

Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

DECISIONS OF 99TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 11-09-2025 (PART-I MDL&R PORTAL AGENDA)

99th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 11th September, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathologist, Riphah Health Care Services, Riphah University,	Member
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital	Member

	Pharmacist).	
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
8.	Prof Dr M Nadeen Ahmed, Department of radiology, Agha Khan University Hospital,	Member (attended meeting through videolink)
9.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
10.	Asif Jalil, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants. The Evaluators assisted the secretary in presenting the agenda of the meeting.

Item No. I. CONFIRMATION OF MINUTES OF 97th and 98th meetings of Medical Device Board.

Decision: The Board confirmed the minutes of 97th and 98th meeting of MDB.

License Meeting Agenda

Import License Agenda

Evaluator Name: Muhammad Amin (Evaluator-IX)

New Applications

Sr.No.	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	<p>Name of Establishment: Javed & Sons Surgical</p> <p>Office Address: 435, Mohallah G Block, Gulshan e Ravi,</p> <p>Godown Address: 1-D, AM Colony, Near E Block, Gulshan e Ravi, , Lahore</p> <p>Challan No: 0477524141</p> <p>Fee: Rs 26100 /-</p> <p>Date of Submission: 21 August 2025</p> <p>Tracking ID: MDMC-250821-14024</p>	<p>Name: Aiman Farooq</p> <p>CNIC No: 3310034004490</p> <p>Qualification: Doctor of Pharmacy</p> <p>Experience: Incharge Warehouse (from December 2022 to June 2024)</p>	<p>Designation: Owner</p> <p>Name: Mohsin Javed</p> <p>CNIC No: 3520227414375</p> <p>Address: House No 435, Mohallah G Block, Gulshan-e-Ravi, Samanabad Town, Lahore</p>	Approved
2	<p>Name of Establishment: AA Ortho Implants</p> <p>Office Address: House No: 97C, Madni Town, Hajvery Housing Scheme</p> <p>Godown Address: SHOP NUMBER 7, MAIN CANAL</p>	<p>Name: Gul Naz</p> <p>CNIC No: 3520105395754</p> <p>Qualification: Doctor of pharmacy</p> <p>Experience: Regulatory Officer (from January 2024 to -)</p>	<p>Designation: CEO</p> <p>Name: Jamshaid Iqbal</p> <p>CNIC No: 3520195639841</p> <p>Address: House no. 13, street no 16-A, main</p>	Approved

	ROAD, NEAR SAHARI BAKERY, MEDICAL COLLEGE, LAHORE., Lahore Challan No: 993713637744 Fee: Rs 26100 /- Date of Submission: 12 August 2025 Tracking ID: MDMC- 250812-12630		bazar no 2 ghaziabad society, cantt, lahore.	
3	Name of Establishment: Plusmedical International Office Address: Basement Saddique Chamber 68- Mozang Road Lahore Godown Address: Basement Saddique Chamber 68- Mozang Road Lahore Lahore, Lahore Challan No: 081121223534 Fee: Rs 26100 /- Date of Submission: 01 September 2025 Tracking ID: MDMC- 20250901-14600	Name: Numan Shabbir CNIC No: 3510208165265 Qualification: BSc BioMedical Engineering Experience: Service Engineer (from August 2022 to April 2025)	Designation: CEO Name: Khalid Munir CNIC No: 3510206539585 Address: H. No. 71, St. No. 31, B Block, Abu Bakr Saddique Colony, Band Road, Lahore. Designation: Partner Name: Yasmin Akhter CNIC No: 3740141909804 Address: H. No. 71, St. No. 31, B Block, Abu Bakr Saddique Colony, Band Road, Lahore.	Approved
4	Name of Establishment: WE MOOVERS Office Address: Office no S- 38 ,second floor,AL Makkah	Name: Muhammad Adil Aman CNIC No: 3520246323023 Qualification:	Designation: Owner Name: MUHAMMAD SHOAIB ASGHAR CNIC No:	Approved

	<p>Centre, Hall Road, ., Lahore</p> <p>Godown Address: Office no S-38 ,second floor,AL Makkah Centre, Hall Road, ., Lahore Lahore, Lahore</p> <p>Challan No: 214707959</p> <p>Fee: Rs 25000 /-</p> <p>Date of Submission: 31 July 2025</p> <p>Tracking ID: MDMC-250731-11638</p>	<p>Pharm D</p> <p>Experience: Pharmacist (from July 2025 to -)</p>	<p>3520251740575</p> <p>Address: Feroz pura road, house no 201,Mohala Ahsan Block Nishter Colony , Lahore</p>	
5	<p>Name of Establishment: Medical Solutions</p> <p>Office Address: TM Plaza , 1st Floor , Shop No F 1 , DAV College Road</p> <p>Godown Address: TM Plaza , 1st Floor Shop No 1, DAV College Road Rawalpindi Cantt, Rawalpindi</p> <p>Challan No: 7152294328</p> <p>Fee: Rs 25000 /-</p> <p>Date of Submission: 23 July 2025</p> <p>Tracking ID: MDMC-250723-10954</p>	<p>Name: Muneem Fatima</p> <p>CNIC No: 3630236346186</p> <p>Qualification: Pharma D</p> <p>Experience: Quality Control Pharmacist (from January 2019 to November 2022) Quality Control Head (from January 2023 to -)</p>	<p>Designation: Owner</p> <p>Name: Naqash Arshad Mughal</p> <p>CNIC No: 3740588864145</p> <p>Address: House 144-B, Street No. 11, Jhangir Road , Nadeem Abad, Sir Syed Colony, Rawalpindi Cantt.</p>	Approved
6	<p>Name of Establishment: AAK SCIENTIFIC CORPORATION</p> <p>Office Address: Plot # 59,</p>	<p>Name: Zahida Ibrahim</p> <p>CNIC No: 3520220493822</p> <p>Qualification:</p>	<p>Designation: CEO</p> <p>Name: Muhammad Imran Shahzad</p> <p>CNIC No:</p>	Approved

<p>Second Floor Commercial Area Umer Block, Bahria Town Lahore</p> <p>Godown Address: Plot No. 59, Second Floor Commercial Area, Umer Block Bahria Town , Lahore</p> <p>Challan No: 675449705</p> <p>Fee: Rs 26100 /-</p> <p>Date of Submission: 29 August 2025</p> <p>Tracking ID: MDMC-20250829-14526</p>	<p>B. Pharm</p> <p>Experience: Stability and Validation Analyst (from May 2012 to March 2014)</p>	<p>3520225823353</p> <p>Address: House 1257, Overseas-B, Street 11 Bahria Town Lahore</p> <p>Designation: Director</p> <p>Name: Humaira Ali</p> <p>CNIC No: 3520227792646</p> <p>Address: House No. 1257 Overseas B, Street 11, Bahria Town Lahore</p>	
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Deferred Applications of Licences

Sr.No.	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	<p>Name of Establishment: Global Traders</p> <p>Office Address: 1st floor Tehzeeb Furniture & Home Decor, Opposite Honda North University Road</p> <p>Godown Address: 1st Floor Tehzeeb Furniture, Opposite Honda North University Road, Peshawar</p> <p>Challan No: Rs 545352941346</p> <p>Fee: Rs 25000 /-</p> <p>Date of Submission: 28 July 2025</p> <p>Tracking ID: MDMC-250728-11328</p>	<p>Name: Mansoor Saeed</p> <p>CNIC No: 1730114709821</p> <p>Qualification: Doctor of Pharmacy</p> <p>Experience: Pharmacist (from January 2024 to March 2025)</p>	<p>Designation: Owner</p> <p>Name: Haroon Ur Rashid</p> <p>CNIC No: 1730110421727</p> <p>Address: House No. 88, Street No. 05, Sector F-1, Phase-6 Hayatabad Peshawar</p>	approved

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Renewal of licence Applications

Sr.No.	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	License: ELI-00583 Issue Date: 17 August 2020 Name of Establishment: BNS TRADING EST Office Address: Office No. 339, 3rd Floor, Land Mark Plaza, Jail Road, Lahore Godown Address: Office no 339, 3rd floor, Landmark Plaza Jail Road Lahore, Lahore Challan No: 30284184671 Fee: Rs 12000 /- Date of Submission: 02 August 2025 Tracking ID: MDMC-20250802-01344	Name: Sohaib Ahmed Khan CNIC No: 3520241012617 Qualification: Pharm-D Experience: Pharmacist (from December 2018 to -)	Designation: CEO Name: Muhammad Nadeem Aftab CNIC No: 3520170794333 Address: House no 244, Allama Iqbal Road, Mustafabad Lahore	Deferred for submission of differential fee as per applicable SRO of fee.

Site Verification Applications

Evaluator Name: Muhammad Amin (Evaluator-IX)

Sr.No.	Name of Establishment along with address	CEO/ Director /Proprietor (s) details	Minutes/Decision
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1	<p>Name of Establishment: Quintex Healthcare</p> <p>Office Address: Near Makhan Shah Darbar, Masjid Ibraheem Street, Gajjumata Lahore</p> <p>Factory Address: Near KIPS College Sialkot-Daska road Jaserwala Daska, Daska</p> <p>Challan No: 88832228</p> <p>Fee: Rs 9000 /-</p> <p>Date of Submission: 19 August 2025</p> <p>Tracking ID: MDMC-250819-12937</p>	<p>Designation: CEO</p> <p>Name: Atif Hassan</p> <p>CNIC No: 3460116917923</p> <p>Address: Muhallah Shaheen Town, Opposite Star CNG, Gujranwala road , Daska</p> <p>Designation: CEO</p> <p>Name: Atif Hassan</p> <p>CNIC No: 3460116917923</p> <p>Address: Muhallah Shaheen Town, Opposite Star CNG, Gujranwala road , Daska</p> <p>Designation: Director</p> <p>Name: MUBARIK ALI</p> <p>CNIC No: 3460174192847</p> <p>Address: Muhallah Shaheen Town, Opposite Star CNG, Gujranwala road , Daska</p>	<p>Rejected. The site does not meet the requirements of establishment of medical devices facility under Medical Devices Rules, 2017.</p>
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Local Manufacture Product

Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

New Applications

Sr.No.	Name & Address of Establishment	Name of Medical Devices with Class, Shelf life, codes, Size	Minutes/Decision
1	<p>Monitor Health International (Pvt) Ltd</p> <p>Plot No.147, Phase II Alama Iqbal Industrial City, Faisalabad Industrial Estate, SEZ Sahianwala Interchange Motoruvay, M-</p>	<p>Brand name:</p> <p>Monitor Health Autodisable & Safety</p>	<p>Approved with 2 years shelf life.</p>

4, Faisalabad, Faisalabad ELM-0102 Challan No.: 09577854 Fee: Rs 26100 Date of submission: 06 August 2025 Tracking ID: MDMR-20250806-00001	Syringe (0.5cc,1.0cc,3.0cc,5.0cc) Generic Name: Auto-disable Syringe Class B Device/Accessories Name: Auto-disable Syringe Shelf life/service life: 5 Years Sizes/Codes: UUDS JSNR 0.5ml,1.0ml,3.0ml,5.0ml Specify grouping: Single	
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Import Product

AGENDA FOR CLASS A MEDICAL DEVICES

New Applications

Evaluator Name: Waqar Ahmed (Evaluator-II)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6000 /- Challan No.: 339600697 Date of submission: 30 July 2025	Manufacturer (as per FSC) Hologic, Inc. Address: 250 Campus Drive Marlborough, MA 01752, USA ISO 13485: Submitted Issue Date: 2022-10-03 Validity Date: 2025-10-02	Brand Name: Compass Stainer Generic Name: Compass Stainer Class A Device/Accessories Name: compass stainer	Approved

	Tracking ID: MDMR-20250730-00012	<p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online.</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online.</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-01</p> <p>Validity Date: 2027-04-30</p> <p>Notarization Status: Apostille</p>	<p>Shelf life/service life: NA</p> <p>Codes/Sizes (if any): ASY-05576/</p> <p>Specify grouping: Single</p> <p>Storage condition: 10-40°C (50 to 102°F)</p>	
2	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 05787688</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (No</p>	Approved

	<p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR-20250724-00011</p>	<p>Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-01</p> <p>Validity Date: 2032-03-31</p> <p>Notarization Status: PAKISTAN APOSTILLE</p>	<p>Additive Tube)</p> <p>Class A</p> <p>Device/Accessories Name: MERUX NYCOTECH Vacuum Blood Test Tube (No Additive Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	
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3	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 53623972067</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR- 20250724-00013</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (Clot Activator Tube)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>MERUX NYCOTECH Vacuum Blood Test Tube (Clot Activator Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	Approved
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		Issue Date: 2025-03-01 Validity Date: 2032-03-31 Notarization Status: PAKISTAN APOSTILLE		
4	Chohan & Company 21 BAHADURABAD BLOCK 2, Karachi, Karachi Fee: Rs 6000 /- Challan No.: 83605488135 Date of submission: 24 July 2025 Tracking ID: MDMR-20250724-00014	Manufacturer SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China ISO 13485: Submitted Issue Date: 2022-05-20 Validity Date: 2028-05-01 Notarization Status: PAKISTAN APOSTILLE EC Certificate FSC: Submitted Issue Date: 2024-12-05 Validity Date: 2025-11-23 Issuing Authority: Shanghai Municipal Medical Products Administration Attestation Status: PAKISTAN APOSTILLE LOA: Submitted Issue Date: 2025-03-01 Validity Date: 2032-03-31	Brand Name: TUBER VAC MERUX NYCOTECH Generic Name: Vacuum Blood Test Tube (Gel & Clot Activator Tube) Class A Device/Accessories Name: MERUX NYCOTECH Vacuum Blood Test Tube (Gel & Clot Activator Tube) Shelf life/service life: 36 Months Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved

		Notarization Status: PAKISTAN APOSTILLE		
5	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 131664556507</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR- 20250724-00015</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-01</p> <p>Validity Date: 2032-03-31</p> <p>Notarization Status: PAKISTAN APOSTILLE</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (Lithium Heparin Tube)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>MERUX NYCOTECH Vacuum Blood Test Tube (Lithium Heparin Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	Approved

6	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 538846925</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR-20250724-00016</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-01</p> <p>Validity Date: 2032-03-31</p> <p>Notarization Status: PAKISTAN APOSTILLE</p>	<p>Brand Name:</p> <p>TUBER VACG MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (Sodium Heparin Tube)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>MERUX NYCOTECH Vacuum Blood Test Tube (Sodium Heparin Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	Approved
7	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX</p>	Approved

	<p>2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 39208568927</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR-20250724-00010</p>	<p>MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-01</p>	<p>NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (Sodium Citrate 9NC Tube)</p> <p>Class A</p> <p>Device/Accessories Name: MERUX NYCOTECH Vacuum Blood Test Tube (Sodium Citrate 9NC Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	
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		Validity Date: 2032-03-31 Notarization Status: PAKISTAN APOSTILLE		
8	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 9024753180</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR- 20250724-00001</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (EDTA K2 Tube)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>MERUX NYCOTECH Vacuum Blood Test Tube (EDTA K2 Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	Approved

