,000/- Challan no. 2072924 Dated: 11.03.2021			
193.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (Lic No. ELI-00402) R&I Date: (21/Mar/2023) Fee details: Amount paid: PKR 5,000/- Paid Slip / challan No.: 312194754875 Dated: (10/03/2023)	Name of Manufacturer: IVF Prime Sağlık Ürünleri San. Ve Ticaret. A.Ş. Address: Çamlıca Mah. Anadolu Blv. N Blok No: 20 N İç Kapi No: 1 Yenimahalle/Ankara/TURKEY <u>Free Sale Certificate</u> Date of issue: 24 May 2021 Validity: 36 months <u>ISO 13485 certificate</u> Validity: 16-Oct-2023 <u>Letter of authorization:</u> Dated: 2022-07-18	Brand Name: Embryo Shield Generic Name: Embryo Shield Inline Filter Model: ES002 Sizes: Height: 25 cm Diameter: 73mm MD Group: Single use Class-A Declaration of conformity: Issuance date: 03.01.2022 Shelf Life: The product's shelf life was identified as 3 years according to the raw material. Storage conditions: The device has not got any radioactivity property. The products are stored at 05- 24 °C and at low humidity (40-60% RH) before being shipped to the customer. Excessive storage conditions such as exposure to direct sunlight and / or storage on or near radiators may destroy the product.	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.
194.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park,	Name of Manufacturer: IVF Prime Sağlık Ürünleri San. Ve Ticaret. A.Ş. Address: Çamlıca Mah. Anadolu Blv. N Blok No: 20 N İç Kapi No: 1 Yenimahalle/Ankara/TURKEY <u>Free Sale Certificate</u>	Brand Name: Embryo Shield Generic Name: Embryo Shield Inline Filter Model: ES001 Sizes: Height: 30 cm Diameter: 73mm	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.

	Korangi Creek, Karachi. (Lic No. ELI-00402) R& I Date: (21/Mar/2023) Fee details: Amount paid: PKR 5,000/- Paid Slip / challan No.: 4337117616 Dated: (10/03/2023)	Date of issue: 24 May 2021 Validity: 36 months ISO 13485 certificate Validity: 16-Oct-2023 Letter of authorization: Dated: 2022-07-18	MD Group: Single use Class-A Declaration of conformity: Issuance date: 02.01.2023 Shelf Life: The product's shelf life was identified as 3 years according to the raw material. Storage conditions: The device has not got any radioactivity property. The products are stored at 05- 24 °C and at low humidity (40-60% RH) before being shipped to the customer. Excessive storage conditions such as exposure to direct sunlight and / or storage on or near radiators may destroy the product.	
195.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (Lic No. ELI-00402) R&I Date: 16.08.2024 Fee details: Amount Paid: 5,000/- Challan no. 6148156532 Dated: 09.05.2024	Name of Manufacturer: Anhui Deepblue Medical Technology Co., Ltd. Address: 4th Floor D-1 # Zone, Pearl Industrial Park 106 Innovation Avenue, High-Tech Development Zone 230088 Hefei, Anhui, China & No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, China. FSC: <u>Validity:</u> July 2, 2025 ISO Certificate: <u>Valid From:</u> 14.11.2023 <u>Valid Until:</u> 21.06.2024 EC Certificate: <u>Valid From:</u> 27.06.2023 <u>Valid till:</u> 25.05.2027 Letter of Authorization: <u>Valid From:</u> May 7, 2024 <u>Valid Until:</u> May 7, 2026	Brand Name: Epithelial Tissue Staining Solution Generic Name: Epithelial Tissue Staining Solution Product Code: ET2CO-X Model: Ordinary/Improved Packing Specifications: 1/2/3/5/10/20/50/100 pcs/box or 3/5/8/10/12/15 ml/bottle MD Group: Kit Class: A Declaration of Conformity <u>Issuance date:</u> 29.06.2023 Shelf Life: 24 Months Storage conditions: Sealed and stored in a ventilated and dry place at -10 °C to 40°C. After the foil pouch is unsealed, the test device should be used as soon as possible.	Approved.
196.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek,	Name of Manufacturer: Anhui Deepblue Medical Technology Co., Ltd. Address: 4th Floor D-1 # Zone, Pearl Industrial Park 106 Innovation Avenue, High-Tech Development Zone 230088 Hefei, Anhui, China. FSC:	Brand Name: LH Ovulation Test (Colloidal Gold) Generic Name: LH Ovulation Test (Colloidal Gold) Model: Strip/Midstream Specifications: 1 Pcs/bag, 3/5/10/20/50/100 pcs/box	Approved, Subject to submission of valid copy of FSC, EC, ISO Certificate.

	Karachi. (Lic No. ELI-00402) R&I Date: 18.10.2023 Fee details: Amount Paid: 5,000/- Challan no. 3826481779 Dated: 22.05.2023 Additional Challan: Amount Paid: 20,000/- Challan no. 9865525291 Dated: 25.09.2023	<u>Validity:</u> Sep 4, 2024 ISO Certificate: <u>Valid From:</u> 22.06.2021 <u>Valid Until:</u> 21.06.2024 EC Certificate: <u>Valid From:</u> 22.06.2018 <u>Valid Until:</u> 21.06.2023 Letter of Authorization: <u>Dated:</u> 18.05.2023 <u>Validity:</u> 3 Years	MD Group: Kit Class: B Declaration of Conformity <u>Issuance date:</u> 09.01.2019 Shelf Life: 24 Months Storage Condition: The test kit can be stored at temperatures between 4 to 30 °C in the sealed pouch for 24 months. Should be Kept away from direct sunlight, moisture and heat.	
197.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (Lic No. ELI-00402) R&I Date: 18.10.2023 Fee details: Amount Paid: 5,000/- Challan no. 42403086334 Dated: 22.05.2023 Additional Challan: Amount Paid: 20,000/- Challan no. 86392209181 Dated:	Name of Manufacturer: Anhui Deepblue Medical Technology Co., Ltd. Address: 4th Floor D-1 # Zone, Pearl Industrial Park 106 Innovation Avenue, High-Tech Development Zone 230088 Hefei, Anhui, China. FSC: <u>Validity:</u> March 24, 2024 ISO Certificate: <u>Valid From:</u> 22.06.2021 <u>Valid Until:</u> 21.06.2024 EC Certificate: <u>Valid From:</u> 26.05.2022 <u>Valid till:</u> 25.05.2027 Letter of Authorization: <u>Dated:</u> 18.05.2023 <u>Validity:</u> 3 Years	Brand Name: IGFBP-1(PROM) Test Cassette (Colloidal Gold) Generic Name: IGFBP-1(PROM) Test Cassette (Colloidal Gold) Model: Strip, cassette: 1/3/5/10/20/50/100 pcs/box MD Group: Kit Class: B Declaration of Conformity <u>Issuance date:</u> 29.07.2020 Shelf Life: 24 Months. Use within 1 hour after opening. Storage conditions: 4 to 30°C, stored in dark and dry conditions, cryopreserved should be avoided.	Approved, Subject to submission of valid copy of FSC, EC, ISO Certificate.

	22.09.2023			
198.	Applicant Name: M/s. Galaxy Pharma Pvt. Ltd. Address: Plot No. FD-35-36-A7, National Industrial Park, Korangi Creek, Karachi. (Lic No. ELI-00402) R& I Date: (12/April/2021) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 2072910 Dated: (12/April/2021)	Name of Manufacturer: INVO Bioscience™ 5582 Broadcast Court Sarasota, Florida 34240 USA Physical Manufacturer: Contract Manufacturer NextPhase Medical Devices LLC 88 Airport Drive, Rochester, New Hampshire 03867 USA Free Sale Certificate Issued by U.S Food and Drug Administration (FDA) Validity: (30.04.2022) ISO 13485 certificate Validity: 02-04-2023 EC Certificate: Validity: (26.05.2024) Letter of authorization: Validity: 2024-08-07	Brand Name: INVOCell™ Culture Device Generic Name: INVOCell™ Culture Device Model: FG-002 Sizes: The retention device comes in a single size: 70mm. MD Group: Single Class-B Declaration of conformity: Issuance date: (13/NOV/2019) Shelf Life 6 Years Storage conditions: Store at Room temperature below 25°C (77°F) away from moisture and direct heat.	Approved, Subject to submission of valid copy of LOA, FSC, EC, ISO Certificate.
199.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 5627218377 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Undis-Catheter Mount Class: B MD group: Single	Deferred for submission of DRAP R&I receiving and paid bank challan.

200.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 5627218377 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Undis-Catheter Mount Class: B MD group: Single	Deferred for submission of DRAP R&I receiving and paid bank challan.
201.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 9916977914 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Undis-Closed Suction System Class: B MD group: Set	Deferred for submission of DRAP R&I receiving and paid bank challan.