		Administration Attestation Status: PAKISTAN APOSTILLE LOA: Submitted Issue Date: 2025-03-01 Validity Date: 2032-03-31 Notarization Status: PAKISTAN APOSTILLE		
9	Chohan & Company 21 BAHADURABAD BLOCK 2, Karachi, Karachi Fee: Rs 6000 /- Challan No.: 9818242627 Date of submission: 24 July 2025 Tracking ID: MDMR-20250724-00005	Manufacturer SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD Address: Building A, No. 599 Wanhua Road, Zhelin Town, Fengxian Area, Shanghai, China ISO 13485: Submitted Issue Date: 2022-05-20 Validity Date: 2028-05-01 Notarization Status: PAKISTAN APOSTILLE EC Certificate FSC: Submitted Issue Date: 2024-12-05 Validity Date: 2025-11-23 Issuing Authority: Shanghai Municipal Medical Products Administration Attestation Status: PAKISTAN	Brand Name: TUBER VAC MERUX NYCOTECH Generic Name: Vacuum Blood Test Tube (Glucose Tube) Class A Device/Accessories Name: MERUX NYCOTECH Vacuum Blood Test Tube (Glucose Tube) Shelf life/service life: 36 Months Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved

		<p>APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2022-03-01</p> <p>Validity Date: 2032-03-31</p> <p>Notarization Status: PAKISTAN APOSTILLE</p>		
10	<p>Chohan & Company</p> <p>21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 17677667118</p> <p>Date of submission: 24 July 2025</p> <p>Tracking ID: MDMR- 20250724-00007</p>	<p>Manufacturer</p> <p>SHANGHAI ORSIN MEDICAL TECHNOLOGY CO.,LTD</p> <p>Address: Building A, No. 599 Wanhua Road, Zhelin Town,Fengxian Area,Shanghai,China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-05-20</p> <p>Validity Date: 2028-05-01</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-12-05</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Vacuum Blood Test Tube (Sodium Citrate Tube)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>MERUX NYCOTECH Vacuum Blood Test Tube (Sodium Citrate Tube)</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p>	Approved

		<p>Validity Date: 2025-11-25</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2025-11-23</p> <p>Issuing Authority: Shanghai Municipal Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-01</p> <p>Validity Date: 2032-03-31</p> <p>Notarization Status: PAKISTAN APOSTILLE</p>	<p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	
11	<p>Aqib trading company pvt ltd</p> <p>Nowshera, Nowshera</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 78233209</p> <p>Date of submission: 26 July 2025</p> <p>Tracking ID: MDMR-20250726-00007</p>	<p>Manufacturer</p> <p>Jiangxi Hongda Medical Equipment Group Ltd.</p> <p>Address: 39 South Shengli Road, Jinxian County, Nanchang city, Jiangxi Province, China 331700</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-07-01</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: notarized</p>	<p>Brand Name:</p> <p>BT-TEX (Nitrile Examination Gloves) Powdered free</p> <p>Generic Name:</p> <p>Single use medical Examination Gloves, Nitrile (Powdered free)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Single use medical Examination Gloves, Nitrile (Powdered free)</p>	Approved

		<p>EC Certificate Issue Date: 2024-06-10 Validity Date: 2029-06-10 Issuing Authority: TUV SUD Attestation Status: certified</p> <p>FSC: Submitted Issue Date: 2023-11-02 Validity Date: 2025-11-02 Issuing Authority: certificate for exportation of medical products Attestation Status: certified</p> <p>Issue Date: 2023-11-02 Validity Date: Issuing Authority: certificate for exportation of medical products Attestation Status: certified</p> <p>Issue Date: 2023-11-02 Validity Date: Issuing Authority: certificate for exportation of medical products Attestation Status: certified</p> <p>LOA: Submitted Issue Date: 2024-09-04 Validity Date: 2029-09-04 Notarization Status: notarized</p>	<p>Shelf life/service life: 60 Months</p> <p>Codes/Sizes (if any): Powdered free/XS, S, M, L, XL</p> <p>Specify grouping: Single</p> <p>Storage condition: Indoor storage in no corrosive gas, well-ventilated and cleaned space</p>	
12	Aqib trading company pvt ltd	<p>Manufacturer</p> <p>Nanjing 3H Medical Products</p>	Brand Name:	Approved

	<p>Nowshera, Nowshera</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 5973496293</p> <p>Date of submission: 25 July 2025</p> <p>Tracking ID: MDMR-20250725-00041</p>	<p>Co., Ltd</p> <p>Address: located at NO.1, NO.5 Zhushan Road, Gaochun Economic Development Zone, Nanjing 211300 Jiangsu Province, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-09-30</p> <p>Validity Date: 2026-10-18</p> <p>Notarization Status: notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-07-26</p> <p>Validity Date: 2026-07-26</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-07-26</p> <p>Validity Date: 2026-07-26</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2024-07-26</p> <p>Validity Date: 2026-07-26</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2024-07-26</p>	<p>AT-ZINC</p> <p>Generic Name:</p> <p>Zinc Oxide Adhesive Plaster</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Zinc Oxide Adhesive Plaster</p> <p>Shelf life/service life: 60 Months</p> <p>Codes/Sizes (if any):</p> <p>N/A/1cm*9.1m 1.25cm*9.1m</p> <p>2cm*9.1m</p> <p>2.5cm*9.1m</p> <p>3.8cm*9.1m</p> <p>5cm*9.1m 6cm*9.1m</p> <p>7.5cm*9.1m</p> <p>8cm*9.1m</p> <p>10cm*9.1m</p> <p>15cm*9.1m</p> <p>1.25cm*5m 2.5cm*5m</p> <p>5cm*5m</p> <p>7.5cm*5m</p> <p>1.25cm*0.6m</p> <p>2.5cm*0.6m</p> <p>5cm*0.6m 7.5cm*0.6m</p> <p>1.9cm*0.46m</p> <p>25cm*0.46m</p> <p>25cm*0.92m</p> <p>25cm*1.3m</p> <p>5cm*1.3m 4.5cm*0.1m</p> <p>6cm*0.1m</p> <p>4.5cm*0.12m</p> <p>6cm*0.12m</p> <p>2.5cm*10m</p> <p>5cm*10m 10cm*10.m</p> <p>15cm*10m</p> <p>20cm*10m</p>	
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		<p>Validity Date: 2026-07-26</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>LOA: Submitted</p> <p>Issue Date:</p> <p>Validity Date: 2030-01-01</p> <p>Notarization Status: notarized</p>	<p>1cm*130cm</p> <p>1.25cm*1.3m</p> <p>2cm*1.3m 3.8cm*1.3m</p> <p>7.5cm*1.3m</p> <p>8cm*1.3m</p> <p>10cm*1.3m</p> <p>15cm*1.3m</p> <p>1cm*3.5m</p> <p>1.25cm*3.5m 2cm*3.5m</p> <p>2.5cm*3.5m</p> <p>3.8cm*3.5m</p> <p>5cm*3.5m</p> <p>6cm*3.5m 7.5cm*3.5m</p> <p>8cm*3.5m</p> <p>10cm*3.5m</p> <p>15cm*3.5m</p> <p>1cm*4.5m</p> <p>1.25cm*4.5m</p> <p>2cm*4.5m 2.5cm*4.5m</p> <p>3.8cm*4.5m</p> <p>5cm*4.5m</p> <p>6cm*4.5m</p> <p>7.5cm*4.5m 8cm*4.5m</p> <p>10cm*4.5m</p> <p>15cm*4.5m</p> <p>1cm*5.0m</p> <p>2cm*5m</p> <p>3.8cm*5m 6cm*5.0m</p> <p>8cm*5m</p> <p>10cm*5m</p> <p>15cm*5m</p> <p>1cm*6.5m</p> <p>1.25cm*6.5m</p> <p>2cm*6.5m 2.5cm*6.5m</p> <p>3.8cm*6.5m</p> <p>5cm*6.5m</p> <p>6cm*6.5m</p> <p>7.5cm*6.5m 8cm*6.5m</p>	
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			10cm*6.5m 15cm*6.5m 1.25cm*10m 1cm*10m 2cm*10m 3.8cm*10m 6cm*10m 7.5cm*10m 8cm*10m 1.25cm*13.7m 2cm*13.7m 2.5cm*13.7m 3.8cm*13.7m 5cm*13.7m 6cm*13.7m 7.5cm*13.7m 8cm*13.7m 10cm*13.7m 15cm*13.7m 2.5cm*6m 5cm*6m 10cm*6m 10cm*9m 1.2cm*50m 1.8cm*50m 2.4cm*50m 4.8cm*50m 4cm*10m Specify grouping: Single Storage condition: This product should be stored in a dry, , well ventilated, fireproof and rodentproof environment.	
13	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6000 /-	Manufacturer (as per FSC) Hologic, Inc. Address: 4 Navigator Rd LONDONDERRY, NH USA 03053	Brand Name: ThinPrep Pap Test Filters Generic Name: ThinPrep Filters Class A	Approved

	Challan No.: 041099566 Date of submission: 30 July 2025 Tracking ID: MDMR-20250730-00004	ISO 13485: Submitted Issue Date: 2022-10-03 Validity Date: 2025-10-02 Notarization Status: Apostille EC Certificate Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online FSC: Submitted Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: US FDA Attestation Status: eCFG can be accessed online Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online LOA: Submitted Issue Date: 2025-05-01 Validity Date: 2026-05-01 Notarization Status: Apostille	Device/Accessories Name: thinprep pap test filters Shelf life/service life: 24 Months Codes/Sizes (if any): 70208-001/ Specify grouping: Single Storage condition: n/a	
14	Aqib trading company pvt ltd	Manufacturer Nanjing 3H Medical Products	Brand Name:	Approved

	<p>Nowshera, Nowshera</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 70672364662</p> <p>Date of submission: 25 July 2025</p> <p>Tracking ID: MDMR-20250725-00042</p>	<p>Co., Ltd</p> <p>Address: located at NO.1, NO.5 Zhushan Road, Gaochun Economic Development Zone, Nanjing 211300 Jiangsu Province, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-09-30</p> <p>Validity Date: 2026-10-18</p> <p>Notarization Status: notarized</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date: 2030-04-02</p> <p>Issuing Authority: lotus NL B.V</p> <p>Attestation Status: certified</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-03-06</p> <p>Validity Date: 2026-03-06</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2024-03-06</p> <p>Validity Date: 2026-03-06</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2024-03-06</p> <p>Validity Date: 2026-03-06</p>	<p>AT-Crepe</p> <p>Generic Name:</p> <p>Elastic Cohesive Bandage</p> <p>Class A</p> <p>Device/Accessories Name: Elastic Cohesive Bandage</p> <p>Shelf life/service life: 60 Months</p> <p>Codes/Sizes (if any): N/A/12.5x4000?25x4000?50x, 4000?75x4000?100x4000, 150x4000?12.5x4500? 25x4500?50x4500? 75x4500?100x4500? 150x4500 12.5x5000? 25x5000?5 0x5000?75x5000? 100x5000?150x5000</p> <p>Specify grouping: Single</p> <p>Storage condition: The product should generally be stored in a clean, cool, dry and ventilated warehouse It should not be mixed with toxic, harmful and odorous items.</p>	
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		<p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>LOA: Submitted</p> <p>Issue Date:</p> <p>Validity Date: 2030-01-01</p> <p>Notarization Status: notarized</p>		
15	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1</p> <p>Cantt rawalpindi,Pakistan,</p> <p>Rawalpindi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 3904422102</p> <p>Date of submission: 30 July 2025</p> <p>Tracking ID: MDMR-20250730-00023</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Hologic, Inc.</p> <p>Address: 4 Navigator Rd</p> <p>LONDONDERRY, NH USA</p> <p>03053</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-02</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE can be accessed online</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p>	<p>Brand Name:</p> <p>ThinPrep PreservCyt Solution</p> <p>Generic Name:</p> <p>ThinPrep PreservCyt solution (Preservative and antibacterial medium)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>ThinPrep PreservCyt solution</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): ASY-14753/100x20ml vials</p> <p>Specify grouping: Single</p> <p>Storage condition: 15°C–30°C</p>	Approved

		<p>Attestation Status: eCOE can be accessed online</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE can be accessed online</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-01</p> <p>Validity Date: 2027-05-01</p> <p>Notarization Status: Apostille</p>		
16	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrach-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 4540373230</p> <p>Date of submission: 02 August 2025</p> <p>Tracking ID: MDMR-20250802-00011</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Philips Medizin Systeme Böblingen GmbH</p> <p>Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY</p> <p>Manufacturing Site (as per FSC)</p> <p>Nicolay GmbH</p> <p>Address: Graf-Zeppelin-Straße 21 72292 Nagold Deutschland</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p>	<p>Brand Name:</p> <p>Remote Event Marker</p> <p>Generic Name:</p> <p>Event Marker</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Remote Event Marker</p> <p>Shelf life/service life: 6 Years</p> <p>Codes/Sizes (if any):</p> <p>989803143411/</p> <p>Specify grouping: Single</p> <p>Storage condition: -40°C to 70°C</p>	Approved

		<p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>		
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		ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized EC Certificate FSC: Submitted Issue Date: 2025-06-18 Validity Date: 2030-06-17 Issuing Authority: Baden Wurttemberg Attestation Status: Embassy of Pakistan attested LOA: Submitted Issue Date: 2025-06-11 Validity Date: 2030-05-12 Notarization Status: Notarized		
17	HOSPICARE SYSTEMS Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi- 75350, Pakistan, Karachi Fee: Rs 6000 /- Challan No.: 0702887705 Date of submission: 02 August 2025 Tracking ID: MDMR- 20250802-00009	Legal Manufacturer (as per FSC) Philips Medizin Systeme Böblingen GmbH Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY Manufacturing Site (as per FSC) Gemeinnuetzige Werkstaetten und Wohnstaetten GmbH Address: Robert-Bosch-Straße 15 71116 Gärtringen Germany	Brand Name: Reusable Leg Belt Generic Name: Reusable Leg Belt Class A Device/Accessories Name: Reusable Leg Belt Shelf life/service life: 5 Years Codes/Sizes (if any): M4601A/15m x 32mm Specify grouping: Single	Approved

		<p>ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized</p> <p>EC Certificate FSC: Submitted Issue Date: 2025-06-18 Validity Date: 2030-06-17 Issuing Authority: Baden Wurttemberg Germany Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted Issue Date: 2025-06-11 Validity Date: 2030-05-12 Notarization Status: Notarized</p> <p>ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized</p> <p>EC Certificate FSC: Submitted Issue Date: 2025-06-18 Validity Date: 2030-06-17 Issuing Authority: Baden Wurttemberg Germany</p>	Storage condition: -20 to 65 C	
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		<p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>		
18	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1</p> <p>Cantt rawalpindi,Pakistan,</p> <p>Rawalpindi</p> <p>Fee: Rs 6000 /-</p>	<p>Manufacturer (as per FSC)</p> <p>NEW ERIE SCIENTIFIC LLC</p> <p>Address: 20 POST RD</p> <p>Portsmouth, NH USA 03801</p> <p>ISO 13485: Submitted</p>	<p>Brand Name:</p> <p>ThinPrep Imaging System</p> <p>Microscope Slides</p> <p>Generic Name:</p> <p>Microscope Slides</p>	Approved

	Challan No.: 5900614237 Date of submission: 01 August 2025 Tracking ID: MDMR-20250801-00003	Issue Date: 2022-10-03 Validity Date: 2025-10-02 Notarization Status: Notarized EC Certificate Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online FSC: Submitted Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online LOA: Submitted Issue Date: 2025-05-01 Validity Date: 2027-04-30 Notarization Status: Apostille	Class A Device/Accessories Name: ThinPrep Imaging system microscope slides Shelf life/service life: Months Codes/Sizes (if any): 70825-001/ Specify grouping: Single Storage condition: na	
19	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan,	Legal Manufacturer (as per FSC) Hologic, Inc.	Brand Name: PreservCyt Collection Medium	Approved

	<p>Rawalpindi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 4587189138</p> <p>Date of submission: 11 August 2025</p> <p>Tracking ID: MDMR-20250811-00042</p>	<p>Address: 4 Navigator Rd LONDONDERRY, NH USA 03053</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-08-02</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE can be accessed online</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE can be accessed online</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE can be accessed online</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-01</p> <p>Validity Date: 2027-05-01</p>	<p>Generic Name:</p> <p>Collection Medium</p> <p>Class A</p> <p>Device/Accessories Name: PreservCyt™ Collection Medium</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): ASY- 14762/</p> <p>Specify grouping: Single</p> <p>Storage condition: 15°C–30°C</p>	
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		Notarization Status: Apostille		
20	<p>BRIOGENE Pvt Ltd</p> <p>196-A SMCHS Karachi, Karachi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 22909342</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00056</p>	<p>Manufacturer</p> <p>Xiamen Zeesan Biotech Co., Ltd</p> <p>Address: 884-1 and 884-2 Lianting Road, (Xiang An) Industrial Area, Torch High-Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-17</p> <p>Validity Date: 2025-10-21</p> <p>Notarization Status: Apostilled</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-01-10</p> <p>Validity Date: 2026-01-10</p> <p>Issuing Authority: People Republic of china</p> <p>Attestation Status: Apostilled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-20</p> <p>Validity Date: 2027-12-31</p> <p>Notarization Status: Notarized</p>	<p>Brand Name:</p> <p>Lab-Aid 824s DNA Extraction Kit</p> <p>Generic Name:</p> <p>DNA Extraction Kit</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Lab-Aid 824s DNA Extraction Kit</p> <p>Shelf life/service life: 12 Months</p> <p>Codes/Sizes (if any): Lab-Aid 824s (48 test/kit)/</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: 2 TO 30 C</p>	<p>Deferred for confirmation of class of medical device and submission of differential fee accordingly</p>
21	<p>BRIOGENE Pvt Ltd</p> <p>196-A SMCHS Karachi, Karachi</p> <p>Fee: Rs 6300 /-</p>	<p>Manufacturer</p> <p>Xiamen Zeesan Biotech Co., Ltd</p> <p>Address: 884-1 and 884-2 Lianting Road, (Xiang An)</p>	<p>Brand Name:</p> <p>Sanity 2.0 System</p> <p>Generic Name:</p> <p>Sanity 2.0 System (PCR)</p>	<p>Approved</p>

	Challan No.: 569387559013 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808-00059	Industrial Area, Torch High-Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China ISO 13485: Submitted Issue Date: 2023-10-17 Validity Date: 2025-10-21 Notarization Status: Notarized EC Certificate FSC: Submitted Issue Date: 2025-06-30 Validity Date: 2026-01-16 Issuing Authority: People's republic of china Attestation Status: apostilled LOA: Submitted Issue Date: 2025-06-20 Validity Date: 2027-12-31 Notarization Status: Notarized	Instrument) Class A Device/Accessories Name: Sanity 2.0 System Shelf life/service life: 5 Years Codes/Sizes (if any): Sanity 2.0/ Specify grouping: System Storage condition: 4 0 °C ~ 55°C, relative humidity of	
22	HOSPICARE SYSTEMS Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrach-e-Faisal, Karachi-75350, Pakistan, Karachi Fee: Rs 6000 /- Challan No.: 4608691942 Date of submission: 02 August 2025 Tracking ID: MDMR-	Legal Manufacturer (as per FSC) Philips Medizin Systeme Böblingen GmbH Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY Manufacturing Site (as per FSC) Nicolay GmbH Address: Graf-Zeppelin-Straße	Brand Name: MECG Adapter Cable Generic Name: MECG Cable Class A Device/Accessories Name: MECG Adapter Cable Shelf life/service life: 18 Months	Approved

	20250802-00012	<p>21 72292 Nagold Deutschland</p> <p>ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized</p> <p>EC Certificate FSC: Submitted Issue Date: 2025-06-18 Validity Date: 2030-06-17 Issuing Authority: Baden Wurttemberg Germany Attestation Status: Embassy of Pakistan Attested</p> <p>LOA: Submitted Issue Date: 2025-06-11 Validity Date: 2030-05-12 Notarization Status: Notarized Market Authorization Holder Philips Electronics Singapore Pte Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763</p> <p>ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized</p>	<p>Codes/Sizes (if any): M1363A/ Specify grouping: Single Storage condition: -40°C to 70°C</p>	
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		<p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan Attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan Attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p>		
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		Notarization Status: Notarized		
23	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 020206121803</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR- 20250807-00010</p>	<p>Manufacturer</p> <p>NEW ERIE SCIENTIFIC LLC</p> <p>Address: 20 POST RD Portsmouth, NH USA 03801</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-02</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDR H</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDR H</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p>	<p>Brand Name:</p> <p>ThinPrep Arcless Microscope Slides</p> <p>Generic Name:</p> <p>Microscope Slides</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>ThinPrep Arcless Microscope Slides</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 70126- 002/</p> <p>Specify grouping: Single</p> <p>Storage condition: na</p>	Approved

		<p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille</p>		
24	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrach-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 76388994598</p> <p>Date of submission: 02 August 2025</p> <p>Tracking ID: MDMR-20250802-00010</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Philips Medizin Systeme Böblingen GmbH</p> <p>Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY</p> <p>Manufacturing Site (as per FSC)</p> <p>Gemeinnuetzige Werkstaetten und Wohnstatten GmbH</p> <p>Address: Robert-Bosch-Straße 15 71116 Gärtringen Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p>	<p>Brand Name:</p> <p>Reusable Abdominal Belt</p> <p>Generic Name:</p> <p>Reusable Belt</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>reusable abdominal belts</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any):</p> <p>M4602A/1.3m x 60mm</p> <p>Device/Accessories Name:</p> <p>reusable abdominal belts</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any):</p> <p>M4603A/15m x 60mm</p> <p>Specify grouping: Family</p> <p>Storage condition: -20 to 60 C</p>	Approved

		<p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: NOTarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>		
25	HOSPICARE SYSTEMS Emarah Suites, 9th Floor, Plot#	Legal Manufacturer (as per FSC)	Brand Name: Philips Fetal Monitoring	Approved

	<p>8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi- 75350, Pakistan, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 589128027795</p> <p>Date of submission: 01 August 2025</p> <p>Tracking ID: MDMR- 20250801-00011</p>	<p>Philips Medizin Systeme Böblingen Gmbh</p> <p>Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY</p> <p>Manufacturing Site (as per FSC) Blumberg GmbH & Co KG</p> <p>Address: Kalkumer Straße 46, 40885 Ratingen, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Württemberg Germany</p> <p>Attestation Status: Attested from embassy of Pakistan</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p>	<p>Recording Paper</p> <p>Generic Name:</p> <p>Fetal Recording Paper</p> <p>Class A</p> <p>Device/Accessories Name: Fetal Monitoring Recording paper</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): M1910A/</p> <p>Device/Accessories Name: Fetal Monitoring Recording paper</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): M1911A/</p> <p>Device/Accessories Name: Fetal Monitoring Recording paper</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): M1913A/</p> <p>Specify grouping: Family</p> <p>Storage condition: -20 to 60 C</p>	
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		<p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Attested from embassy of Pakistan</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>		
26	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 8940597288</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00028</p>	<p>Manufacturer</p> <p>NEW ERIE SCIENTIFIC LLC</p> <p>Address: 20 POST RD Portsmouth, NH USA 03801</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-02</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via</p>	<p>Brand Name:</p> <p>ThinPrep Pap Test Microscope Slides</p> <p>Generic Name:</p> <p>Microscope Slides</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>ThinPrep Pap Test Microscope Slides</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 70303-001/</p> <p>Specify grouping: Single</p> <p>Storage condition: na</p>	Approved

		<p>www.access.fda.gov/fecv/CDRH</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via www.fda.gov/fecv/CDRH</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille</p>		
27	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1</p> <p>Cantt rawalpindi,Pakistan,</p> <p>Rawalpindi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 01766422552</p> <p>Date of submission: 04 August 2025</p> <p>Tracking ID: MDMR-</p>	<p>Legal Manufacturer (as per FSC)</p> <p>NEW ERIE SCIENTIFIC LLC</p> <p>Address: 20 POST RD</p> <p>Portsmouth, NH USA 03801</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-02</p>	<p>Brand Name:</p> <p>ThinPrep UroCyte Microscope Slides</p> <p>Generic Name:</p> <p>Thinprep urocyte microscope slides</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Thinprep urocyte microscope</p>	Approved

	20250804-00017	<p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online via www.access.fda.gov/fecv/CDRH</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online via www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online via www.access.fda.gov/fecv/CDRH</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille</p>	<p>slides</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 70471-001/</p> <p>Specify grouping: Single</p> <p>Storage condition: na</p>	
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28	<p>A.M. Distributors.pk 37-C, 4th Floor, Lane-8, Bukhari Commercial,Phase-VI, D.H.A. Karachi, Pakistan, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 3434713477</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00051</p>	<p>Manufacturer M/s Anhui Tianrun Medical Packaging Material CO., LTD.</p> <p>Address: located at No.29 Chaoyang Road, Yixiu District, 246003 Anqing City, Anhui Province, People's of Republic of China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-24</p> <p>Validity Date: 2027-08-23</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-02-28</p> <p>Validity Date: 2027-02-27</p> <p>Issuing Authority:</p> <p>Attestation Status: Apposite</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-06-21</p> <p>Validity Date: 2027-06-20</p> <p>Notarization Status: Notarized</p>	<p>Brand Name: Crepe Paper</p> <p>Generic Name: Medical Crepe Paper</p> <p>Class A</p> <p>Device/Accessories Name: Medical Crepe Paper</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): TRCP2020,TRCP3030,TRCP4 040,TRCP5050,TRCP6060,TR CP7575,TRCP9090,TRCP1001 00,TRCP120120,/20cm x 20cm,30cm x 30cm,40cm x 40cm,50cm x 50cm,60cm x 60cm,75cm x 75cm,90cm x 90cm,100cm x 100cm, 120cm x 120cm</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temperature</p>	<p>Deferred for Free slae certificate from concerned regulator authority of China.</p>
29	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi- 75350, Pakistan, Karachi</p> <p>Fee: Rs 6300 /-</p>	<p>Manufacturer Philips Medical system</p> <p>Address: 3000 Minuteman Road, Andover, MA 01810- 1099 USA</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: Foam Wet Gel ECG Electrode</p> <p>Generic Name: Foam Wet Gel ECG Electrode</p> <p>Class A</p>	<p>approved</p>

	Challan No.: 1901666745 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808-00004	Issue Date: 2024-11-11 Validity Date: 2027-11-10 Notarization Status: NOTARIZED EC Certificate Issue Date: 2025-06-05 Validity Date: 2030-05-13 Issuing Authority: CIBG NETHERLAND Attestation Status: EMBASSY OF PAKISTAN ATTESTED FSC: Submitted Issue Date: 2025-06-05 Validity Date: 2030-05-13 Issuing Authority: Ministry of Health, Welfare and Sport CIBG Netherland Attestation Status: Embassy of Pakistan attested LOA: Submitted Issue Date: 2025-05-12 Validity Date: 2030-05-12 Notarization Status: Notarized	Device/Accessories Name: Foam Wet Gel ECG Electrode Shelf life/service life: 24 Months Codes/Sizes (if any): 40493E/ Specify grouping: Single Storage condition: -41°C to 30°C	
30	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6000 /-	Manufacturer NEW ERIE SCIENTIFIC LLC Address: 20 POST RD Portsmouth, NH USA 03801 ISO 13485: Submitted	Brand Name: ThinPrep Non-Gynecological Microscope Slides Generic Name: Non-Gynecological	approved

	<p>Challan No.: 75952822848</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00022</p>	<p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-02</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: eCFG can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p>	<p>Microscope Slides</p> <p>Class A</p> <p>Device/Accessories Name: ThinPrep Non-Gynecological Microscope Slides</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 70372-001/</p> <p>Specify grouping: Single</p> <p>Storage condition: na</p>	
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		Notarization Status: Apostille		
31	<p>Royal Enterprise</p> <p>Shop Number 5, Karimji Building , Opposite HBL , North Napier Road, Karachi - Pakistan, Karachi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 3501851038</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR-20250806-00016</p>	<p>Manufacturer</p> <p>HEBEI JIEDE MEDICAL EQUIPMENT CO., LTD</p> <p>Address: NO 518, CHUNFENG STREET, JIZHOU DISTRICT, HENGSHUI CITY, HEBEI PROVINCE, CHINA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-12</p> <p>Validity Date: 2027-08-11</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date:</p> <p>Validity Date: 2027-03-09</p> <p>Issuing Authority: Peoples republic of china</p> <p>Attestation Status: Apostilled</p> <p>LOA</p>	<p>Brand Name:</p> <p>WEWELL</p> <p>Generic Name:</p> <p>ELECTRIC MEDICAL BED</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>ELECTRIC MEDICAL BED</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Model JDC01, JDC01-1, JDC01-2, JDC01-3, JDC01-4, JDC01-5, JDC03, JDC03-1, JDC03-2, JDC03-3, JDC03-4, JDC05, JDC05-1, JDC05-2, JDC05-3, JDC19-1, JDC20-1, JDC21/</p> <p>Specify grouping: Family</p> <p>Storage condition: -10C TO 50C</p>	approved
32	<p>United Healthcare</p> <p>Plot No 330 Block 3, DMCHS, Alamgir Road Bahadurabad, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 92180852702</p> <p>Date of submission: 11 August</p>	<p>Manufacturer</p> <p>YANGZHOU SHUNKANG MEDICAL EQUIPMENT CO., LTD.</p> <p>Address: NO. 70 ANYI NORTH ROAD, BAOYING COUNTY, YANGZHOU CITY, JIANGSU PROVINCE, CHINA</p>	<p>Brand Name:</p> <p>STAR VETERINARY NEEDLE</p> <p>Generic Name:</p> <p>VETERINARY NEEDLE</p> <p>Class A</p> <p>Device/Accessories Name:</p>	Deferred for Free sale certificate from concerned regulator authority of China mentioning the applied device.