202.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 0339245705 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Disposable Anesthesia Breathing Circuit Class: B MD group: Set	Deferred for submission of DRAP R&I receiving and paid bank challan.
203.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 164878026701 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Disposable Anesthesia Mask Class: B MD group: Single	Deferred for submission of DRAP R&I receiving and paid bank challan.

204.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 7508062254 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31	Brand Name: Disposable Breathing Filter Class: B MD group: Single	Deffered for submission of DRAP R&I receiving and paid bank challan.
205.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 65313147163 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31	Brand Name: Disposble Heated Wire Circuit Class: B MD group: Set	Deffered for submission of DRAP R&I receiving and paid bank challan.
206.	Applicant Name: Total	Name of Manufacturer: Brand name LEO LIFE	Brand Name: Heat And Moisture Exchanger	Deffered for submission of DRAP R&I receiving and paid bank challan.

	Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 285643559988 PKR: 31,000/-	SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31	Class: B MD group: Single	
207.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 63631796733 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31	Brand Name: High Flow Nasal Cannula Class: B MD group: System	Deffered for submission of DRAP R&I receiving and paid bank challan.
208.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11	Brand Name: Nasal Oxygen Cannula Class: B MD group: Single	Deffered for submission of DRAP R&I receiving and paid bank challan.

	(ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 158351075 PKR: 31,000/-	Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31		
209.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 9677848547 PKR: 31,000/-	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website: http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31	Brand Name: Nebulizer Tube Class: B MD group: Set	Deffered for submission of DRAP R&I receiving and paid bank challan.
210.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No:	Name of Manufacturer: Brand name LEO LIFE SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China Tel: 0086-575-8521 5008 Fax: 0086-575-8521 5007 Website:	Brand Name: Oxygen Mask Class: B MD group: Set	Deffered for submission of DRAP R&I receiving and paid bank challan.

	01559847379 PKR: 31,000/-	http://www.undis.cn/ LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity:2028-12-31		
211.	Applicant Name: M/S ORBIT DIAGNOSTICS Address of Importer: 403, PLAZA 55, BEHRIA TOWN-IV, CIVIC CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021 Fee Details. Fee Challan No. 798161636403 Paid Fee. 25000 dated 07-09-2021	Name of Manufacturer: SHIJIAZHUANG HIPRO BIOTECHNOLOGY Co., LTD (Manufacturing site) No. 3 Building, Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang, P.R. CHINA LOA Valid till 01 April 2026 FSC: Country of Origin China Validity: 23-11-2025 OR EC Certificate CE Certificate Validity: April 2027 ISO 13485 Validity: 16 July 2026 Production Quality Management System Certificate (ISO 13485:2016) ISO 13485 Notifying Body TÜV Rheinland LGA Products GmbH	Brand Name: Renal Function Reagents Class B Shelf Life: 01 Year Glycosylated Hemoglobin (HbA1c) Test Kits: 65322 Alpha-1 Microglobulin Test Kit: 53923 Beta-2 Microglobulin Test Kit: 53927 Retinol Binding Protein Test Kit: 53971 Cystatin C Test Kit: 48178 Microalbuminuric Test Kit: 59042 Neutrophil Gelatinase Associated Lipocalin Test Kit: 47426 Storage Condition: 2-8 C	Approved.
212.	Applicant Name: M/S ORBIT DIAGNOSTICS Address of Importer: 403, PLAZA 55, BEHRIA TOWN-IV, CIVIC	Name of Manufacturer: SHIJIAZHUANG HIPRO BIOTECHNOLOGY Co., LTD (Manufacturing site) No. 3 Building, Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang,	Brand Name: Autoimmunity Reagents Class B Shelf Life: 01 Year Immunoglobulin A Test Kit: 54979	Approved.

	CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021 Fee Details. Fee Challan No. 983821857 Paid Fee. 25000 dated 07-09-2021	P.R. CHINA LOA Valid till 01 April 2026 FSC: Country of Origin China Validity: 23-11-2025 OR EC Certificate CE Certificate Validity: April 2027 ISO 13485 Validity: 16 July 2026 Production Quality Management System Certificate (ISO 13485:2016) ISO 13485 Notifying Body TÜV Rheinland LGA Products GmbH	Immunoglobulin E Test Kit: 53782 Immunoglobulin G Test Kit: 53787 Immunoglobulin M Test Kit: 53795 Storage Condition: 2-8 C	
213.	Applicant Name: M/S ORBIT DIAGNOSTIC S Address of Importer: 403, PLAZA 55, BEHRIA TOWN-IV, CIVIC CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021 Fee Details. Fee Challan No. 312680029 Paid Fee. 25000 dated 07-09-2021	Name of Manufacturer: SHIJIAZHANG HIPRO BIOTECHNOLOGY Co., LTD (Manufacturing site) No. 3 Building, Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang, P.R. CHINA LOA Valid till 01 April 2026 FSC: Country of Origin China Validity: 23-11-2025 OR EC Certificate CE Certificate Validity: April 2027 ISO 13485 Validity: 16 July 2026	Brand Name: Infection Reagents Class B Shelf Life: 01 Year Procalcitonin Test Kit: 54316 Serum Amyloid A Test Kit: 53453 High-Sensitive C- Reactive Protein: 53705 Storage Condition: 2-8 C	Approved.

		Production Quality Management System Certificate (ISO 13485:2016) ISO 13485 Notifying Body TÜV Rheinland LGA Products GmbH		
214.	Applicant Name: M/S ORBIT DIAGNOSTICS Address of Importer: 403, PLAZA 55, BEHRIA TOWN-IV, CIVIC CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021 Fee Details. Fee Challan No. 68278541 Paid Fee. 25000 dated 07-09-2021	Name of Manufacturer: SHIJIAZHUANG HIPRO BIOTECHNOLOGY Co., LTD (Manufacturing site) No. 3 Building, Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang, P.R. CHINA LOA Valid till 01 April 2026 FSC: Country of Origin China Validity: 23-11-2025 OR EC Certificate CE Certificate Validity: April 2027 ISO 13485 Validity: 16 July 2026 Production Quality Management System Certificate (ISO 13485:2016) ISO 13485 Notifying Body TÜV Rheinland LGA Products GmbH	Brand Name: Cardiovascular Disease Reagents Class B Shelf Life: 01 Year D-Dimer Test Kit: 47343 Homocysteine Test Kit: 53751 Heart Fatty Acid Binding Protein Test Kit: 53377 Creatine Kinase Isoenzyme MB Test Kit: 61385 Cardiac Troponin I Test Kit: 47399 Myohemoglobin Test Kit: 59042 Amino-Terminal pro-brain natriuretic peptide Test Kits: 47355 Lipoprotein (a) Test Kit: 53438 Lipoprotein Phospholipase A2 Test Kit: 53112 Storage Condition: 2-8 C	Approved.
215.	Applicant Name: M/S ORBIT DIAGNOSTICS Address of Importer: 403, PLAZA	Name of Manufacturer: SHIJIAZHUANG HIPRO BIOTECHNOLOGY Co., LTD (Manufacturing site) No. 3 Building,	Brand Name: 25- Hydroxy-Vitamin D Test Kit (Immune Fluorescence Detection Method)	Approved.

	55, BEHRIA TOWN-IV, CIVIC CENTRE ISLAMABAD. PAKISTAN ELI-00630 Date of R& I 13 Sep 2021 Fee Details. Fee Challan No. 98682668831 Paid Fee. 25000 dated 07-09-2021	Fangyi Tech. Park, No. 313 Zhujiang RD, Shijiazhuang, P.R. CHINA LOA Valid till 01 April 2026 FSC: Country of Origin China Validity: 23-11-2025 OR EC Certificate CE Certificate Validity: April 2027 ISO 13485 Validity: 16 July 2026 Production Quality Management System Certificate (ISO 13485:2016) ISO 13485 Notifying Body TÜV Rheinland LGA Products GmbH	Class B Shelf Life: 01 Year Storage Condition: 2-8 C	
216.	Applicant Name: M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN ELI-00240 Date of R& I 03/01/2024 Fee Rs. 5,030/ through slip no.	Name of Manufacturer: HOSPITAL & HOMECARE IMP. & EXP. CO., LTD, NANJING Manufacturing Site: ROOM 618-611 NO.5 ZHONGTAI INTERNATIONAL PLAZA NO.311, JIANGDONG ROAD, NANJING, CHINA. Tel: +86-025-87783278 LOA: Original Agency agreement notarized by CCPIT certificate no; 233201A0/001310 dated 2023/02/14 LOA Validity: 10-02-2028 FSC: - MHRA (UK) FREE SALE CERTIFICATE No.	Brand Name: CARE EAR EYRINGE Class A Shelf Life: 5 Years Codes/Sizes: 90ml	Approved.