	2025 Tracking ID: MDMR-20250811-00022	ISO 13485: Submitted Issue Date: 2023-05-04 Validity Date: 2026-05-03 Notarization Status: EC Certificate FSC: Submitted Issue Date: 2025-06-19 Validity Date: 2027-06-19 Issuing Authority: Attestation Status: LOA: Submitted Issue Date: 2025-06-28 Validity Date: 2039-06-27 Notarization Status:	STAR VETERINARY NEEDLE Shelf life/service life: 60 Months Codes/Sizes (if any): Not Applicable/8G, 9G, 10G, 11G, 12G, 13G, 14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G Specify grouping: Single Storage condition: Store in a cool, clean, dry and insect-free location. Protect from direct sunlight and damp conditions.	
33	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6300 /- Challan No.: 1663242747 Date of submission: 11 August 2025 Tracking ID: MDMR-20250811-00033	Manufacturer CooperSurgical, Inc. USA Address: 95 Corporate Drive Trumbull, Connecticut 06611 United States of America ISO 13485: Submitted Issue Date: 2024-12-07 Validity Date: 2027-12-06 Notarization Status: yes EC Certificate Issue Date: 2024-10-11 Validity Date: 2026-10-10	Brand Name: Medscand Sample Collection Kit Generic Name: Sample Collection Kit Class A Device/Accessories Name: Medscand Sample Collection Kit Shelf life/service life: Years Codes/Sizes (if any): 70124-001/ Specify grouping: IVD Kit	approved

		<p>Issuing Authority: US FDA Attestation Status: eCFG can be accessed online.</p> <p>FSC: Submitted Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: US FDA Attestation Status: eCFG can be accessed online Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: US FDA Attestation Status: eCFG can be accessed online</p> <p>LOA: Submitted Issue Date: 2025-05-01 Validity Date: 2027-05-01 Notarization Status: Apostille</p>	Storage condition: na	
34	<p>Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6300 /- Challan No.: 91442457 Date of submission: 15 August 2025 Tracking ID: MDMR-20250815-00013</p>	<p>Manufacturer Hologic, Inc. Address: 4 Navigator Rd LONDONDERRY, NH USA 03053</p> <p>ISO 13485: Submitted Issue Date: 2022-10-03 Validity Date: 2025-10-02 Notarization Status: Notarized</p>	<p>Brand Name: ThinPrep UroCyt PreservCyt Solution Generic Name: PreservCyt Solution Class A Device/Accessories Name: ThinPrep UroCyt PreservCyt Solution Shelf life/service life: 24</p>	approved

		<p>EC Certificate</p> <p>Issue Date: 2024-10-23</p> <p>Validity Date: 2026-10-22</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE-can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG-can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCOE-can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG-can be accessed online</p> <p>LOA: Submitted</p>	<p>Months</p> <p>Codes/Sizes (if any): ASY-15311/</p> <p>Specify grouping: Single</p> <p>Storage condition: 15°C–30°C</p>	
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		<p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille</p>		
35	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrach-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 527553964455</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00023</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Philips Medizin Systeme Böblingen GmbH</p> <p>Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY</p> <p>Manufacturing Site (as per FSC)</p> <p>Philips Goldway (Shenzhen) Industrial Inc.</p> <p>Address: No.2 Keji North 3rd Road Nanshan District 518057 Shenzhen People's Republic of China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-03-26</p> <p>Validity Date: 2025-10-05</p> <p>Issuing Authority: Notarized</p> <p>Attestation Status:</p> <p>FSC: Submitted</p>	<p>Brand Name:</p> <p>Efficia Rack</p> <p>Generic Name:</p> <p>Efficia Rack (863330)</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Efficia Rack</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 863330/</p> <p>Specify grouping: Single</p> <p>Storage condition: -20 to 50 C</p>	approved

		<p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germnay</p> <p>Attestation Status: Embassy of Pakistant attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-03-26</p> <p>Validity Date: 2025-10-05</p> <p>Issuing Authority: Notarized</p> <p>Attestation Status:</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germnay</p> <p>Attestation Status: Embassy of Pakistant attested</p> <p>LOA: Submitted</p>		
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		Issue Date: 2025-06-11 Validity Date: 2030-05-12 Notarization Status: Notarized		
36	<p>BRIOGENE Pvt Ltd 196-A SMCHS Karachi, Karachi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 4356629673</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00057</p>	<p>Legal Manufacturer (as per FSC) Xiamen Zeesan Biotech Co., Ltd</p> <p>Address: 884-1 and 884-2 Lianting Road, (Xiang An) Industrial Area, Torch High-Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-17 Validity Date: 2025-10-21 Notarization Status: Apostilled</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-30 Validity Date: 2026-01-11 Issuing Authority: People's republic of china Attestation Status: Apostilled</p> <p>Issue Date: 2025-04-28 Validity Date: 2030-04-04 Issuing Authority: Ministry of Health, welfare, and sport CIBG Netherland Attestation Status: Apostilled</p>	<p>Brand Name: ZEESAN MTB DNA Extraction Kit (Sanity2.0)</p> <p>Generic Name: MTB DNA Extraction Kit</p> <p>Class A</p> <p>Device/Accessories Name: MTB DNA Extraction Kit (Sanity2.0)</p> <p>Shelf life/service life: 14 Months</p> <p>Codes/Sizes (if any): MTB DNA Extraction Kit (Sanity 2.0)/24 tests/kit</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: 2 TO 30 C</p>	Deferred for confirmation of class of the medical device and submission of differential fee accordingly.

		LOA: Submitted Issue Date: 2025-06-20 Validity Date: 2027-12-31 Notarization Status: Notarized		
37	Global Marketing Services 111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi Fee: Rs 6300 /- Challan No.: 472800870 Date of submission: 12 August 2025 Tracking ID: MDMR-20250812-00025	Legal Manufacturer (as per FSC) Rovers Medical Devices B.V., Address: Rovers Medical Devices B.V., Lekstraat 10 5347 KV Oss, The Netherlands ISO 13485: Submitted Issue Date: 2023-11-22 Validity Date: 2026-10-22 Notarization Status: Notarized EC Certificate Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online FSC: Submitted Issue Date: 2024-10-11 Validity Date: 2026-10-10 Issuing Authority: USFDA Attestation Status: eCFG can be accessed online Issue Date: 2024-10-11	Brand Name: Rovers® Cervex-Brush® Generic Name: Rovers Cervex-Brush Class A Device/Accessories Name: Rovers Cervex-Brush Shelf life/service life: 36 Months Codes/Sizes (if any): 70671-001/ Specify grouping: Single Storage condition: n/a	approved

		<p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG can be accessed online</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-01</p> <p>Validity Date: 2027-05-01</p> <p>Notarization Status: Apostille</p>		
38	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1</p> <p>Cantt rawalpindi,Pakistan,</p> <p>Rawalpindi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 74319864894</p> <p>Date of submission: 15 August 2025</p> <p>Tracking ID: MDMR-20250815-00005</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Hologic, Inc.</p> <p>Address: 4 Navigator Rd</p> <p>LONDONDERRY, NH USA 03053</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-03</p> <p>Validity Date: 2025-10-25</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA-eCFG</p> <p>Attestation Status: eCFG-can be accessed online via link www.access.fda.gov/fecv/CDRH</p>	<p>Brand Name:</p> <p>ThinPrep Non-Gynecological Filters</p> <p>Generic Name:</p> <p>Non-Gynecological Filters</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>ThinPrep Non-Gynecological Filters</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 70205-001/</p> <p>Specify grouping: Single</p> <p>Storage condition: na</p>	approved

		<p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: FDA</p> <p>Attestation Status: eCFG-can be accessed online via link www.access.fda.gov/fecv/CDRH</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2026-10-10</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: eCFG- can be accessed online</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-05-17</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille</p>		
39	<p>A ONE TRADERS</p> <p>Makkah Tower,3rd Floor, Room NO.303 Namak Mandi ,Peshawar Pakistan, Peshawar</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 76579955</p> <p>Date of submission: 15 August 2025</p> <p>Tracking ID: MDMR-20250815-00006</p>	<p>Manufacturer</p> <p>Zhida Medical Device Co., Ltd.</p> <p>Address: B01, Gaoliangjian Innovation Park, Hongze District 223100 Huaian City, Jiangsu Province ,CHINA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-04-25</p> <p>Validity Date: 2028-04-24</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p>	<p>Brand Name:</p> <p>SAFE+</p> <p>Generic Name:</p> <p>URINE BAG</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>URINE BAG</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): N/A/2000 ML</p> <p>Specify grouping: Single</p> <p>Storage condition:</p>	approved

		<p>Issue Date: 2025-07-28</p> <p>Validity Date: 2027-07-28</p> <p>Issuing Authority: Jiangsu Medical Product Administration</p> <p>Attestation Status: Apostiled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-07</p> <p>Validity Date: 2030-08-06</p> <p>Notarization Status: Notarized</p>	ATTACHED	
40	<p>SINOPAK UNITED INDUSTRIES</p> <p>F2B PTC Compound Near Dalda Foods SITE Karachi, Karachi</p> <p>Fee: Rs 6300 /-</p> <p>Challan No.: 1104458041</p> <p>Date of submission: 16 August 2025</p> <p>Tracking ID: MDMR-20250816-00002</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Sri Trang Gloves (Thailand) Public Company Limited</p> <p>Address: 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, Thailand</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-11-01</p> <p>Validity Date: 2026-10-31</p> <p>Notarization Status: Yes</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-05-27</p> <p>Validity Date: 2027-05-26</p> <p>Issuing Authority: FDA Thailand</p> <p>Attestation Status: Yes</p>	<p>Brand Name:</p> <p>Sri Trang Latex Powder Free Examination Gloves</p> <p>Generic Name:</p> <p>Latex Powder Free Examination Gloves</p> <p>Class A</p> <p>Device/Accessories Name:</p> <p>Latex Powder Free Examination Gloves</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any):</p> <p>N/A/S,M,L,XL</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temperature</p>	approved

		LOA: Submitted Issue Date: 2025-05-30 Validity Date: 2028-05-29 Notarization Status: Yes		
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AGENDA FOR CLASS B, C & D MEDICAL DEVICES

New Applications

Evaluator Name: Sadaf Ahmad (Evaluator-III)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	gesundheit Concerns Plot no 36 , Second floor Marina Commercial Phase 4 Bahria Town, Islamabad Fee: Rs 32400 /- Challan No.: 75173665 Date of submission: 24 August 2025 Tracking ID: MDMR-20250824-00005	Manufacturer Jiangsu Zhiyu Medical Instrument Co., Ltd. Address: No.88 Nan Yuan Road, Industrial Park, West Tiaixing 254000 Jiangsu, P.R. China ISO 13485: Submitted Issue Date: 2024-09-20 Validity Date: 2027-09-22 Notarization Status: CCPIT Notarized EC Certificate: Submitted Issue Date: 2025-06-11 Validity Date: 2026-09-01 Issuing Authority: Jiangsu Medical Products Administration - China	Brand Name: GC Generic Name: Sterile Infusion Sets for single use (with Needle) Class B Device/Accessories Name: Infusion set with needle Shelf life/service life: 5 Years Codes/Sizes (if any): ZY-2/The infusion needle specifications are: 0.45mmx15mmRWLB, 0.5mmx20mmRWLB, 0.55mmx20mmRWLB, 0.6mmx25mmTWLB, 0.7mmx25mmTWLB, 0.8mmx25mmTWLB,	Approved

		Attestation Status: Apostilled FSC provided LOA: Submitted Issue Date: 2025-08-06 Validity Date: 2030-08-05 Notarization Status: CCPIT Notarized	0.9mmx28mmTWLB Specify grouping: Single Storage condition: Temperature: < 54 °C	
2	PULSE SURGICALS Suite No.113, 1st Floor , ALMAS HEIGHTS 190/1 BLOCK 2, P.E.C.H.S , KARACHI, Karachi Fee: Rs 32400 /- Challan No.: 61846727 Date of submission: 20 August 2025 Tracking ID: MDMR-20250820-00003	Legal Manufacturer (as per FSC) MEDPLUS INC. Address: 4th floor, Building 6, No.586, Zhongshun Road, Zhongcun, Panyu District, Guangzhou, 511495, Guangdong, P.R. China ISO 13485: Submitted Issue Date: 2026-02-22 Validity Date: 2026-12-23 Notarization Status: notarized EC Certificate: Submitted Issue Date: 2025-07-08 Validity Date: 2026-03-13 Issuing Authority: CCPIT Attestation Status: Apostilled FSC provided LOA: Submitted Issue Date: 2024-10-22 Validity Date: 2026-10-22 Notarization Status: Notarized	Brand Name: P.CORE Generic Name: Biopsy Needle Class B Device/Accessories Name: Biopsy Needles Shelf life/service life: 5 Years Codes/Sizes (if any): BN-G2/14G*10CM 14G*15CM 14G*20CM 16G*10CM 16G*15CM 16G*20CM 16G*25CM 18G*10CM 18G*15CM 18G*20CM 18G*25CM Specify grouping: Family Storage condition: store in a non-corrosive gas, well-ventilated and clean environment.	Approved

3	<p>Apex Medical (Private) Limited 81 Saif Town Niaz Baig Road Thokar, Lahore, Lahore Fee: Rs 32400 /-</p> <p>Challan No.: 4247476004</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID: MDMR-20250901- 14685</p>	<p>Legal Manufacturer (as per FSC) SUPERMAX GLOVE MANUFACTURING SDN BHD</p> <p>Address: Lot 38 & 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia.</p> <p>ISO 13485: Submitted Issue Date: 2022-07-11 Validity Date: 2025-07-22 Notarization Status: Notarized</p> <p>EC Certificate: Submitted Issue Date: 2025-07-28 Validity Date: 2027-07-27 Issuing Authority: Medical Device Authority Ministry of Health Malaysia Attestation Status: Embassy Attested</p> <p>FSC provided LOA: Submitted Issue Date: 2025-04-29 Validity Date: 2028-04-28 Notarization Status: NOTARIZED</p>	<p>Brand Name: MEDREX</p> <p>Generic Name: STERILE POWDERED LATEX SURGICAL GLOVES</p> <p>Class B</p> <p>Device/Accessories Name: STERILE POWDERED LATEX SURGICAL GLOVES</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): NA/6, 6.5, 7, 7.5, 8, 8.5</p> <p>Specify grouping: Single</p> <p>Storage condition: Temperatures between + 5°C up to + 40°C and a relative humidity no higher than of 85%</p>	Approved
4	<p>Medico International B-235, Satellite Town, B-Block, Rawalpindi, Rawalpindi Fee: Rs 32400 /-</p> <p>Challan No.:</p>	<p>Legal Manufacturer (as per FSC) JOYTECHHEALTHCARECO.,LTD.</p> <p>Address: No.365, Wuzhou Road,Yuhang EconomicDevelopmentZone, Hangzhou City, 311100Zhejiang, China</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: MEDICO</p> <p>Generic Name: Arm-Type Digital Blood Pressure Monitor</p> <p>Class B</p>	Approved

	<p>498209869026</p> <p>Date of submission: 02 September 2025</p> <p>Tracking ID: MDMR-20250902-14717</p>	<p>Issue Date: 2025-04-28</p> <p>Validity Date: 2028-04-27</p> <p>Notarization Status: VALID</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-03-08</p> <p>Validity Date: 2026-05-09</p> <p>Issuing Authority: VALID</p> <p>Attestation Status: GERMANY EMBASSY ATTESTED EU FSC / APOSTILE FSC CHINA BOTH VALID</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-25</p> <p>Validity Date: 2030-04-24</p> <p>Notarization Status: VALID</p>	<p>Device/Accessories Name: Arm-Type Digital Blood Pressure Monitor</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BPM-45/ Specify grouping: Single</p> <p>Storage condition: 5-50 DEGREE</p>	
5	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 52200 /-</p> <p>Challan No.: 6330339250</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-11-14</p> <p>Validity Date: 2027-11-13</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2022-03-22</p> <p>Validity Date: 2027-03-21</p> <p>Issuing Authority: MEDSAFE</p>	<p>Brand Name:</p> <p>Optiflow Switch Filtered Nasal Interface With Anesthesia Mask</p> <p>Generic Name:</p> <p>Nasal Interface with Anesthesia Mask Class B</p> <p>Device/Accessories Name: Optiflow Switch Filtered Nasal Interface With Anesthesia Mask Compatibility Small</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): AA041S/SMALL</p>	approved

	MDMR-20250901-14656	<p>NEWZEALAND</p> <p>Attestation Status: Apostilled</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-01</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: notarized</p>	<p>Device/Accessories Name: Optiflow Switch Filtered Nasal Interface With Anesthesia Mask Compatibility Medium</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): AA041M/medium</p> <p>Device/Accessories Name: Optiflow Switch Filtered Nasal Interface With Anesthesia Mask Compatibility Large</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): AA041L/Large</p> <p>Specify grouping: Family</p> <p>Storage condition: 18-26 °C</p>	
6	<p>Premier Sales (Private) Limited</p> <p>Plot No. 1-A/15, Sector 15, Korangi Industrial Area, Karachi, Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 078927790</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID: MDMR-20250901-14666</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Embecka Medical II LLC</p> <p>Address: 300 Kimball Drive Parsippany, New Jersey 07054 United States of America</p> <p>Manufacturing Site (as per FSC)</p> <p>Embecka Medical I LLC</p> <p>Address: 1329 West Highway 6 Holdrege Nebraska 68949 United States of America</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-02-25</p>	<p>Brand Name: Embecka Ultra -Fine™</p> <p>Generic Name: Insulin Syringe</p> <p>Class B</p> <p>Device/Accessories Name: Ultra-Fine™ Insulin Syringes</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 326674/Insulin syringe with needle length of 6mm, gauge size of 31G and volume capacity of 1mL</p> <p>Specify grouping: Single</p>	approved

		<p>Validity Date: 2027-08-16</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-07-11</p> <p>Validity Date: 2026-07-10</p> <p>Issuing Authority: US Food & Drug Administration</p> <p>Attestation Status: Apostilled</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-16</p> <p>Validity Date: 2026-12-31</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-02-25</p> <p>Validity Date: 2027-08-16</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-07-11</p> <p>Validity Date: 2026-07-10</p> <p>Issuing Authority: US Food & Drug Administration</p> <p>Attestation Status: Apostilled</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-16</p> <p>Validity Date: 2026-12-31</p>	<p>Storage condition: Protect from heat and moisture</p>	
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		Notarization Status: Notarized		
7	M.A TECH Upper Basement Memmona Centre Mouj darya Road Lahore, Lahore Fee: Rs 31000 /- Challan No.: 5219606347 Date of submission: 25 August 2025 Tracking ID: MDMR-20250825-00007	Legal Manufacturer (as per FSC) JOYTECH HEALTHCARE CO., LTD Address: NO 365,WUZHOU ROAD 311100 HANGZHOU, ZHEJIANG PROVINCE CHINA www.sejoy.com ISO 13485: Submitted Issue Date: 2025-04-28 Validity Date: 2027-04-28 Notarization Status: CCPIT APPROVED EC Certificate: Submitted Issue Date: 2024-05-10 Validity Date: 2026-05-09 Issuing Authority: ZHEJIANG MEDICAL PRODUCTS ADMINISTRATION Attestation Status: APOSTILLE APPROVED FSC provided LOA: Submitted Issue Date: 2025-06-24 Validity Date: 2030-06-23 Notarization Status: CCPIT APPROVED	Brand Name: dr-core Generic Name: DIGITAL BLOOD PRESSURE MONITOR Class B Device/Accessories Name: DIGITAL BLOOD PRESSURE MONITOR Shelf life/service life: 3 Years Codes/Sizes (if any): DBP-6191/1 Piece per Box Specify grouping: Single Storage condition: ROOM TEMPERATURE	approved
8	Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre,	Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy	Brand Name: SIALOGRAPHY Generic Name: SIALOGRAPHY NEEDLE	approved

	<p>Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 67744206776</p> <p>Date of submission: 28 August 2025</p> <p>Tracking ID: MDMR-20250828- 14403</p>	<p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-11-06</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p> <p>Issuing Authority: Ministero Della Salute</p> <p>Attestation Status: Apostille</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-10</p> <p>Validity Date: 2027-03-10</p> <p>Notarization Status: Duly Notarized</p>	<p>Class B</p> <p>Device/Accessories Name: SIALOGRAPHY NEEDLE / SIALOGRAPHY</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 63027/</p> <p>Device/Accessories Name: SIALOGRAPHY NEEDLE / SIALOGRAPHY</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 63030/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
9	<p>Hearing Care Services</p> <p>Islamabad, Islamabad</p> <p>Fee: Rs 52200 /-</p> <p>Challan No.: 295323580</p> <p>Date of submission: 25 August 2025</p> <p>Tracking ID: MDMR-20250825- 00019</p>	<p>Legal Manufacturer (as per FSC)</p> <p>WSAUD A/S</p> <p>Address: Nymoellevej 6 DK-3540 Lyngø Denmark</p> <p>Manufacturing Site (as per FSC)</p> <p>sivantos Pte Ltd</p> <p>Address: 18 Tai Seng Street # 08-08 Singapore</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-02-18</p> <p>Validity Date: 2025-11-30</p> <p>Notarization Status: Yes</p>	<p>Brand Name: Signia</p> <p>Generic Name: Hearing Aids</p> <p>Class B</p> <p>Device/Accessories Name: Orion C&G P</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): T 200,T 100,200,100,75,50/</p> <p>Specify grouping: Family</p>	Approved BTE only

		EC Certificate: Submitted Issue Date: 2025-06-26 Validity Date: 2027-06-26 Issuing Authority: Denmark Attestation Status: Yes FSC LOA: Submitted Issue Date: 2025-05-27 Validity Date: 2028-09-30 Notarization Status: Yes ISO 13485: Submitted Issue Date: 2025-02-18 Validity Date: 2025-11-30 Notarization Status: Yes EC Certificate: Submitted Issue Date: 2025-06-26 Validity Date: 2027-06-26 Issuing Authority: Denmark Attestation Status: Yes FSC LOA: Submitted Issue Date: 2025-05-27 Validity Date: 2028-09-30 Notarization Status: Yes	Storage condition: room Temperature	
10	MUSLIM SCIENTIFIC	Manufacturer	Brand Name:	approved

	<p>CORPORATION</p> <p>2nd Floor. 03 Syed Mouj Darya Road Lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 2666145266</p> <p>Date of submission: 22 August 2025</p> <p>Tracking ID: MDMR-20250822-00016</p>	<p>JOYTECH Healthcare Co., Ltd.</p> <p>Address: No.365, Wuzhou Road 311100 Hangzhou, Zhejiang Province peoples republic of china City</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-04-28 Validity Date: 2028-04-27</p> <p>Notarization Status: ok</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-08 Validity Date: 2026-05-09</p> <p>Issuing Authority: Chen Yao Attestation Status: ok</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-02 Validity Date: 2030-07-02</p> <p>Notarization Status: ok</p>	<p>CC</p> <p>Generic Name: Upper-Arm type Digital Blood Pressure Monitor</p> <p>Class B</p> <p>Device/Accessories Name: Blood Pressure Monitor</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): TD-4333/ Specify grouping: Single</p> <p>Storage condition: - 25 °C-70 °C</p>	
11	<p>K.M Enterprises</p> <p>KM Mansion 605-D block M.A Johar Town lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 876522188523</p> <p>Date of submission: 14 August 2025</p> <p>Tracking ID:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shandong YUYUAN Latex Gloves Co.,Ltd</p> <p>Address: industrial Zone, Linqing City, 252600, Shandong Province, China.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-12-05 Validity Date: 2027-11-06</p> <p>Notarization Status: Notarized</p>	<p>Brand Name: YuYuan</p> <p>Generic Name: Latex Surgical Gloves Powder Free</p> <p>Class B</p> <p>Device/Accessories Name: YuYuan Sterile Latex Surgical Gloves</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): N/A/6, 6.5, 7, 7.</p>	Approved

	MDMR-20250814-00009	EC Certificate: Submitted Issue Date: 2025-03-01 Validity Date: 2027-02-28 Issuing Authority: SFDA CHINA Attestation Status: Apostilled FSC provided LOA: Submitted Issue Date: 2025-07-31 Validity Date: 2030-03-30 Notarization Status: Notarized	5, 8, 8.5, 9, 9.5 Specify grouping: Single Storage condition: 25C - 30C	
12	Sudais Associates Sudais House, Street No. 07, House No. A1 Khan Bahadur Colony Duran Pur Peshawar Pakistan., Peshawar Fee: Rs 1400 /- Challan No.: 32679680099 Date of submission: 12 August 2025 Tracking ID: MDMR-20250812-00032	Legal Manufacturer (as per FSC) Promisemed Hangzhou Meditech Co., Ltd Address: No: 1388 Cangxing Street, Cangqian Community , Yuhang District, Hangzhou City, 311121 Zhejiang , China ISO 13485: Submitted Issue Date: 2025-01-24 Validity Date: 2027-10-22 Notarization Status: APOSTILLE ATTESTED EC Certificate: Submitted Issue Date: 2024-06-30 Validity Date: 2026-06-30 Issuing Authority: FOREIGN AFFAIRS OFFICE OF ZHEJIANG PROVINCE Attestation Status: APOSTILLE ATTESTED	Brand Name: VeriEcto Generic Name: Semi automatic Biopsy Needle Class B Device/Accessories Name: Semi Automatic Biopsy Needle Shelf life/service life: 5 Years Codes/Sizes (if any): BN-OCR-1, BN-OCR-2, BN-OCR-3./2.1 (14G) x90mm, 2.1 (14G) x100mm, 2.1 (14G) x130mm ,2.1 (14G) x150mm, 2.1 (14G) x160mm, 2.1 (14G) x200mm, 2.1 (14G) x220mm, 1.6 (16G) x90mm, 1.6 (16G) x100m, 1.6 (16G) x130mm, 1.6 (16G) x150mm, 1.6 (16G) x160mm, 1.6 (16G) x200mm, 1.6 (16G) x220mm, 1.2 (18G) x90mm,1.2 (18G) x100mm, 1.2 (18G) x130mm, 1.2 (18G) x150mm, 1.2 (18G)	Approved

		FSC provided LOA: Submitted Issue Date: 2025-05-30 Validity Date: 2030-05-30 Notarization Status: APOSTILLE ATTESTED	x160mm, 1.2 (18G) x200mm, 1.2 (18G) x220mm, 0.9 (20G) x90mm, 0.9 (20G) x100mm, 0.9 (20G) x130mm, 0.9 (20G) x150mm, 0.9 (20G) x160mm, 0.9 (20G) x200mm, 0.9 (20G) x220mm. Specify grouping: Family Storage condition: Store in a dry and ventilated place away from light, avoid the influence of rain, snow and ground moisture, and do not coexist with polluting or toxic chemicals.	
13	Premier Sales (Private) Limited Plot No. 1-A/15, Sector 15, Korangi Industrial Area, Karachi, Karachi Fee: Rs 32400 /- Challan No.: 58737424058 Date of submission: 29 August 2025 Tracking ID: MDMR-20250829-14532	Legal Manufacturer (as per FSC) Embecta Medical II LLC Address: 300 Kimball Drive Parsippany, New Jersey 07054 United States of America Manufacturing Site (as per FSC) Embecta Medical I LLC Address: 1329 West Highway 6 Holdrege Nebraska 68949 United States of America ISO 13485: Submitted Issue Date: 2025-02-25 Validity Date: 2027-08-16 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2024-07-11 Validity Date: 2026-07-10	Brand Name: Embecta Ultra-Fine™ Generic Name: Insulin Syringe Class B Device/Accessories Name: Ultra-Fine™ Insulin Syringes Shelf life/service life: 5 Years Codes/Sizes (if any): 320936/Insulin syringe with needle length of 8mm, gauge size of 30G and volume capacity of 1mL Specify grouping: Single Storage condition: Protect from heat and moisture	approved

		<p>Issuing Authority: US FDA Attestation Status: Apostilled FSC LOA: Submitted Issue Date: 2025-04-16 Validity Date: 2026-12-31 Notarization Status: Notarized ISO 13485: Submitted Issue Date: 2025-02-25 Validity Date: 2027-08-16 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2024-07-11 Validity Date: 2026-07-10 Issuing Authority: US FDA Attestation Status: Apostilled FSC provided LOA: Submitted Issue Date: 2025-04-16 Validity Date: 2026-12-31 Notarization Status: Notarized</p>		
14	<p>The visionventure Company Flat no 1,2nd floor abbas tower ,Near Taqwa masjid Khyber super market</p>	<p>Legal Manufacturer (as per FSC) C-K DENTAL IND.CO.,LTD. Address: 88-50, Sudo-Ro, Bucheon-Si, Gyeonggi-Do, Republic of Korea ISO 13485: Submitted</p>	<p>Brand Name: C-K JECT Generic Name: DISPOSABLE DENTAL NEEDLE</p>	approved

	<p>,Peshawar Cantt, Peshawar</p> <p>Fee: Rs 52200 /-</p> <p>Challan No.: 8036768344</p> <p>Date of submission: 21 August 2025</p> <p>Tracking ID: MDMR-20250821- 00028</p>	<p>Issue Date: 2024-02-16</p> <p>Validity Date: 2024-02-16</p> <p>Notarization Status: Attested/Appostilled</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-31</p> <p>Validity Date: 2030-07-31</p> <p>Issuing Authority: National Institute of Medical Device Safety Information Republic of Korea</p> <p>Attestation Status: Attested/Appostilled</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-20</p> <p>Validity Date: 2028-12-31</p> <p>Notarization Status: Attested/Appostilled</p>	<p>Class B</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 4202-1032/21 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 4203-1033/25 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 4204-1034/30 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK27-38-I/38 MM</p> <p>Device/Accessories Name: C-K JECT</p>	
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			<p>DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK27-40-I/40 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 30G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 4198-1027/12 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 30G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 5888755/16 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 30G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK30-21-I/21 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 30G</p> <p>Shelf life/service life: 5 Years</p>	
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			<p>Codes/Sizes (if any): CK30-25-I/25 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 30G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK30-30-I/30 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 31G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK31-12-I/12 MM</p> <p>Device/Accessories Name: C-K JECT DENTAL DISPOSABLE NEEDLE 27G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): CK27-35-I/35 MM</p> <p>Specify grouping: Family</p> <p>Storage condition: Room temperature</p>	
15	<p>HAZALI BROTHERS</p> <p>1ST FLOOR</p> <p>AZZAINAB COURT</p> <p>CAMPBELL</p>	<p>Manufacturer(as per FSC)</p> <p>Anhui Tiankang Medical Technology Co., Ltd</p> <p>Address: No. 228, Weiyi Road, Economic Development Zone, Tianchang City,</p>	<p>Brand Name:</p> <p>HOSPITAL AND HOMECARE</p> <p>Generic Name:</p> <p>DISPOSABLE INFUSION SET</p>	approved