	984745165022, dated 12/12/23	2022121902289158/1 dated 19/12/2022 Certified by: Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs, dated 12th Sep 2019, Validity: 26/05/2025 ISO: Original Management System Management System Certificate TUV Certificate No: Q5 064660 0037 Rev.02 Notarized by CCPIT certificate no; 223201A0/008860 VALID UNTIL: 2025-05-31		
217.	Applicant Name: Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-00263 Date of R&I: 24-10-2024 Fee Challan No. 6833940550 + 4465916036 Paid fee: 6000 Date: 07-08-2024	Name of Manufacturer: FUJIFILM Corporation 26-30, Nishiazabu 2-chome, Minato-ku, Tokyo, 106 8620, Japan Manufacturing Site: FUJIFILM Healthcare Manufacturing Coporation Kashiwa Office 2-1, Shintayofuta, Kashiwa shi, Chiba, 277-0804, Japan LOA Validity: 31-08-2025 FSC: Country: Japan Validity: N/A CE Certificate Validity: 28-09-2026 ISO 13485 Validity: 30-11-2026	Brand Name: Arietta 750 VE (Diagnostic Ultrasound System) Class B Shelf Life: 07 Years (Service Life) Codes/Sizes: 40761 (GMDN Code)	Approved.

218.	Applicant Name: Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-00263 Date of R&I: 24-10-2024 Fee Challan No. 27593623126 Paid fee: 25000 Date: 07-08-2024	Name of Manufacturer: FUJIFILM Corporation 26-30, Nishiazabu 2-chome, Minato-ku, Tokyo, 106 8620, Japan Manufacturing Site: FUJIFILM Healthcare Manufacturing Coporation Kashiwa Office 2-1, Shintayofuta, Kashiwa shi, Chiba, 277-0804, Japan LOA Validity: 31-08-2025 FSC: Country: Japan Validity: N/A CE Certificate Validity: 28-09-2026 ISO 13485 Validity: 30-11-2026	Brand Name: Arietta 65 (Diagnostic Ultrasound System) Class B Shelf Life: 07 Years (Service Life) Codes/Sizes: 40761 (GMDN Code)	Approved, Subject to pay differential fee of 6000, As fee revised in DRAP Fee Schedule notified in SRO-1324, Dated 30th August 2024.
219.	Applicant Name: Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-00263 Date of R&I: 24-10-2024	Name of Manufacturer: FUJIFILM Corporation 26-30, Nishiazabu 2-chome, Minato-ku, Tokyo, 106 8620, Japan Manufacturing Site: FUJIFILM Healthcare Manufacturing Coporation Kashiwa Office 2-1, Shintayofuta, Kashiwa shi, Chiba, 277-0804, Japan LOA Validity: 31-08-2025 FSC: Country: Japan Validity: N/A CE Certificate Validity: 28-09-2026 ISO 13485 Validity: 30-11-2026	Brand Name: Arietta 750 SE (Diagnostic Ultrasound System) Class B Shelf Life: 07 Years (Service Life) Codes/Sizes: 40761 (GMDN Code)	Approved, Subject to pay differential fee of 6000, As fee revised in DRAP Fee Schedule notified in SRO-1324, Dated 30th August 2024

	Fee Challan No. 16757575298 Paid fee: 25000 Date: 07-08-2024			
220.	MR Medical Pakistan Pvt Ltd, Islamabad. ELI-01008 Application Date:23-11-2023 Fee of Rs. 25000/- Receipt No. 307936977340	M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA Documents submitted: FSC (Germany) issued on 06-01-2024 LOA validity: 14-04-2027 ISO 13485 valid upto 31-08-2026	Brand Name: Mindray Generic Name: Rigid Endoscope Class-B Model number: M004 M029 G 004 G 029 Shelf life: 10 YEARS	Approved subject to submission of fee as per new SRO & valid Free Sale Certificate of any reference country with correct name & address of the manufacturer.
221.	MR Medical Pakistan Pvt Ltd, Islamabad. ELI-01008 Application Date:12-10-2023 Fee of Rs. 25000/- Receipt No. 171000126112	M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA Documents submitted: FSC (Germany) issued on 06-01-2024 LOA validity: 14-04-2027 ISO 13485 valid upto 31-08-2026	Brand Name: Mindray Generic Name: Rigid Endoscope Class-B Model number: M01030A M01000A G01000A G01030A Shelf life: 10 YEARS	Approved subject to submission of fee as per new SRO & valid Free Sale Certificate of any reference country with correct name & address of the manufacturer.
222.	Electro Med Corporation, 53 Mall Avenue, 54 The Mall , Near Panorama Shopping Centre, Lahore. ELI-00163 Application Date: 13-03-2025 Fee of Rs. 6000/-	BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada. Documents submitted: FSC (Canada) validity 03-11-2029 LOA validity: 24-09-2029 ISO 13485 valid upto 18-11-2024	Brand Name: Ultima Cannula Generic Name: Nasal Cannula for Sleep Recorders Class-A Model number: 0582 0582-50 0582PED 0582PED-50 0582S 0582S-50 0582S-F 0582S-F-50 0582S-3 0582S-3-50	Approved subject to submission of fee as per new SRO.

	Receipt No. 0115262623		0582S-7 0582S-7-50 5582 5582-40 8581 8581-50 8582 8582-50 8582PED 8582PED-50 Shelf life: 5 YEARS	
223.	Electro Med Corporation, 53 Mall Avenue, 54 The Mall , Near Panorama Shopping Centre, Lahore. ELI-00163 Application Date: 13-03-2025 Fee of Rs. 31000/- Receipt No. 50980659747	BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada. Documents submitted: FSC (Canada) validity 03-11-2029 LOA validity: 24-09-2029 ISO 13485 valid upto 18-11-2024	Brand Name: MediByte / MediByte Jr Generic Name: Portable Sleep Data Recorders Class-B Model number: MBJRK MP8KN Shelf life: 4 YEARS	Approved subject to submission of fee as per new SRO.
224.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date: 06-09-2023 Fee Challan: No: 35246262 Dated: 07-12-2022	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	TDV Dental Crowns (Dental Crowns) Class-A Shelf life: 5 years Codes/sizes: Product Code: As per FSC	Approved subject to submission of fee as per new SRO.
225.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 0728880343 Dated: 07-12-	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	TDV Dental Polishing Paste (Dental polishing Paste) Class-A Shelf life: 48 months Codes/sizes: Codes/sizes: Product Code 0001060000 0001060002 0001050000	Approved subject to submission of fee as per new SRO.

	2022			
226.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 526776690678 Dated: 07-12-2022	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	TDV Dental Wedges (Dental Wedges) Class-A Shelf life: 5 years Codes/sizes: As per FSC	Approved subject to submission of fee as per new SRO.
227.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 4136615975 Dated: 07-12-2022.	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	TDV Dental Finishing & polishing strips (Dental Finishing & polishing strips) Class-A Shelf life: 5 years Codes/sizes: As per FSC	Approved subject to submission of fee as per new SRO.
228.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 72850555423 Dated: 07-12-2022.	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	TDV Dental Matrices System (Dental Matrices system) Class-A Shelf life: 5 years Codes/sizes: As per FSC	Approved subject to submission of fee as per new SRO.
229.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA:	TDV Tools for Dentistry (Tools for Dentistry) Class-A Shelf life: 5 years Codes/sizes: 0005020002 0005040000 0005040016	Approved subject to submission of fee as per new SRO.

	Date : 06-09-2023 Fee Challan: No: 53403531055 Dated: 07-12-2022	Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025	0005040023 0005040024 0005040025 0005040026 0005040027 0005030003 0005030006 0005030009 0005010000	
230.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 314195573726 Dated: 07-12-2022	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025. EC Certificate: Validity: 31-12-2028	TDV Finishing & polishing Discs (Finishing & polishing sandpaper Discs) Class-B Shelf life: 5 years Codes/sizes: 0005020002 0005040000 0005040016 0005040023 0005040024 0005040025 0005040026 0005040027 0005030003 0005030006 0005030009 0005010000	Approved subject to submission of fee as per new SRO & valid FSC of reference country or EC Certificate.
231.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 06-09-2023 Fee Challan: No: 516936057 Dated: 07-12-2022	Legal manufacturer: TDV Dental LTDA. ADDRESS: XV DE Novembro Street, # 9944, City of Pomerode, State Of Santa Catarina, Brazil. Documents submitted: LOA: Validity:22-08-2025 FSC (electronically signed): Brazil issued on 09-03-2022 ISO 13485 valid upto 25-05-2025.	Optimize (Finishing & Polishing material) Class-B Shelf life: 5 years Codes/sizes: 0000000003 0000000009 0000000010 0000000011 0000000012 0010010016 0010010004	Approved subject to submission of fee as per new SRO & valid FSC of reference country or EC Certificate.
232.	M/S GHAZALI BROTHERS 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN ELI-00240 Date of R& I 13th March 2023 Fee Rs. 5,000/	Meidile (Ningbo) Mother And Infant Products CO. LTD., NO.3-1 South Gongji Road, Linshan Town, Yuyao City, Zhejiang Province, PRC. Documents submitted: LOA: Validity: 22nd Oct, 2027 FSC: China Validity: Oct, 2022.	ACCUMAX BREAST PUMP Class A Shelf Life: 5 Years Codes/Sizes: AX-900, AX-800, AX-188 (W188), AX-999 (DQ-S001-999), AX-111-1001 (D-111-1001), AX-188-999 (RH-188-999), AX-01-99 (S01-S99), AX-189-999 (W189-999)	Approved subject to submission of evidence of submission of fee along with R&I receiving.