	<p>STREET, Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 67647108679</p> <p>Date of submission: 13 August 2025</p> <p>Tracking ID: MDMR-20250813-00012</p>	<p>239300 Anhui China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-21</p> <p>Validity Date: 2027-09-18</p> <p>Notarization Status: CN:0117778-05/CCPIT NO:253400B0/007078</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-08</p> <p>Validity Date: 2026-01-05</p> <p>Issuing Authority: Certificate for Exportation of medical products - People's Republic of China</p> <p>Attestation Status: 25340000100079</p> <p>FSC PROVIDED</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-30</p> <p>Validity Date: 2030-06-29</p> <p>Notarization Status: CCPIT NO: 253400B0/007080</p>	<p>Class B</p> <p>Device/Accessories Name: DISPOSABLE INFUSION SET</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): TK-IV-02, with air vent and Y site/As per Needle Specification (Gauge/Needle length) [27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G] x (5/8" , 3/4" , 7/8" , 1" , 1 1/4" , 1 1/2"), 1.5m tube length</p> <p>Specify grouping: Single</p> <p>Storage condition: Product should be kept in a condition that relative humidity is less than 80%, it also should be free from corrosive gas, cool, dry with good ventilation and clean</p>	
16	<p>K.M Enterprises</p> <p>KM Mansion 605-D block M.A Johar Town lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 76500283498</p> <p>Date of submission: 14 August 2025</p>	<p>Manufacturer (as per FSC)</p> <p>Shandong YuYuan Latex Gloves Co.,Ltd</p> <p>Address: Industrial Zone, Linqing City, 252600, Shandong Province, China.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-12-05</p> <p>Validity Date: 2027-11-06</p> <p>Notarization Status: Notarized</p>	<p>Brand Name: YuYuan</p> <p>Generic Name: Latex Sterile Surgical Gloves Powdered</p> <p>Class B</p> <p>Device/Accessories Name: YuYuan Sterile Latex Surgical Gloves Powdered</p>	approved

	<p>Tracking ID: MDMR-20250814-00008</p>	<p>EC Certificate: Submitted Issue Date: 2025-03-01 Validity Date: 2027-02-28 Issuing Authority: SFDA CHINA Attestation Status: Apostilled FSC PROVIDED LOA: Submitted Issue Date: 2025-07-31 Validity Date: 2030-07-30 Notarization Status: Notarized</p>	<p>Shelf life/service life: 5 Years Codes/Sizes (if any): N/A/6,6.5,7,7.5,8,8.5, 9, 9.5 Specify grouping: Single Storage condition: 25-30C</p>	
17	<p>M.A TECH Upper Basement Memmona Centre Mouj darya Road Lahore, Lahore Fee: Rs 31000 /- Challan No.: 42756570 Date of submission: 23 August 2025 Tracking ID: MDMR-20250823-00007</p>	<p>Manufacturer JOYTECH HEALTHCARE CO., LTD Address: NO 365,WUZHOU ROAD 311100 HANGZHOU, ZHEJIANG PROVINCE CHINA www.sejoy.com ISO 13485: Submitted Issue Date: 2025-04-28 Validity Date: 2028-04-27 Notarization Status: CCPIT APPROVED EC Certificate: Submitted Issue Date: 2024-05-10 Validity Date: 2026-09-05 Issuing Authority: ZHEJIANG MEDICAL PRODUCT ADMINISTRATION Attestation Status: APOSTILLE APPROVED</p>	<p>Brand Name: dr-core Generic Name: DIGITAL THERMOMETER Class B Device/Accessories Name: dr-core DMT-4236 DIGITAL THERMOMETER Shelf life/service life: 3 Years Codes/Sizes (if any): DMT-4236/1 Piece per Pack Specify grouping: Single Storage condition: ROOM TEMPERATURE</p>	approved

		FSC LOA: Submitted Issue Date: 2025-06-24 Validity Date: 2030-06-23 Notarization Status: CCPIT APPROVED		
18	Biotech Services 746 Shadman-1 Lahore, Lahore Fee: Rs 32400 /- Challan No.: 316972736469 Date of submission: 24 August 2025 Tracking ID: MDMR-20250824- 00002	Legal Manufacturer (as per FSC) TOITU Co., LTD Address: 1-5-10, Ebisu-Nishi, Shibuya-Ku, Tokyo, 150-0021 Japan Manufacturing Site (as per FSC) TOITU Co., Ltd. Tsunashima Plant Address: 5-10-3, Tsunashima-Higashi, Kohoku-Ku, Yokohama, Kanagawa Prefecture, Japan ISO 13485: Submitted Issue Date: 2022-10-19 Validity Date: 2025-09-28 Notarization Status: Notary Public Attested EC Certificate: Submitted Issue Date: 2025-07-01 Validity Date: 2027-07-01 Issuing Authority: Ministry of Health, Labour and Welfare Japan Attestation Status: Pakistan Embassy Attested	Brand Name: TOITU Generic Name: Doppler Fetus Detector Class B Device/Accessories Name: Doppler Fetus Detector Shelf life/service life: Years Codes/Sizes (if any): FD-491/- Specify grouping: Single Storage condition: Temperature scope : -20°C~+55°C Relative humidity scope : ≤80%	Deferred as the product falls in class C. Correct the application accordingly along with differential fee.

		<p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-03</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: Notary Public and Pakistan Embassy Attested</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-19</p> <p>Validity Date: 2025-09-28</p> <p>Notarization Status: Notary Public Attested</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-01</p> <p>Validity Date: 2027-07-01</p> <p>Issuing Authority: Ministry of Health, Labour and Welfare Japan</p> <p>Attestation Status: Pakistan Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-03</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: Notary Public and Pakistan Embassy Attested</p>		
19	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San</p>	<p>Brand Name:</p> <p>ISO-SURE</p> <p>Generic Name:</p>	approved

	<p>Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 52200 /-</p> <p>Challan No.: 59365807928</p> <p>Date of submission: 22 August 2025</p> <p>Tracking ID: MDMR-20250822- 00030</p>	<p>Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-11-06</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p> <p>Issuing Authority: Minitero Della Salute</p> <p>Attestation Status: Apostille</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-10</p> <p>Validity Date: 2027-03-10</p> <p>Notarization Status: Duly Notarized</p>	<p>BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Class B</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1807/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1810/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1815/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1907/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION</p>	
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			<p>NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1910/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2110/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2112/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2115/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2012/</p> <p>Device/Accessories Name: ISO-SURE</p>	
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			<p>BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2015/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2020/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2105/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2107/</p> <p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2109/</p>	
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			<p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1912/</p>	
			<p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 1915/</p>	
			<p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2005/</p>	
			<p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2007/</p>	
			<p>Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISA 2009/</p>	

			Device/Accessories Name: ISO-SURE BREAST LOCALIZATION NEEDLE, SINGLE HOOK WIRE Shelf life/service life: 5 Years Codes/Sizes (if any): ISA 2010/ Specify grouping: Family Storage condition: Normal Room Temperature	
20	Biotech Services 746 Shadman-1 Lahore, Lahore Fee: Rs 32400 /- Challan No.: 86593362902 Date of submission: 24 August 2025 Tracking ID: MDMR-20250824- 00001	Legal Manufacturer (as per FSC) TOITU Co., LTD Address: 1-5-10, Ebisu-Nishi, Shibuya- Ku, Tokyo, 150-0021 Japan Manufacturing Site (as per FSC) TOITU Co., Ltd. Tsunashima Plant Address: 5-10-3, Tsunashima-Higashi, Kohoku-Ku, Yokohama, Kanagawa Prefecture, Japan ISO 13485: Submitted Issue Date: 2022-10-19 Validity Date: 2025-09-28 Notarization Status: Notary Public Attested EC Certificate: Submitted Issue Date: 2025-07-01 Validity Date: 2027-07-01 Issuing Authority: Ministry of Health,	Brand Name: TOITU Generic Name: Actocardiograph Fetal Monitor Class B Device/Accessories Name: Actocardiograph Fetal Monitor Shelf life/service life: Days Codes/Sizes (if any): MT-610/- Specify grouping: Single Storage condition: Temperature scope : -20°C~+55°C Relative humidity scope : ≤80%	Deferred as the product falls in class C. Correct the application accordingly along with differential fee.

		<p>Labour and Welfare</p> <p>Attestation Status: Pakistan Embassy Attestation</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-03</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: Notary Public and Pakistan Embassy Attested</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-10-19</p> <p>Validity Date: 2025-09-28</p> <p>Notarization Status: Notary Public Attested</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-01</p> <p>Validity Date: 2027-07-01</p> <p>Issuing Authority: Ministry of Health, Labour and Welfare</p> <p>Attestation Status: Pakistan Embassy Attestation</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-03</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: Notary Public and Pakistan Embassy Attested</p>		
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21	<p>Merlin International</p> <p>3rd Floor, 41 Office, Jail Road, Landmark Plaza,, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 5850776753</p> <p>Date of submission: 28 August 2025</p> <p>Tracking ID: MDMR-20250828- 14490</p>	<p>Manufacturer (as per FSC)</p> <p>M/s Chifeng Tianbo Medical Device Co., Ltd.</p> <p>Address: Zhongjing Industrial Park Economic Development Area, Ningcheng District, Chifeng 024200, Inner Mongolia, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-01-06</p> <p>Validity Date: 2028-02-17</p> <p>Notarization Status: CCPIT & Apostilled</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-13</p> <p>Validity Date: 2027-05-12</p> <p>Issuing Authority: Chifeng City Market Supervision and Administration Bureau</p> <p>Attestation Status: CCPIT & Apostilled</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-01-02</p> <p>Validity Date: 2030-01-01</p> <p>Notarization Status: CCPIT & Apostille</p>	<p>Brand Name: WELL-FLOW</p> <p>Generic Name: (Sterile Infusion Set without Y-Port for single use)</p> <p>Class B</p> <p>Device/Accessories Name: Sterile Disposable Infusion Set</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IS-G1-JMZ/21G</p> <p>Specify grouping: Single</p> <p>Storage condition: Not more than 38 Degree Centigrade</p>	approved
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Evaluator Name: Dr. Ghayour Ahmed (Evaluator-IV)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
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1	<p>Al Fajar Traders</p> <p>M/S Al Fajar Traders, 133, J Block, Sabazazar, Lahore, Lahore</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 3182663823</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR- 20250806-00030</p>	<p>Manufacturer</p> <p>Zhejiang Runqiang Medical Instruments CO.,Ltd</p> <p>Address: 599,Ruifeng Street, Gaozhao District,Xiuzhou district Jiaxing City,Zhejiang province, China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-05-07</p> <p>Validity Date: 2030-12-31</p> <p>Notarization Status: Apostile</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2023-03-27</p> <p>Validity Date: 2025-12-28</p> <p>Issuing Authority: Zhejiang Food and Drug Administration (Medical Devices Division)</p> <p>Attestation Status: Apostile</p> <p>Issue Date: 2025-03-27</p> <p>Validity Date: 2030-03-26</p> <p>Issuing Authority: TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany</p> <p>Attestation Status: CCPIT</p> <p>LOA: Submitted</p>	<p>Brand Name:</p> <p>Medi Safe</p> <p>Generic Name:</p> <p>Spinal needle</p> <p>Class D</p> <p>Device/Accessories Name: Spinal Needle</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): AN-S/18G × 90 mm 19G × 90 mm 20G × 90 mm 21G × 90 mm 22G × 90 mm 23G × 90 mm 24G × 90 mm 25G × 90 mm 26G × 90 mm 27G × 90 mm</p> <p>Specify grouping: Single</p> <p>Storage condition: cool and dry placeDo not stock heavy load on top</p>	<p>Deferred as the applied sizes are not mentioned in apostilled Free sale certificate/notarized design examination certificate/DoC. Justify/clarify.</p>
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		<p>Issue Date: 2025-07-22</p> <p>Validity Date: 2030-12-31</p> <p>Notarization Status: Apostile</p>		
2	<p>RECH INTERNATIONAL</p> <p>247-B, Block-6, PECHS,, Karachi</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 328050822</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR-20250806-00024</p>	<p>Manufacturer</p> <p>TECRES SPA</p> <p>Address: Via Andrea Doria 6, 37066 Sommacampagna, Verona, Italy</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-11-23</p> <p>Validity Date: 2027-02-26</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-12</p> <p>Validity Date: 2027-12-31</p> <p>Issuing Authority: Ministry of Health of Italy</p> <p>Attestation Status: Apostille</p> <p>Issue Date: 2023-01-17</p> <p>Validity Date: 2028-01-16</p> <p>Issuing Authority: bsi by Royal Charter</p> <p>Attestation Status: notarized</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-16</p>	<p>Brand Name: Mendec Spine</p> <p>Generic Name: Bone Cement</p> <p>Class D</p> <p>Device/Accessories Name: Mendec Spine</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): 1230/</p> <p>Specify grouping: Single</p> <p>Storage condition: Store in a cool, dry place, away from direct sunlight and heat sources.</p>	<p>Deferred for confirmation of storage conditions of product and facility for storage of the applied product with the applicant</p>

		Validity Date: 2027-12-31 Notarization Status: Notarized		
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Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	<p>Life Elements Private Limited</p> <p>Office No. 5-6, Ground Floor, Nawab Plaza, Range Road,, Rawalpindi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 25286284793</p> <p>Date of submission: 31 July 2025</p> <p>Tracking ID: MDMR- 20250731-00004</p>	<p>Legal Manufacturer (as per FSC)</p> <p>SterileCare Inc.</p> <p>Address: 15 Allstate Parkway, Suite 600, Markham ON, L3R, 5B4 Canada</p> <p>Manufacturer SterileCare Inc.</p> <p>Address: 15 Allstate Parkway, Suite 600, Markham ON, L3R, 5B4 Canada</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-06-10</p> <p>Validity Date: 2028-06-09</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-04-22</p> <p>Validity Date: 2026-05-19</p> <p>Issuing Authority: Food, Health & Consumer Products of Canada</p> <p>Attestation Status: It's Notarized but being both Canada & Pakistan member of the Hague Convention, there is no need of Apostille of these documents otherwise it</p>	<p>Brand Name: KiteLock 4% Sterile Catheter Lock Solution</p> <p>Generic Name: 28mg/mL edetate</p> <p>Class C</p> <p>Device/Accessories Name: KiteLock 4% Sterile Catheter Lock Solutionss</p> <p>Shelf life/service life: 30 Months</p> <p>Codes/Sizes (if any): SC001/3mL Vial</p> <p>Specify grouping: Single</p> <p>Storage condition: 15-30 C (Room Temperature)</p>	<p>Deferred for the submission of valid and apostilled FSC of Health Canada.</p>

		<p>will get unvalid (as communicated of Ambassdor of Pakistan in Canada)</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-02</p> <p>Validity Date: 2030-05-02</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-06-10</p> <p>Validity Date: 2028-06-09</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-04-22</p> <p>Validity Date: 2026-05-19</p> <p>Issuing Authority: Food, Health & Consumer Products of Canada</p> <p>Attestation Status: It's Notarized but being both Canada & Pakistan member of the Hague Convention, there is no need of Apostille of these documents otherwise it will get unvalid (as communicated of Ambassdor of Pakistan in Canada)</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-02</p> <p>Validity Date: 2030-05-02</p> <p>Notarization Status: Notarized</p>		
2	Moody Global	Legal Manufacturer (as per FSC)	Brand Name:	approved

	<p>Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 17659133</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00043</p>	<p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): N10Mpro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 60°C, Humidity: 10% to 95%</p>	
3	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building,</p>	<p>Brand Name:</p> <p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p>	approved

	<p>Fee: Rs 64800 /-</p> <p>Challan No.: 806018760</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00015</p>	<p>Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: notarized</p>	<p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): K18pro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 70°C , Humidity: 5% to 93%</p>	
4	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 933083281243</p> <p>Date of submission:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p>	approved

	08 August 2025 Tracking ID: MDMR-20250808-00003	Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: PEOPLES REPUBLIC OF CHINA Attestation Status: APOSTILLE FSC LOA: Submitted Issue Date: 2024-11-01 Validity Date: 2029-10-31 Notarization Status: NOTARIZED	Codes/Sizes (if any): K1/N/A Specify grouping: Single Storage condition: Storage Temperature: -20°C to 70°C , Humidity: 5% to 93%	
5	Moody Global Services Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad Fee: Rs 64800 /- Challan No.: 41445956276 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808-00045	Legal Manufacturer (as per FSC) Shenzhen Comen Medical Instruments Co., Ltd. Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China ISO 13485: Submitted Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED	Brand Name: COMEN Generic Name: Multi-parameter Patient Monitor Class C Device/Accessories Name: Multi-parameter Patient Monitor Shelf life/service life: 10 Years Codes/Sizes (if any): N15 /N/A Specify grouping: Single Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%	approved

		EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: PEOPLES REPUBLIC OF CHINA Attestation Status: APOSTILLE FSC LOA: Submitted Issue Date: 2024-11-01 Validity Date: 2029-10-31 Notarization Status: notarized		
6	Moody Global Services Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad Fee: Rs 64800 /- Challan No.: 4943252820 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808-00051	Legal Manufacturer (as per FSC) Shenzhen Comen Medical Instruments Co., Ltd. Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China ISO 13485: Submitted Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: PEOPLES REPUBLIC	Brand Name: COMEN Generic Name: Multi-parameter Patient Monitor Class C Device/Accessories Name: Multi-parameter Patient Monitor Shelf life/service life: 10 Years Codes/Sizes (if any): C 80/N/A Specify grouping: Single Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%	approved

		<p>OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: notarized</p>		
7	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 66420192</p> <p>Date of submission: 09 August 2025</p> <p>Tracking ID: MDMR-20250809-00006</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-26</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): C 30/N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 60°C, Humidity: 10% to 95%</p>	approved

		LOA: Submitted Issue Date: 2024-11-01 Validity Date: 2029-10-31 Notarization Status: NOTARIZED		
8	BRIOGENE Pvt Ltd 196-A SMCHS Karachi, Karachi Fee: Rs 64800 /- Challan No.: 0320546976 Date of submission: 08 August 2025 Tracking ID: MDMR- 20250808-00060	Legal Manufacturer (as per FSC) Xiamen Zeesan Biotech Co., Ltd Address: 884-1 and 884-2 Lianting Road, (Xiang An) Industrial Area, Torch High- Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China ISO 13485: Submitted Issue Date: 2023-10-17 Validity Date: 2025-10-21 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2025-05-06 Validity Date: 2026-05-26 Issuing Authority: Ministry of Health, Welfare, sport CIBG NETHERLAND Attestation Status: Apostilled FSC submitted LOA: Submitted Issue Date: 2025-06-20 Validity Date: 2027-12-31 Notarization Status: Notarized	Brand Name: ZEESAN MTB/MDR Test Kit (Sanity2.0) Generic Name: MTB/MDR Test Kit Class C Device/Accessories Name: MTB/MDR Test Kit (Sanity2.0) Shelf life/service life: 18 Months Codes/Sizes (if any): 801181/ Specify grouping: IVD Kit Storage condition: -25~8°C	approved
9	Moody Global Services	Legal Manufacturer (as per FSC) Shenzhen Comen Medical Instruments Co.,	Brand Name:	approved

	<p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 68673277</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00048</p>	<p>Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): N12MPro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 60°C , Humidity: 10% to 95%</p>	
10	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district,</p>	<p>Brand Name:</p> <p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Class C</p>	approved

	<p>Fee: Rs 64800 /-</p> <p>Challan No.: 27327276450</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00052</p>	<p>Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): N15MPro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage</p> <p>Temperature: -20°C to 60°C ,</p> <p>Humidity: 10% to 95%</p>	
11	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 0248171199</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00008</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): K12pro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage</p> <p>Temperature: -20°C to 70°C ,</p>	approved

		EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: PEOPLES REPUBLIC OF CHINA Attestation Status: APOSTILLE FSC submitted LOA: Submitted Issue Date: 2024-11-01 Validity Date: 2029-10-31 Notarization Status: NOTARIZED	Humidity: 5% to 93%	
12	BRIOGENE Pvt Ltd 196-A SMCHS Karachi, Karachi Fee: Rs 64800 /- Challan No.: 5146156196 Date of submission: 08 August 2025 Tracking ID: MDMR- 20250808-00062	Legal Manufacturer (as per FSC) Xiamen Zeesan Biotech Co., Ltd Address: 884-1 and 884-2 Lianting Road, (Xiang An) Industrial Area, Torch High- Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China ISO 13485: Submitted Issue Date: 2023-10-17 Validity Date: 2025-10-21 Notarization Status: Apostilled EC Certificate: Submitted Issue Date: 2025-05-06 Validity Date: 2026-05-26 Issuing Authority: Ministry of health, welfare and Support CIBG Netherland Attestation Status: Apostilled	Brand Name: ZEESAN MDR-TB Test Kit (Sanity2.0) Generic Name: MDR-TB Test Kit Class C Device/Accessories Name: MDR-TB Test Kit (Sanity2.0) Shelf life/service life: 18 Months Codes/Sizes (if any): 801177/ Specify grouping: IVD Kit Storage condition: -25~8°C	approved

		FSC submitted LOA: Submitted Issue Date: 2025-06-20 Validity Date: 2027-12-31 Notarization Status: Notarized		
13	Moody Global Services Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad Fee: Rs 64800 /- Challan No.: 443443140 Date of submission: 09 August 2025 Tracking ID: MDMR-20250809-00010	Legal Manufacturer (as per FSC) Shenzhen Comen Medical Instruments Co., Ltd. Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China ISO 13485: Submitted Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: PEOPLES REPUBLIC OF CHINA Attestation Status: APOSTILLE FSC submitted LOA: Submitted Issue Date: 2024-11-01	Brand Name: COMEN Generic Name: Multi-parameter Patient Monitor Class C Device/Accessories Name: Multi-parameter Patient Monitor Shelf life/service life: 10 Years Codes/Sizes (if any): ND 12/N/A Specify grouping: Single Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%	approved

		Validity Date: 2029-10-31 Notarization Status: NOTARIZED		
14	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 41262134198</p> <p>Date of submission: 09 August 2025</p> <p>Tracking ID: MDMR-20250809-00009</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): ND 15/N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%</p>	approved
15	Moody Global	Legal Manufacturer (as per FSC)	Brand Name:	approved

	<p>Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 01823191617</p> <p>Date of submission: 09 August 2025</p> <p>Tracking ID: MDMR-20250809-00011</p>	<p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-26</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): ND10/N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage</p> <p>Temperature: -20°C to 60°C</p> <p>Humidity: 10% to 95%</p>	
16	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building,</p>	<p>Brand Name:</p> <p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p>	approved

	<p>Fee: Rs 64800 /-</p> <p>Challan No.: 2319471460</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00012</p>	<p>Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: notarized</p>	<p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): K15pro /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 70°C , Humidity: 5% to 93%</p>	
17	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 193930292498</p> <p>Date of submission:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Vital Signs Monitor</p> <p>Class C</p> <p>Device/Accessories Name: Vital Signs Monitor</p> <p>Shelf life/service life: 5 Years</p>	approved

	09 August 2025 Tracking ID: MDMR-20250809-00013	Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED EC Certificate: Submitted Issue Date: 2024-12-25 Validity Date: 2026-01-21 Issuing Authority: CCPIT Attestation Status: APOSTILLE FSC submitted LOA: Submitted Issue Date: 2024-11-01 Validity Date: 2029-10-31 Notarization Status: NOTARIZED	Codes/Sizes (if any): NC 3/N/A Specify grouping: Single Storage condition: Ambient temperature: -20°C~+60°C(without ear thermometer) - 20°C~+55°C(with ear thermometer)	
18	Moody Global Services Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad Fee: Rs 64800 /- Challan No.: 20814890847 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808-00052	Legal Manufacturer (as per FSC) Shenzhen Comen Medical Instruments Co., Ltd. Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China ISO 13485: Submitted Issue Date: 2024-03-18 Validity Date: 2026-03-31 Notarization Status: NOTARIZED EC Certificate: Submitted	Brand Name: COMEN Generic Name: Multi-parameter Patient Monitor Class C Device/Accessories Name: Multi-parameter Patient Monitor Shelf life/service life: 10 Years Codes/Sizes (if any): C50 /N/A Specify grouping: Single Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%	approved

		<p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>		
19	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 002181802803</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00049</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): N10 /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: -20°C to 60°C Humidity: 10% to 95%</p>	approved

		<p>Attestation Status: APOSTILLE</p> <p>FSC submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>		
20	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 7966135743</p> <p>Date of submission: 11 August 2025</p> <p>Tracking ID: MDMR-20250811-00045</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Ventana Medical Systems</p> <p>Address: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-04-17</p> <p>Validity Date: 2030-04-16</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC submitted</p>	<p>Brand Name:</p> <p>VENTANA pan-TRK (EPR17341) Assay</p> <p>Generic Name:</p> <p>VENTANA pan-TRK (EPR17341) Assay</p> <p>Class C</p> <p>Device/Accessories Name:</p> <p>VENTANA pan-TRK (EPR17341) Assay</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 09365583001/</p> <p>Specify grouping: Single</p> <p>Storage condition: 2 - 8°C</p>	approved

		<p>LOA: Submitted Issue Date: 2023-01-17 Validity Date: 2027-01-16 Notarization Status: Notarized</p> <p>ISO 13485: Submitted Issue Date: 2024-06-30 Validity Date: 2027-06-29 Notarization Status: Notarized</p> <p>EC Certificate: Submitted Issue Date: 2025-04-17 Validity Date: 2030-04-16 Issuing Authority: Baden Württemberg Attestation Status: Embassy Attested</p> <p>FSC LOA: Submitted Issue Date: 2023-01-17 Validity Date: 2027-01-16 Notarization Status: Notarized</p>		
21	<p>Moody Global Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 21793963626</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p>	<p>Brand Name: COMEN</p> <p>Generic Name: Multi-parameter Patient Monitor Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p>	approved

	<p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR- 20250808-00047</p>	<p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC Submitted</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: notarized</p>	<p>Codes/Sizes (if any): N12 /N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage</p> <p>Temperature: -20°C to 60°C</p> <p>Humidity: 10% to 95%</p>	
22	<p>BRIOGENE Pvt Ltd</p> <p>196-A SMCHS Karachi, Karachi</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 2351901776</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR- 20250808-00061</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Xiamen Zeesan Biotech Co., Ltd</p> <p>Address: 884-1 and 884-2 Lianting Road, (Xiang An) Industrial Area, Torch High- Tech Zone, Xiamen City, Fujian Province, 361101, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-17</p> <p>Validity Date: 2025-10-21</p> <p>Notarization Status: Apostilled</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-06-30</p>	<p>Brand Name: ZEESAN MTB Test Kit (Sanity2.0)</p> <p>Generic Name: MTB Test Kit</p> <p>Class C</p> <p>Device/Accessories Name: MTB Test Kit (Sanity2.0)</p> <p>Shelf life/service life: 18 Months</p> <p>Codes/Sizes (if any): 801176/</p> <p>Specify grouping: IVD Kit</p>	approved

		Validity Date: 2026-01-28 Issuing Authority: People's republic of china Attestation Status: Apostilled FSC submitted LOA: Submitted Issue Date: 2025-06-20 Validity Date: 2027-12-31 Notarization Status: Notarized	Storage condition: 2~8°C	
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Renewal of import products

Evaluator Name: Dr. Ghayour Ahmed (Evaluator-IV)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	Product Registration Number/Enlistment: MDIR-0001694 Ferozsons Laboratories Limited P.O. Ferozsons Amangarh, Nowshera KPK, Nowshera Fee: Rs 32400 /- Challan No.: 90230668882 Date of submission: 07 August 2025 Tracking ID: MDMR-20250807-00034	Manufacturer Boston Scientific Corporation Address: 4100 Hamline Ave N Saint Paul, MN USA 55112 Manufacturing Site (as per FSC) Boston Scientific Limited Address: Cashel Road CLONMEL, Tipperary IRELAND	Brand Name: VIGILANT EL ICD Generic Name: Implantable Cardioverter Defibrillator Class D Device/Accessories Name: VIGILANT EL ICD Shelf life/service life: 2 Years Codes/Sizes (if any): D233/ Specify grouping: Single	Deferred for clarification from principal manufacturer as the name of manufacturer is different in Free sale certificate and in ISO 13485/Design examination certificate. Accordingly provide documents.