	through slip no. 136672990, dated 07/03/2023			
233.	Cardiac Care 848-C Shadman -1, Lahore ELI-00070 R&I 03-03- 2020 Fee Challan No Cardiac Care 848-C Shadman -1, Lahore ELI-00070 R&I 03-03- 2020 Fee Challan No 1931030 dated 28-02-20 dated 28-02-20	VYGON Address: 5 rue Adeline - 95440 Ecouen – FRANCE. Documents submitted: FSC issued date: 24/07/2023 LOA valid : 31/12/2026 ISO 13485 valid upto 09-05-2027	CVP manometer (Manometer tube for venous pressure measurement + extension line) Class A Shelf Life: 05 years Codes 80297.00C	Approved
234.	Radiant Medical Private Limited 06-Sher Shah Block New Garden Town Lahore, Pakistan. ELI-00135 Date of R& I 28-Jan-2025 Fee Rs. 5,000/ Fee Challan No 1931030	Inami & Co. Ltd., 24-2, Hongo 3-Chome, Bunkyo-ku, Tokyo 113-0033, Japan. Documents submitted: FSC issued date: 15/10/2024 LOA valid : 01/10/2025 ISO 13485 valid upto 31-07-2027	L-0187-LED LED Slit Lamp Class A Shelf Life: 07 years Codes 80297.00C	Approved
235.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altat Hussain Road, New Challi, Karachi- 74000, Pakistan Lic. No. ELI-00161 R&I: 16/07/2020	BonreeMedical Co., Ltd. Address: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, People's Republic Of China LOA: Validity: 31/12/2030 FSC: CHINA ISSUANCE DATE: 25/10/2023 VALIDITY: 24/10/2025 ISO 13485: ISSUANCE DATE: 06/09/2022 EXPIRY DATE: 31/07/2025 EC Certificate: ISSUANCE DATE: 10/02/2020 EXPIRY DATE: 26/05/2024	COMFORT CARE AEROSOL MASK CLASS: B Shelf life 5 years SIZES: ADULT/CHILD/ PEDIATRIC/NEW BORN Submission 16/07/2020	Approved subject clarification of the brand name as per FSC and submission of valid Ce certificate

236.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 16/07/2020	BonreeMedical Co., Ltd. Address: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, People's Republic Of China LOA: Validity: 31/12/2030 FSC: CHINA ISSUANCE DATE: 25/10/2023 VALIDITY: 24/10/2025 ISO 13485: ISSUANCE DATE: 06/09/2022 EXPIRY DATE: 31/07/2025 EC Certificate: ISSUANCE DATE: 10/02/2020 EXPIRY DATE: 26/05/2024 Renewal applied	K&K TRACHAEL TUBE CLASS: B Shelf life 5 years SIZES: CUFFED :2.5/3.0/3.5/4.0/4.5/5.0/5.5/ 6.0/6.5/7.0/7.5/8.0/8.5/9.0 UNCUFFED :2.5/3.0/3.5/4.0/4.5/5.0/5.5 Submission 16/07/2020	Approvedcuffed subject to submission of the valid CE certificate and brand name clarification since in the FSC is Endotracheal tube and applied is K&K TRACHAEL TUBE
237.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 16/07/2020	BonreeMedical Co., Ltd. Address: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, People's Republic Of China LOA: Validity: 31/12/2030 FSC: CHINA ISSUANCE DATE: 25/10/2023 VALIDITY: 24/10/2025 ISO 13485: ISSUANCE DATE: 06/09/2022 EXPIRY DATE: 31/07/2025 EC Certificate: ISSUANCE DATE: 10/02/2020	COMFORT CARE OXYGEN MASK CLASS: B Shelf life 5 years SIZES: ADULT/CHILD/ PEDIATRIC Submission 16/07/2020	Approved subject to submission of the CE certificate and R&I receiving's and valid fee slip
238.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 28/02/2020	Jiangsu Weikang Jiejing Medical Apparatus Co.,Ltd Address: No.18,Wenzhou Road,Economic Development District, Shuyang, Jiangsu Province, China. LOA: Validity: not written FSC: CHINA 27/11/2025 ISO 13485: ISSUANCE DATE: 21/04/2023 EXPIRY DATE: 28/04/2025	GREEN DISPOSABLE sterile CATHETERS SIZE & MODEL: Disposable Foley Catheter (Fr6,fr8,fr10,fr12,fr14,fr16, fr18,fr20,fr22,fr24,fr26,fr28) Disposable Suction Catheter (Fr6,fr8,fr10,fr12,fr14,fr16, fr18,fr20) Disposable Nelaton Catheter (Fr6,fr8,fr10,fr12,fr14,fr16, fr18,fr20,fr22,fr24,fr26,fr28, fr30,fr32,fr34)	Deferred for submission of the brand name clarification or revise the From 7A as per FSC. Also provide valid Ce certificate Provide fresh LOA

		EC Certificate: ISSUANCE DATE: 26/04/2019 EXPIRY DATE: 16/04/2025	CLASS: B Shelf life 5 years Submission 28/02/2020	
239.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altat Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 28/02/2020	Jiangsu Weikang Jiejing Medical Apparatus Co.,Ltd Address: No.18,Wenzhou Road,Economic Development District, Shuyang, Jiangsu Province, China. LOA: Validity not written issued in 2019 FSC: CHINA 27/11/2025 ISO 13485: ISSUANCE DATE: 21/04/2023 EXPIRY DATE: 28/04/2025 EC Certificate: ISSUANCE DATE: 26/04/2019 EXPIRY DATE: 16/04/2024	GREEN DISPOSABLE STERILE TUBES SIZE & MODEL: Disposable Stomach Tubes (Fr6,fr8,fr10,fr12,fr14,fr16,fr18,fr20) Disposable Feeding (Nasogastric) Tubes (fr4,fr5,fr6,fr7,fr8,fr10,fr12,fr14) CLASS: B Shelf life 5 years Submission 28/02/2020	Deferred for submission of clarification regarding the brand name as per FSC and revise form 7A. also provide valid Ce certificate and fresh LOA
240.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altat Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 28/02/2020	Jiangsu Weikang Jiejing Medical Apparatus Co.,Ltd Address: No.18,Wenzhou Road,Economic Development District, Shuyang, Jiangsu Province, China. LOA: Validity: 31/12/2030 FSC: CHINA 27/11/2025 ISO 13485: ISSUANCE DATE: 21/04/2023 EXPIRY DATE: 28/04/2025 EC Certificate: ISSUANCE DATE: 26/04/2019 EXPIRY DATE: 16/04/2025	COMFORT CARE NASAL OXYGEN CANNULA SIZE: ADULT/CHILD/ PEDIATRIC/NEW BORN CLASS: B Shelf life 5 years Submission 28/02/2020	Approved subject to submission of the valid Ce certificate and fresh LOA
241.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altat Hussain Road, New Challi,	M/S. SHANGHAI KINMED IMPORT & EXPORT CO., LTD ADD: SUIT L, 12TH FLOOR, NO.588 YINGKOU ROAD, SHANGHAI, CHINA Tel:+86 21 61172171 Fax:+86 21 61172173	COMFORT CARE SUCTION CONNECTING TUBE WITH YANKUER HANDLE CLASS: B Shelf life	Deferred for submission of the embassy attested valid FSc and notarized CE certificate

	Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 08/01/2025	LOA: Validity: 31/12/2030 FSC: CHINA 20/12/2025 ISO 13485: ISSUANCE DATE: 14/09/2024 EXPIRY DATE: 26/09/2027 EC Certificate: ISSUANCE DATE: 21/05/2024 EXPIRY DATE: 20/05/2029	5 years	
242.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 08/01/2025	M/S. SHANGHAI KINMED IMPORT & EXPORT CO., LTD ADD: SUIT L, 12 TH FLOOR, NO.588 YINGKOU ROAD, SHANGHAI, CHINA Tel:+86 21 61172171 Fax:+86 21 61172173 LOA: Validity: 31/12/2030 FSC: CHINA 20/12/2025 ISO 13485: ISSUANCE DATE: 14/09/2024 EXPIRY DATE: 26/09/2027 EC Certificate: ISSUANCE DATE: 21/05/2024 EXPIRY DATE: 20/05/2029	COMFORT CARE DISPOSABLE SURGICAL BLADE (without handle) SIZE: 10g/11g/12g/15g/20g/21g/22g/23g/24g CLASS: B Shelf life 5 years	Approved subject to submission of the R&I receiving's and Ce certificate
243.	New Pakistan Traders. Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi-74000, Pakistan Lic. No. ELI-00161 R&I: 08/01/2025	ZIBO EASTMED HEALTHCARE PRODUCTS CO., LTD NO.118, HUAGUANG ROAD, ZHANGDIAN DISTRICT, ZIBO 255000, SHANDONG, CHINA LOA: Validity: 25/12/2029 FSC: CHINA 27/12/2027 ISO 13485: ISSUANCE DATE: 17/08/2022 EXPIRY DATE: 16/08/2025	COMFORT CARE I.V. FLOW REGULATOR (DIA FLOW) CLASS: B Shelf life 5 years	Approved subject to submission of the notarized and valid CE certificate along with the valid FSC having the applied product. Submit stability studies
244.	Name Rech International, Karachi Address of	Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA FSC	ACP Double syringe	Deferred for submission of the embassy attested FSC Submit Revised Form

	Importer 247/B, Block 6 PECHS Shahrah-e- Faisal Karachi Fee 5000	Valid til 19.09.2026 LOA- Validity- 30TH June,2027 ISO 13485- Validity 21-11-2025 Full Quality Assurance Certificate Or Equivalent: FQA-Validity- 26-05-24	Class A Shelf life N/A ABS-1001 ABS-1001-L ABS-1001-S ABS-10010S ABS-10011 ABS-10014 ABS-1002 ABS-10026-15 ABS-10027 ABS-10064 ABS-10066 ABS-1050 ABS-10080 HORIZON 24-AH ABS-10056 37227 AR-10055	7A having the correct class and submit differential fee
245.	Name Rech International, Karachi Address of Importer 247/B, Block 6 PECHS Shahrah-e- Faisal Karachi Date of R& I Submission date: Aug,2024 Fee Rs 5,000	Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA FSC Valid til 19.09.2026 LOA- Validity- 30TH June,2027 ISO 13485- Validity 21-11-2025 Full Quality Assurance Certificate Or Equivalent: FQA-Validity- 26-05-24	Scopes Class A Shelf life N/A AR-3000AW AR-3350- 1930 AR3350-2430 AR-3350-2470 AR3350-2730 AR-3350- 2770 AR-3350-2930 AR-3350-3030 AR3350-3070 AR-3350- 4030H AR-3350-4030R AR-3350-4031 AR-3350-4070H AR3350-5230 AR-3350-5270 AR-3351-1000 AR-3351-1000L AR3351-1030 AR-3351-1030L AR-3351-1045 AR-3351-1045L AR3351-3030 AR-3351-5500 AR-3351-5500L AR-3351-5530 AR3351-5530L AR3351-5545 AR-3351- 5545L AR-3352-5500 AR-3352-5500L AR3352-5530 AR-3352- 5530L AR-3352-5545 AR-3352-5545L AR3355-0001 AR-3355- 1930 AR-3355-2430 AR-3355-2470 AR3355-2730 AR-3355-2770 AR-3355-3070 AR-3355-4000 AR3355-4030 AR-3355- 4030H AR-3355-4031 AR-3355-4070H AR3355-5230 AR-3355- 5270 S76248 AR-3350-4030H AR3350-4071 AR-3351-1031 AR-3352-5531 AR-3351-1001 AR3352-5501	Deferred for submission of the embassy attested FSC or clarify the brand name. Submit Revised Form 7A having the correct class and submit differential fee
246.	Name Rech International, Karachi Address of Importer 247/B, Block 6 PECHS Shahrah-e- Faisal Karachi Date of R& I Submission date: Aug,2024 Fee Rs 5,000	Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA FSC Valid til 19.09.2026 LOA- Validity- 30TH June,2027 ISO 13485- Validity 21-11-2025 Full Quality Assurance Certificate Or Equivalent: FQA-Validity- 26-05-24	Arthroscopic hand set (Instruments) Class A Shelf life N/A	Deferred for submission of the embassy attested FSC R&I receiving Fee slip
247.	Name Rech International, Karachi Address of	Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA FSC	Power and shaver Class A AR-8300 AR-8305 AR-8310 AR-	Deferred for submission of the embassy attested FSC or clarify the

Importer 247/B, Block 6 PECHS Shahrah-e- Faisal Karachi Date of R& I Submission date: Aug,2024 Fee Rs 5,000	Valid til 19.09.2026 LOA- Validity- 30TH June,2027 ISO 13485- Validity 21-11-2025 Full Quality Assurance Certificate Or Equivalent: FQA-Validity- 26- 05-24	8315C AR-8330F AR-8330FK AR- 8330FO AR-8330H AR-8330RH AR-8330SJ AR-8330SJO AR- 8330SV AR-8330TK AR-8330TO AR-8330V AR-8330VO AR-8332H AR-8332RH AR-8350CDS AR- 8350DS AR-8350PR AR-8350ST AR-8380BC AR-8380DC AR- 8380DS AR-8380EX AR-8380SR AR-8380ST AR-8380SW AR- 8400BC AR-8400CBC AR- 8400CDC AR-8400CDS AR- 8400CEX AR-8400CRE AR- 8400CSR AR-8400CSS AR- 8400CST AR-8400CTD AR- 8400CTS AR-8400DC AR-8400DS AR-8400EX AR-8400HSO AR- 8400OBE AR-8400PR AR- 8400RBE AR-8400SR AR-8400ST AR-8400TD AR-8402C AR-8485- 14 AR-8500BC AR-8500BL AR- 8500COE AR-8500COT AR- 8500CRE AR-8500DS AR-8500EX AR-8500FOE AR-8500FOS AR-8500FOT AR- 8500HSO AR-8500OBE AR- 8500RBE AR-8500SR AR-8500ST AR-8500TBT AR-8500TD AR- 8550BC AR-8550COE AR- 8550COS AR-8550COT AR- 8550CRE AR-8550DC AR-8550DS AR-8550EX AR-8550FOE AR- 8550FOS AR-8550FOT AR- 8550HSO AR-8550OBT AR- 8550PR AR-8550RBE AR-8550SR AR-8550ST AR-7300DS AR- 7300OBT AR-7300RBE AR- 7300SR AR-7400TD "AR- 8500OBE (8-flute)" AR-200 AR- 400DAO AR-400 AR-400UBH AR-400ATK AR-400UBC AR- 400UBC-4 AR-400WMC AR- 400SAG AR-400DK74 AR- 400DJ40 AR-400DJ74 AR- 400DJH50 AR-400DJH74 AR- 400DZH AR-400DT AR-400DHA AR-400ARL AR-400RZH AR- 400UB AR-400PD AR-200C AR- 200M AR-200M-ISO AR-200SP AR-300 AR-300-040S AR-300- 041S AR-300-042S AR-300-043S AR-300-044S AR-300-045S AR- 300-050S AR-300-051S AR-300- 052S AR-300-406S AR-300-407S AR-300-450S AR-300-B001 AR- 300-B002 AR-300-B003 AR-300- B004 AR-300-B101 AR-300-B102 AR-300-B201 AR-300-B202 AR-	brand name. Submit Revised Form 7A having the correct class and submit differential fee
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			300-B301S AR-300/600F-EU AR-300ATK AR-300B AR-300B-2 AR-300C AR-300C-G AR-300CA AR-300DAO-2 AR-300DJ AR-300DJH AR-300DK30 AR-300DK45 AR-300E AR-300H AR-300HKEY AR-300KEY AR-300L AR-300LBH AR-300PD24 AR-300RAO AR-300RJ AR-300SAG AR-300SR AR-300WD16 AR-600 AR-600-000S AR-600-001S AR-600-002S AR-600-003S AR-600-004S AR-600-005S AR-600-006S AR-600-007S AR-600-010S AR-600-011S AR-600-012S AR-600-013S AR-600-020S AR-600-021S AR-600-022S AR-600-025S AR-600-026S AR-600-050S AR-600-051S AR-600-052S AR-600-053S AR-600-103S AR-600-104S AR-600-106S AR-600-107S AR-600-110S AR-600-150S AR-600-151S AR-600-250S AR-600-300S AR-600-301S AR-600-302S AR-600-303S AR-600-304S AR-600-305S AR-600-306S AR-600-307S AR-600-310S AR-600-311S AR-600-312S AR-600-313S AR-600-350S AR-600-351S AR-600-352S AR-600-353S AR-600ARL AR-600ATK AR-600C AR-600C-G AR-600DAO AR-600DAOP AR-600DAOT AR-600DJ AR-600DJH AR-600DK AR-600DZH AR-600GC AR-600HKEY AR-600KEY AR-600L AR-600LBH AR-600PD-2 AR-600PD-3 AR-600RAOP AR-600RJ AR-600RK AR-600RZH AR-600SAG AR-600SAGAO AR-600SAGMIS AR-600SAGS AR-600SR AR-600SRS AR-600WD-2 OEM01525000 OEM04005900 OEM04013500 OEM04364100 OEM04653500 OEM04725700 OEM04725900 OEM04726000 OEM04726100 OEM04726200 OEM04800400 OEM04800500 OEM06202400 OEM06290600 AR-400UBH-1 AR-400ATK-1 AR-400RJ74 AR-400RAOP AR-400DHS AR-400UBC-3 AR-600DHS AR-600C-3 AR-400AC-1 S-N1 AR-200H AR-200CA AR-400DS AR-400PRAO AR-400PRMT AR-400PRHU AR-400SR 220500799 220501330 220202293 220501328 AR-600-301S AR-600-302S AR-600-353S
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248.	M/s RECH International, Karachi ELI-00257	/s Beijing Libeier Bio-engineering Institute Co., Ltd. 12 Chuangxin Road, Changping Science and Technology Park, Changping Area, Beijing, P. R. China FSC: China Validity: 2025.10.26 LOA Validity: 31-Dec-2026	Brand Name; Soprano Posterior cervical screw rod system instrument set Generic Name; Orthopedic Manual Surgical Instrument Set Class A	Deferred for submission of the valid and embassy attested FSC valid Ce certificate. Submit R&I receiving and fee slip.
249.	NI healthcare products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi ELI-01117	Legal Manufacturer: Nanyang Major Medical Products Co Ltd Address: No. 16 County Road, Jinhua Town, Wenchang District, Nanyang City, Henan Province, China FSC: China Validity: 29-02-2024 LOA 04-01-2029	Brand Name: WARMA Hyperthermia System full body Blanket Generic Name: Warming Blanket Class: A Shelf Life: 5 years Sizes: 220*120 cm 230*75cm 120*100cm 140*100cm	Approved
250.	NI healthcare products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi ELI-01117	Legal Manufacturer: Medcaptain Medical Technology CO Ltd. Legal Address: 12th floor Baiwang No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, Peoples Republic of China Manufacturing Address Medcaptain Medical Technology CO Ltd. Building C Jiale Science and Technology Industrial Park Matian Street, Guangming 518106 Shenzhen, Guangdong, Peoples Republic of China Tel: +86-755-269563369 Fax: +86-755-26001651 mc.service@medcaptain.com FSC: China Validity: 19-12-2024 LOA Validity: 14-08-2027	Brand Name: Navi-60 Generic Name: Vienilluminator (Finder) Class: A Shelf Life: 05years	Approved
251.	NI healthcare products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi ELI-01117	Manufacturer: Medcaptain Medical Technology CO Ltd. Legal Address: 12th floor Baiwang No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, Peoples Republic of China Manufacturing Address Medcaptain Medical Technology CO Ltd. Building C Jiale Science and Technology Industrial Park Matian Street, Guangming 518106 Shenzhen, Guangdong, Peoples Republic of China FSC: China Validity: 19-03-2025 LOA Validity: 14-08-2027	Brand Name: Video Laryngoscope VS10S/VS-10M/VS10H Generic Name: Video Laryngoscope Class: A Shelf Life: 05years	Approved
252.	NI healthcare products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi ELI-01117	Legal Manufacturer: Mcreat (GUAGNZHOO) Bio-Tech CO. Ltd Address: 3rd Floor, b15 Huachuang Industry Area Jinshan, Shiji Town, Panyu District, Guangzhou, Guangdong China. FSC: China Validity: 24-03-2026 LOA Validity: 31-12-2026	Brand Name: Mcreat Suction Liner Bag and Canister Generic Name: Suction Liner Bag and Canister Class A Shelf Life: 02years Sizes: 1500ml 2000ml 2500ml	Approved with the Suction Liner Bag

253.	Alpha Initiative (Private) Limited Address: Suite # 9, Ground Floor, Khudadad Heights, Main Margala Road, E-11, Islamabad (ELI-01278)	<u>Legal Manufacturer:</u> The Fred Hollows Intraocular Lens Laboratory Tilganga Eye Center P.O.Box # 561,Postal Code#44600, Gaushala, Kathmandu, Nepal (+977) 1 597 0048 <u>FSC:</u> Country Validity: 29-04-2025 <u>LOA</u> Validity: 24-09-2028 <u>CE Certificate</u> Validity: 31-12-2027 <u>ISO 13485</u> Validity: 08-12-2025	Brand Name: Tecsoft tetra (Generic name): Sterile Foldable Acrylic Intraocular Lens. Class: C Shelf Life: 4 years Group: Single	Approved
254.	Alpha Initiative (Private) Limited Address: Suite # 9, Ground Floor, Khudadad Heights, Main Margala Road, E-11, Islamabad (ELI-01278)	<u>Legal Manufacturer:</u> The Fred Hollows Intraocular Lens Laboratory Tilganga Eye Center P.O.Box # 561,Postal Code#44600, Gaushala, Kathmandu, Nepal (+977) 1 597 0048 <u>FSC:</u> Country Validity: 29-04-2025 <u>LOA</u> Validity: 24-09-2028 <u>CE Certificate</u> Validity: 31-12-2027 <u>ISO 13485</u> Validity: 08-12-2025	Brand Name: Tecsoft Flex (Generic name): Sterile Foldable Acrylic Intraocular Lens. Class: C Shelf Life: 4 years Group: Single	Approved
255.	Alpha Initiative (Private) Limited Address: Suite # 9, Ground Floor, Khudadad Heights, Main Margala Road, E-11, Islamabad (ELI-01278)	<u>Legal Manufacturer:</u> The Fred Hollows Intraocular Lens Laboratory Tilganga Eye Center P.O.Box # 561,Postal Code#44600, Gaushala, Kathmandu, Nepal (+977) 1 597 0048 <u>FSC:</u> Country Validity: 29-04-2025 <u>LOA</u> Validity: 24-09-2028 <u>CE Certificate</u> Validity: 31-12-2027 <u>ISO 13485</u> Validity: 08-12-2025	Brand Name: The Fred Hollows, One Sterile Intraocular lens (Generic name): Sterile One Piece Rigid PMMA Intraocular Lens. Class: C Shelf Life: 5 years Group: Single Codes/Sizes: Model FA60B	Approved

256.	ELATE CC PVT LTD Suite No.1, 2, 3, ST-3, Block- 3, Gulshan-e- Iqbal, Karachi- Pakistan. ELI-00294	Legal Manufacturer: Shaoxing Undis Medical Technology Co., Ltd Manufacturing Site: No. 12 Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA, Date of R&I 31-12-2024 FSC: Country of Origin- China Validity: 13-DEC- 2026 FSC: Applied on CE LOA Validity: 30-12- 2027 EC Certificate Validity: 19-06-2023 Extension letter attached ISO 13485 Validity: 19-06-2025	Brand Name YBH Disposable Anesthesia Breathing Circuit with Accessories Generic Name ANESTHESIA BREATHING CIRCUIT Class B Shelf Life: 3 years for Anesthesia Breathing Circuit , Silicone breathing circuit, Disposable Breathing Filter, Breathing Bags 5 years for Disposable Heated Wire circuit Codes/Sizes: ANESTHESIA BREATHING CIRCUIT ACCA-160、 ACCA-240、 ACCP-160、 ACCN-160、 BCCA-160、 BCCA-240、 BCCP-160、 BCCN-160 Silicone breathing circuit HXG-09-04, HXG-09-05, HXG-09-06 Disposable Heated Wire circuit 、 CH0102 Disposable Breathing Filter HMEF02、 HMEF03、 HMEF04 Breathing Bags HXN-02-01、	Approved YBH Disposable Anesthesia Breathing Circuit subject to submission of the R&I receiving and fee slip along with the stability studies. Apply and submit separate fee for the others

			HXN-02-02, HXN-02-03	
257.	ELATE CC PVT LTD Suite No.1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal, Karachi- Pakistan. ELI-00294	Legal Manufacturer: M/s Armstrong Medical Ltd Manufacturing Site: Wattstown Business Park, Newbridge Road, Coleraine BTS52 IBS , Date of R&I 31-12-2024 FSC: Country of Origin- UK Validity: 12-05-2029 LOA Validity: 30-12-2027 EC Certificate Validity: 19-04-2023 Extension letter attached ISO 13485 Validity: 19-04-2026	Brand Name Nasal Interface Generic Name Nasal Cannula Class B Shelf Life: 5 years Codes/Sizes: Aquanase AMNS-1005, AMNS- 1004-002, AMNS-2006- 002, AMNS-2004- 002, AMNS-1006, AMNS- 1006- 002, AMNS-2005- 002, AMNS- 2005, AMNS-2004. Neonatal and Paediatric High Flow Cannula AMNC-2005, AMNC- 2004, AMNC-2003, AMNC-2002, AMNC-2001	Approved Nasal Interface subject to submission of the R&I receiving and fee slip along with the stability studies. Apply and submit separate fee for the others
258.	ELATE CC PVT LTD Suite No.1, 2, 3, ST-3, Block-3, Gulshan-e- Iqbal, Karachi- Pakistan. ELI-00294	Legal Manufacturer: M/s Armstrong Medical Ltd Manufacturing Site: Wattstown Business Park, Newbridge Road, Coleraine, Date of R&I 31-12-2024 FSC: Country of Origin- UK Validity: 12-05-2029 LOA Validity: 30-12-2027 EC Certificate Validity: 19-04-2023 Extension letter attached ISO 13485 Validity: 19-04-2026	Brand Name AQUAVENT CPAP SYSTEM Generic Name CPAP SYSTEM Class B Shelf Life: 5 years Codes/Sizes: Aquaavent CPAP system AMPCPUK01272, AMPCPUK01275, AMPCPUK01258, AMCP1408- 003, AMCP1408-002, AMCP1408- 011 Aquaavent Heated humidified oxygen system AMHO1509-008, AMHO1509-055, AMHO1509-050, AMHO1509-017, PEP Valves	Approved AQUAVENT CPAP SYSTEM subject to submission of the R&I receiving and fee slip along with the stability studies. Apply and submit separate fee for the others

			AMPV8015, AMPV8012, AMPV8010, AMPV8007, AMPV8005, AMPV8003. Accessories AquaVent Gas Flow Driver AMFD140i-UK, AMFD140i-UK2	
259.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12 th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: 05-04-2022 Fee Submission Detail: Amount: 25,000/- Challan No. 97369378126	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye FSC: FSC Turkey Issued on 14-01-2022 Valid for 36 Months) Turkey and EU Letter of Authorization: Issued on 01-01-2022 Valid Till 31-12-2025 ISO: ISO Turkey Issued on 02-02-2022 Valid Till 01-02-2025 Production Quality Assurance Certificate: Attached with Dossier CE: CE Turkey Issued on 29-04-2021 Valid Till 27-05-2024	Sasan Medical Disposable Pressure Monitoring Set Codes/Sizes: SB00020DN SB00020SN Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies
260.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12 th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: 05-04-2022 Fee	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye FSC: FSC Turkey Issued on 14-01-2022 Valid for 36 Months) Turkey and EU Letter of Authorization: Issued on 01-01-2022 Valid Till 31-12-2025 ISO: ISO Turkey Issued on 02-02-2022 Valid Till 01-02-2025 Production Quality Assurance	Sasan Medical Disposable Extension Line Codes/Sizes: SL50120EN SL10100CN SL10085CN SL10460CN Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies

	<u>Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. 8331001977	Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on 29-04-2021 Valid Till 27-05-2024		
261.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: 05-04-2022 Fee <u>Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. 040952296457	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye <u>FSC:</u> FSC Turkey Issued on 14-01-2022 Valid for 36 Months) Turkey and EU <u>Letter of Authorization:</u> Issued on 01-01-2022 Valid Till 31-12-2025 <u>ISO:</u> ISO Turkey Issued on 02-02-2022 Valid Till 01-02-2025 Production Quality Assurance Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on 29-04-2021 Valid Till 27-05-2024	Sasan Medical Disposable Tubing Set Adult with Filter Codes/Sizes: SD01151FP SDC4440EN SDC4441EN SDC5441EN SDC4331EN Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies
262.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: 05-	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye <u>FSC:</u> FSC Turkey Issued on 14-01-2022 Valid for 36 Months) Turkey and EU <u>Letter of Authorization:</u> Issued on 01-01-2022 Valid Till 31-12-2025 <u>ISO:</u> ISO Turkey Issued on 02-02-2022 Valid Till 01-02-2025	Sasan Medical Disposable Multi Perfusion Set Codes/Sizes: SM00160SN Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies

	<u>04-2022 Fee Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. 9018711208	Production Quality Assurance Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on <u>29-04-2021</u> Valid Till <u>27-05-2024</u>		
263.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: <u>05-</u> <u>04-2022 Fee Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. 0936426079	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dayyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye <u>FSC:</u> FSC Turkey Issued on <u>14-01-2022</u> Valid for 36 Months) Turkey and EU <u>Letter of Authorization:</u> Issued on <u>01-01-2022</u> Valid Till <u>31-12-2025</u> <u>ISO:</u> ISO Turkey Issued on <u>02-02-2022</u> Valid Till <u>01-02-2025</u> Production Quality Assurance Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on <u>29-04-2021</u> Valid Till <u>27-05-2024</u>	Sasan Medical Disposable Aspiration Set Codes/Sizes: SR00010SP SR00060SP Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies
264.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Ve Uretim VE Pazarlama A.S Address: Dayyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye <u>FSC:</u> FSC Turkey Issued on <u>14-01-2022</u> Valid for 36 Months) Turkey and EU <u>Letter of Authorization:</u> Issued on <u>01-01-2022</u> Valid Till <u>31-12-2025</u> <u>ISO:</u>	Sasan Medical Disposable Blood Cardioplegia Set Adult Codes/Sizes: SK00321HN Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies

	Submission: <u>05-04-2022 Fee</u> <u>Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. <u>434801506</u>	ISO Turkey Issued on <u>02-02-2022</u> Valid Till <u>01-02-2025</u> Production Quality Assurance Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on <u>29-04-2021</u> Valid Till <u>27-05-2024</u>		
265.	M/S Medica Address: Office No. 1, Mezzanine Floor, Plot No. C, 12th Commercial Street, Phase II Extension, Defence Housing Authority, Karachi-75500, Pakistan. ELI-00237 Date of dossier Submission: <u>05-04-2022 Fee</u> <u>Submission</u> <u>Detail:</u> Amount: 25,000/- Challan No. <u>268035088964</u>	Name of Legal Manufacturer: Sasan Saglik Malzemeleri Uretim VE Pazarlama A.S Address: Dagyaka Mah 2004 Cad. No:6 Kahramankazan Ankara Turkiye <u>FSC:</u> FSC Turkey Issued on <u>14-01-2022</u> Valid for 36 Months) Turkey and EU <u>Letter of Authorization:</u> Issued on <u>01-01-2022</u> Valid Till <u>31-12-2025</u> <u>ISO:</u> ISO Turkey Issued on <u>02-02-2022</u> Valid Till <u>01-02-2025</u> Production Quality Assurance Certificate: Attached with Dossier <u>CE:</u> CE Turkey Issued on <u>29-04-2021</u> Valid Till <u>27-05-2024</u>	Sasan Medical Disposable Hemofiltration Set Codes/Sizes: SU0042SP SU0011SP SU0051SP Class B Fee Rs. 25000/- Shelf Life 03 Years	Approved subject to submission of the valid FSC, ISO 13485 and notarized Ce certificate. Also submit Fee slip and stability studies
266.	(ELI-00157)	Molnlycke Health Care AB Gamlestadsvagen 3C Box13080, SE-402 52 Goteborg, Sweden Manufacturing Site: Molnlycke Health Care Sdn Bhd, Malaysia Date of R&I 10-12-2024 FSC: Country of Origin Issu date 13-02-2023 LOA Validity: 31-12-2025	Biogel (Surgical Gloves) Class B Shelf Life: 03 years Codes/Sizes: Biogel Surgeons (82255, 82260, 82265, 82270, 82275, 82280, 82285, 82290) Biogel M (82355, 82360, 82365, 82370, 82375, 82380, 82380, 82390) Biogel Super-Sensitive (82555, 82560, 82565, 82570, 82575, 82580,	Approved Biogel Surgeons subject to submission of the stability studies. Apply separately for the others and submit Fee for the others

		ISO 13485 Validity: 27-11-2027	82585, 82590) Biogel NeoDerm (42955, 42960, 42965, 42970, 42975, 42980, 42985, 42990) Biogel Eclipse (75155, 75160, 75165, 75170, 75175, 75180, 75185, 75190) Biogel Eclipse Indicator Underglove (73255, 73260, 73265, 73270, 73275, 73280, 73285, 73290) Biogel Eclipse Indicator System (60755, 60760, 60765, 60770, 60775, 60780, 60785) Biogel Skinsense (50955, 50960, 50965, 50970, 50975, 50980, 50985, 50990) Biogel Skinsense Indicator Underglove (40655, 40660, 40665, 40670, 40675, 40680, 40685, 40690) Biogel Skinsense Indicator System (28855, 28860, 28865, 28870, 28875, 28880, 28885) Biogel PI Micro Indicator (48555, 48560, 48565, 48570, 48575, 48580, 48585, 48590) Biogel PI Micro Indicator Underglove (48955, 48960, 48965, 48970, 48975, 48980, 48985, 48990) Biogel PI Micro Indicator System (48355, 48360, 48365, 48370, 48375, 48380, 48385) Biogel PI UltraTouch (40955, 40960, 40965, 40970, 40975, 40980, 40985, 40990) Biogel PI Indicator Underglove (41655, 41660, 41665, 41670, 41675, 41680, 41685, 41690) Biogel PI Indicator System (41455, 41460, 41465, 41470, 41475, 41480, 41485)	
267.	TRI-TECH INTERNATIONAL	Spencer Italia srl – located at Via Provinciale, 12 - 43038 Sala Baganza PR – Italy FSC Italy issued 9.04.2024 .	EKO-S 60 Barella Autocaricante/ Self Loading Stretcher Code CA 80001	Approved subject to submission of the R&I receiving and fee slip not

		ISO valid till 04.8.2024 LAO valid till 25.08.2025	Class A Shelf life N/A letter attached	submitted
268.	TRI-TECH INTERNATIO NAL	Spencer Italia srl – located at Via Provinciale, 12 - 43038 Sala Baganza PR – Italy FSC Italy issued 9.04.2024 . ISO valid till 04.8.2024 LAO valid till 25.08.2025	EKO-S 68 Barella Autocaricante/ Self Loading Stretcher Code CA 80002 Class A Shelf life N/A	Approved subject to submission of the R&I receiving and fee slip not submitted
269.	TRI-TECH INTERNATIO NAL	Spencer Italia srl – located at Via Provinciale, 12 - 43038 Sala Baganza PR – Italy FSC Italy issued 9.04.2024 . ISO valid till 04.8.2024 LAO valid till 25.08.2025	EKO-MAX SISTEMA DI FISSAGGIO Code ST42723 Class A Service life 05 years	Approved subject to submission of the R&I receiving and fee slip not submitted
270.	DIGITAL IMAGING SYSTEMS 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road , Lahore- 54000, Pakistan, Ph: 92-42- 35407151-53, Fax: 92-42- 35407154 Licence no: ELI-00094 Date of Issuance: 03- 08-2018	<u>Legal Manufacturer:</u> M/s Abbott Medical, 4 Robbins Road, Westford, MA 01886 USA <u>Manufacturing Site:</u> M/s Abbott Medical, 4 Robbins Road, Westford, MA 01886 USA	Dragonfly Opstar Imaging Catheter 1014651 Class D Shelf life: 02 Years	Approved
271.	M/s Kain Medical, Ali Bhai Center 3rd Floor Office # 35 Main Shahrah-e- Qauideen, Karachi (ELI-00506)	<u>Legal Manufacture:</u> M/s Zhejiang Chuangxiang Medical Technology Co., Ltd., Room 101, 201, 301, 401, 501, Building 50 No.650 Hongfeng Road Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province 311100, P.R. China FSC China valid till 08-12-2026	G-TEC Sclerotherapy Needles Class B Shelf life: 03 Years Codes/Sizes: MD-A-SY-2423-2106 MD-A-SY-2423-2306 MD-A-SY-2423-2506 MD-A-SY-2418-2106 MD-A-SY-2418-2306	Approved

		ISO 13485 Valid Till 09-11-2026 CE Certification Valid till 23-07-2029	MD-A-SY-2418-2506	
272.	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 13-03-2025 <u>Fee Challan No.</u> 50980659747 dated: 10-03-2025	<u>Legal Manufacture</u> BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada <u>Manufacturing Site (s):</u> BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada <u>LOA:</u> Validity: 24-09-2029 <u>FSC:</u> Country of Origin Validity: 03-11-2029 <u>EC Certificate:</u> Validity: 31-12-2028 <u>ISO 13485:</u> Validity: 18-11-2027	<u>Brand Name:</u> MediByte / MediByte Jr <u>(Generic Name):</u> Portable Sleep Data Recorders <u>Class B</u> <u>Shelf life:</u> 04 Years - <u>Codes/Sizes:</u> MP8KN MBJRK	Approved subject to submission of fee as per revised SRO for Family
273	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 13-03-2025 <u>Fee Challan No.</u> 0115262623 dated: 10-03-2025	<u>Legal Manufacture</u> BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada <u>Manufacturing Site (s):</u> BRAEBON Medical Corporation, 1-100 Schneider Road, Kanata, Ontario, K2K 1Y2, Canada <u>FSC:</u> Validity: 03-11-2029 <u>LOA:</u> Validity: 24-09-2029	<u>Brand Name:</u> Ultima Cannula <u>(Generic Name):</u> Nasal Cannula for Sleep Recorders <u>Class A</u> <u>Shelf life:</u> 05 Years - <u>Codes/Sizes:</u> 0582 0582-50	Approved subject to submission of fee as per revised SRO for Family

			0582PED 0582PED-50 0582S 0582S-50 0582S-F 0582S-F-50 0582S-3 0582S-3-50 0582S-7 0582S-7-50 5582 5582-40 8581 8581-50 8582 8582-50 8582PED 8582PED-50	
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LOCAL REGISTRATION/ENLISTMENT

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [744-7L]	ACCUJECT Auto-Disable Syringe Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 6572962470. Sizes: ACCUJECT Auto-Disable Syringe 3ml (With 23G,24G,25G,26G, 27G Needle), ACCUJECT Auto-Disable Syringe 5ml (With 23G,24G,25G,26G, 27G Needle)	Approved
2.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [745-7L]	ACCUSET Disposable Infusion Set Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 11602393831 Sizes: ACCUSET IV Set (Without Y-Port and Filter), ACCUSET IV Set(With Y-Port and Filter), ACCUSET IV Set(Luer Lock Connector + Bulb + Y-Port + Filter + Air Vent),	Approved
3.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [746-7L]	ACCUJECT Disposable Syringe Class: B Shelf Life: 5 Years Sizes: ACCUJECT Disposable Syringe 1ml (With 27G Needle), ACCUJECT Disposable Syringe 1ml (With 21G Needle), ACCUJECT Disposable Syringe 1ml (With 22G Needle), ACCUJECT Disposable Syringe 1ml (With 23G Needle),	Deferred for confirmation manufacturing & testing facility for the applied product.

		ACCUJECT Disposable Syringe 1ml (With 24G Needle), ACCUJECT Disposable Syringe 1ml (With 25G Needle), ACCUJECT Disposable Syringe 1ml (With 26G Needle), ACCUJECT Disposable Syringe U-100 (U-100 With 30G Needle), ACCUJECT Disposable Syringe U-100 (U-100 With 31G Needle), ACCUJECT Disposable Syringe 10ml (With 21G Needle), ACCUJECT Disposable Syringe 10ml (With 22G Needle), ACCUJECT Disposable Syringe 10ml (With 23G Needle), ACCUJECT Disposable Syringe 10ml (With 24G Needle), ACCUJECT Disposable Syringe 10ml (With 25G Needle), ACCUJECT Disposable Syringe 10ml (With 26G Needle), ACCUJECT Disposable Syringe 20ml (With 21G Needle), ACCUJECT Disposable Syringe 30ml (With 21G Needle), ACCUJECT Disposable Syringe 50ml (Catheter tip), ACCUJECT Disposable Syringe 50ml (21G Needle), ACCUJECT Disposable Syringe 60ml (Catheter tip), ACCUJECT Disposable Syringe 60ml (With 21G Needle) Fee: 50,000 Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 167436043	
4.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [747-7L]	ACCUJECT Hypodermic Syringe ACCUFLOW IV Cannula ACCUJECT Butterfly Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 834392091518 Sizes:), ACCUJECT Butterfly (14G), ACCUJECT Butterfly (15G), ACCUJECT Butterfly (16G), ACCUJECT Butterfly (17G), ACCUJECT Butterfly (18G), ACCUJECT Butterfly (19G), ACCUJECT Butterfly (20G), ACCUJECT Butterfly (21G), ACCUJECT Butterfly (22G), ACCUJECT Butterfly (23G), ACCUJECT Butterfly (24G)	Deferred the product confirmation manufacturing & testing facility for the applied product. Furthermore, only one product ACCUJECT Butterfly will be considered in the current application. For the other two types the firm will have to submit Prescribed Form & fee.
5.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [748-7L]	ACCUJECT Disposable Hypodermic Needle Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 56335280 Sizes: Disposable Hypodermic Needle (18G), ACCUJECT Disposable Hypodermic Needle (20G) ACCUJECT Disposable Hypodermic Needle (21G), ACCUJECT Disposable Hypodermic Needle (22G), ACCUJECT Disposable Hypodermic Needle (23G), ACCUJECT Disposable Hypodermic Needle	Approved

		(24G), ACCUJECT Disposable Hypodermic Needle (25G), ACCUJECT Disposable Hypodermic Needle (26G), ACCUJECT Disposable Hypodermic Needle (27G), ACCUJECT Disposable Hypodermic Needle (30G), ACCUJECT Disposable Hypodermic Needle (31G)	
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