		<p>ISO 13485: Submitted Issue Date: 2023-10-21 Validity Date: 2026-10-20 Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted Issue Date: 2024-06-05 Validity Date: 2026-06-04 Issuing Authority: US-FDA Attestation Status: Apostilled</p> <p>Issue Date: 2024-06-05 Validity Date: 2026-06-04 Issuing Authority: US-FDA Attestation Status: Apsotilled</p> <p>LOA: Submitted Issue Date: 2025-02-10 Validity Date: 2025-12-31 Notarization Status: Notarized</p> <p>ISO 13485: Submitted Issue Date: 2023-10-21 Validity Date: 2026-10-20 Notarization Status:</p>	<p>Storage condition: Ambient Conditions</p>	
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		<p>Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apsotilled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-02-10</p> <p>Validity Date: 2025-12-31</p> <p>Notarization Status: Notarized</p>		
2	<p>Product Registration Number/Enlistment: MDIR-0001693</p> <p>Ferozsans Laboratories Limited</p> <p>P.O. Ferozsans Amangarh, Nowshera KPK, Nowshera</p> <p>Fee: Rs 32400 /-</p>	<p>Manufacturer</p> <p>Boston Scientific Corporation</p> <p>Address: 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>Manufacturing Site (as per FSC)</p>	<p>Brand Name: VIGILANT X4 CRT-D</p> <p>Generic Name: Cardiac Resynchronization Therapy Defibrillator</p> <p>Class D</p> <p>Device/Accessories Name: VIGILANT X4 CRT-D</p>	<p>Deferred for clarification from principal manufacturer as the name of manufacturer is different in Free sale certificate and in ISO 13485/Design examination certificate. Accordingly provide documents.</p>

	<p>Challan No.: 7326128629</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00045</p>	<p>Boston Scientific Limited</p> <p>Address: Cashel Road CLONMEL, Tipperary IRELAND</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-21</p> <p>Validity Date: 2026-10-20</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-02-10</p> <p>Validity Date: 2025-12-31</p> <p>Notarization Status:</p>	<p>Shelf life/service life: 2 Years</p> <p>Codes/Sizes (if any): G237/</p> <p>Device/Accessories Name: VIGILANT X4 CRT-D</p> <p>Shelf life/service life: 2 Years</p> <p>Codes/Sizes (if any): G247/</p> <p>Specify grouping: Family</p> <p>Storage condition: Ambient Conditions</p>	
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		<p>Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-21</p> <p>Validity Date: 2026-10-20</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-02-10</p> <p>Validity Date: 2025-12-31</p> <p>Notarization Status: Notarized</p>		
3	Product Registration Number/Enlistment: Ferozsans Laboratories	Manufacturer Boston Scientific Corporation	Brand Name: VIGILANT EL ICD	Deferred for clarification from principal manufacturer as the name of manufacturer is different in Free sale certificate and in ISO 13485/Design

	<p>Limited</p> <p>P.O. Ferozsons Amangarh, Nowshera KPK, Nowshera</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 32986338469</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR- 20250806-00023</p>	<p>Address: 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>Manufacturing Site (as per FSC)</p> <p>Boston Scientific Limited</p> <p>Address: Cashel Road CLONMEL, Tipperary IRELAND</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-21</p> <p>Validity Date: 2026-10-20</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US- FDA</p> <p>Attestation Status: Attested</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US- FDA</p> <p>Attestation Status: Apostilled</p>	<p>Generic Name:</p> <p>Implantable Cardioverter Defibrillator</p> <p>Class D</p> <p>Device/Accessories Name: VIGILANT EL ICD</p> <p>Shelf life/service life: 2 Years</p> <p>Codes/Sizes (if any): D232/ Specify grouping: Single</p> <p>Storage condition: Ambient Conditions</p>	<p>examination certificate. Accordingly provide documents.</p>
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		<p>LOA: Submitted</p> <p>Issue Date: 2025-02-10</p> <p>Validity Date: 2025-12-31</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-10-21</p> <p>Validity Date: 2026-10-20</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Attested</p> <p>Issue Date: 2024-06-05</p> <p>Validity Date: 2026-06-04</p> <p>Issuing Authority: US-FDA</p> <p>Attestation Status: Apostilled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-02-10</p> <p>Validity Date: 2025-12-31</p> <p>Notarization Status:</p>		
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		Notarized		
4	<p>Product Registration Number/Enlistment:</p> <p>Intek Corporation</p> <p>Office 517, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000., Rawalpindi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 80328352907</p> <p>Date of submission: 14 August 2025</p> <p>Tracking ID: MDMR-20250814-00004</p>	<p>Legal Manufacturer (as per FSC)</p> <p>TERUMO MEDICAL CORP.</p> <p>Address: 950 ELKTON BLVD. ELKTON, MD USA 21921</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-01-31</p> <p>Validity Date: 2028-02-15</p> <p>Notarization Status: TÜV Rheinland LGA Products GmbH</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-09-16</p> <p>Validity Date: 2026-09-15</p> <p>Issuing Authority: US Department of Health and Human Services</p> <p>Attestation Status: Director of Regulatory Office of US Department of Health and Human Services</p> <p>Issue Date: 2024-09-16</p> <p>Validity Date: 2026-09-15</p> <p>Issuing Authority: US Department of Health and</p>	<p>Brand Name:</p> <p>Destination Sheath</p> <p>Generic Name:</p> <p>Destination Carotid Guiding Sheath</p> <p>Class D</p> <p>Device/Accessories Name: Destination Sheath</p> <p>Shelf life/service life: 30 Months</p> <p>Codes/Sizes (if any): RSC01 RSC02 RSC03 RSC04 RSC05 RSC06 RSC07 RSC08/</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temperature</p>	<p>Deferred for submission of differential fee of family as per applicable SRO.</p>

		Human Services Attestation Status: Director Office Of Regulatory program US Department of Health and Human Services LOA: Submitted Issue Date: 2025-01-08 Validity Date: 2026-03-31 Notarization Status: Please find attached Dubai chamber attested Authorization letter		
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Renewal Applications

Evaluator Name: Waqar Ahmed (Evaluator-II)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	Product Registration Number/Enlistment: F.W.DISTRIBUTORS Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi Fee: Rs 6000 /- Challan No.: 79925056875 Date of submission: 06 August 2025	Legal Manufacturer (as per FSC) SCW Address: M/s SCW MEDICATH LTD No.4, Baolong 6th Road, Baolong Industrial Town, Longgang, District Shenzhen, China ISO 13485: Submitted Issue Date: 2024-07-08	Brand Name: SCW MEDICATH CONNECTING TUBING Generic Name: High Pressure Angiography Connecting Tubbing Class A Device/Accessories Name: High Pressure Angiography Connecting Tubbing Shelf life/service life: 3 Years Codes/Sizes (if any): O.D-	Approved

	<p>Tracking ID: MDMR-20250806-00010</p>	<p>Validity Date: 2027-07-08</p> <p>Notarization Status: APOSTILLED BY FOREIGN AFFAIRS OFFICE OF SHENZHEN MUNICIPALITY</p> <p>EC Certificate</p> <p>Issue Date: 2015-07-09</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: TUV Rheinland®</p> <p>Attestation Status: Appostiled</p> <p>FSC: Submitted</p> <p>Issue Date: 2021-08-19</p> <p>Validity Date: 2026-08-18</p> <p>Issuing Authority: FOREIGN AFFAIRS OFFICE OF SHENZHEN MUNCIPIALITY</p> <p>Attestation Status: EMBASSY ATTESTED</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-12-10</p> <p>Validity Date: 2027-12-10</p> <p>Notarization Status: APOSTILLED BY FOREIGN AFFAIRS OFFICE OF SHENZHEN MUNICIPALITY</p>	<p>3.6MM/30CM,60CM,120CM,150CM</p> <p>Specify grouping: Single</p> <p>Storage condition: This product should be stored in a cool dry environment, avoid direct sunlight.</p>	
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Renewal Applications

Evaluator Name: Sadaf Ahmad (Evaluator-III)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	<p>Product Registration Number/Enlistment:</p> <p>K.M Enterprises</p> <p>KM Mansion 605-D block M.A Johar Town lahore, Lahore</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 10997294562</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID: MDMR-20250901-14642</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Euromed for Medical Industries</p> <p>Address: Area No. 10 Block(i) Free Zone, Nasr City, Cairo, Egypt.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-07-17</p> <p>Validity Date: 2028-07-16</p> <p>Notarization Status: YES</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2022-02-07</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: EGYPTIAN DRUG AUTHORITY</p> <p>Attestation Status: YES</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-15</p> <p>Validity Date: 2030-04-14</p> <p>Notarization Status: YES</p>	<p>Brand Name:</p> <p>EURO</p> <p>Generic Name:</p> <p>FOLEY CATHETER LATEX, SILICON COATED</p> <p>Class B</p> <p>Device/Accessories Name: EURO FOLEY CATHETER LATEX, SILICON COATED</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 2WAY&3WAY/6Fr,8Fr,10Fr,12Fr,14Fr,16Fr,18Fr</p> <p>Specify grouping: Family</p> <p>Storage condition: 30C</p>	Approved
2	Product Registration	Manufacturer	Brand Name:	approved

	<p>Number/Enlistment: Usmanco International 220 Block-3 D. M. C. H. S., S.Abdul Tawwab Road,, Karachi Fee: Rs 15700 /- Challan No.: 09277255 Date of submission: 01 September 2025 Tracking ID: MDMR-20250901-14672</p>	<p>M/s Jiangxi Sanxin Medtec Co. Ltd Address: Address: No. 999 Fushan Road XiaoLan Economic development Zone Nanchang 330200, Jiangxi, P.R. China ISO 13485: Submitted Issue Date: 2024-11-27 Validity Date: 2028-01-13 Notarization Status: Notarized by China Council for the promotion of international trade (CCPIT) EC Certificate: Submitted Issue Date: 2025-05-08 Validity Date: 2027-05-08 Issuing Authority: China Council for the promotion of international trade (CCPIT) Attestation Status: Apostilled by Embassy of Pakistan in China FSC provided LOA: Submitted Issue Date: 2021-06-23 Validity Date: 2026-06-22 Notarization Status: Notarized by China Council for the Promotion of International Trade (CCPIT)</p>	<p>YI XIN Generic Name: Auto Disable Syringe Class B Device/Accessories Name: Yi XIN Auto Disable Syringe Shelf life/service life: 5 Years Codes/Sizes (if any): N/A/0.5ml, 1ml, 2ml, 2.5ml, 3ml, 5 ml Specify grouping: Single Storage condition: Store at room temperature and keep away from sunlight.</p>	
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3	<p>Product Registration Number/Enlistment:</p> <p>Sadqain Healthcare Pvt Ltd</p> <p>Safari villas 2, commercial complex, 3rd floor, bahria town ph-7, Rawalpindi</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 400859978</p> <p>Date of submission: 27 August 2025</p> <p>Tracking ID: MDMR-20250827-14371</p>	<p>Legal Manufacturer (as per FSC)</p> <p>M/s. Intersurgical Limited</p> <p>Address: Intersurgical Limited Crane House, Molly Millars Lane, Wokingham, Berkshire,</p> <p>Manufacturing Site (as per FSC)</p> <p>UAB Intersurgical</p> <p>Address: Arnioniu 60, Pabrade, Lithuania, LT-18170</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-12-04</p> <p>Validity Date: 2026-11-26</p> <p>Notarization Status: valid</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-10-01</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: STATE HEALTHCARE ACCREDITATION AGENCY UNDER THE MINISTRY OF HEALTH</p> <p>Attestation Status: VERIFIED</p> <p>FSC PROVIDED</p> <p>LOA: Submitted</p> <p>Issue Date: 2021-03-01</p>	<p>Brand Name:</p> <p>SILVER KNIGHT ANTI-MICROBAL MAPLESON D DELUXE BAIN COAXIAL BREATHING SYSTEM WITH 2L BAG, $\geq 1.6M$</p> <p>Generic Name:</p> <p>Mapleson D and Deluxe Bain coaxial Breathing System</p> <p>Class B</p> <p>Device/Accessories Name: Silver knight anti-microbial mapleson D deluxe bain coaxial breathing system with 2l bag $\geq 1.6m$</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 2115100/2l bag = 1.6m</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temp (5-45oC)</p>	<p>Deferred for differential fee for system as per applicable SRO</p>
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		<p>Validity Date: 2026-03-01 Notarization Status: VALID ISO 13485: Submitted Issue Date: 2023-12-04 Validity Date: 2026-11-26 Notarization Status: valid EC Certificate: Submitted Issue Date: 2024-10-01 Validity Date: 2028-12-31 Issuing Authority: STATE HEALTHCARE ACCREDITATION AGENCY UNDER THE MINISTRY OF HEALTH Attestation Status: VERIFIED FSC LOA: Submitted Issue Date: 2021-03-01 Validity Date: 2026-03-01 Notarization Status: VALID</p>		
4	<p>Product Registration Number/Enlistment: Sudais Associates Sudais House, Street No. 07, House No. A1 Khan Bahadur Colony Duran Pur Peshawar Pakistan., Peshawar Fee: Rs 15000 /-</p>	<p>Legal Manufacturer (as per FSC) DOCTOR JAPAN CO., LTD Address: GYODA FACTORY located at 4-15-1, NAGANO, GYODA-CITY, SAITAMA 361-0023, JAPAN ISO 13485: Submitted</p>	<p>Brand Name: Dr. J Fine Core Generic Name: BIOPSY NEEDLE Class B Device/Accessories Name: (Disposable Semi-automatic</p>	<p>Deferred for differential fee for family as per applicable SRO.</p>

	<p>Challan No.: 8808300225</p> <p>Date of submission: 14 August 2025</p> <p>Tracking ID: MDMR-20250814-00011</p>	<p>Issue Date: 2024-04-24</p> <p>Validity Date: 2026-05-16</p> <p>Notarization Status: Apostille Attested</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-07</p> <p>Validity Date: 2027-07-07</p> <p>Issuing Authority: MINISTER FOR FOREIGN AFFAIR</p> <p>Attestation Status: APOSTILLE ATTESTED</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-20</p> <p>Validity Date: 2030-08-20</p> <p>Notarization Status: APOSTILLE ATTESTED MINISTER FOR FOREIGN AFFAIR</p>	<p>Biopsy Needle</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): FC-14x100, FC-14x150,FC-14x200,FC-16x100,FC-16x150,FC-16x200, FC-16x250mm,FC-18X100,FC-18x150,FC-18x200,FC-18x250,FC-20x100,FC-20x150,FC-20x200,FC-20x250,FC-21x100,FC-21x150,FC-21x200/14Gx100mm,14Gx150m m,14Gx200mm,16Gx100mm,16G x150mm,16Gx200mm,16Gx250m m,18Gx100mm,18Gx150mm,18G x200mm,18Gx250mm,20Gx100m m,20Gx150mm,20Gx200mm,20G x250mm,21Gx100mm,21Gx150m m,21Gx200mm</p> <p>Specify grouping: Family</p> <p>Storage condition: 40°C.</p>	
5	<p>Product Registration Number/Enlistment:</p> <p>Mezan International</p> <p>59BR2 Opposite DCO House Haji Meherban Road Jhelum, Jhelum</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 823012240850</p> <p>Date of submission: 22 August 2025</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Acto GMBH</p> <p>Address: ACTO GMBH Schulstrasse 8,31613 Wietzen Braunschweig Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Acto Pharma</p> <p>Address: Akcaburgaz</p>	<p>Brand Name:</p> <p>ACTODIACIT</p> <p>Generic Name:</p> <p>Citric acid based disinfectant for hemodialysis machines</p> <p>Class B</p> <p>Device/Accessories Name:</p> <p>Actodiacit</p> <p>Shelf life/service life: 3 Years</p>	approved

	Tracking ID: MDMR-20250822-00021	<p>Mahallesi.3038 Sok No.1134522 Esenyurt Istanbul,Turkey & ACTO GMBH Schulstrasse 8,31613 Wietzen Braunschweig Germany</p> <p>ISO 13485: Submitted Issue Date: 2025-03-11 Validity Date: 2028-03-10 Notarization Status: Notarized</p> <p>EC Certificate: Submitted Issue Date: 2024-08-01 Validity Date: Issuing Authority: Staatliches Gewerbeaufsichtsamt Braunschweig Attestation Status: Embassy Attested</p> <p>FSC provided</p> <p>LOA: Submitted Issue Date: 2024-08-13 Validity Date: 2027-08-13 Notarization Status: Notarized</p> <p>ISO 13485: Submitted Issue Date: 2025-03-11 Validity Date: 2028-03-10 Notarization Status: Notarized</p>	<p>Codes/Sizes (if any): N/A/5Liter</p> <p>Specify grouping: Single</p> <p>Storage condition: 3 Years</p>	
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		EC Certificate: Submitted Issue Date: 2024-08-01 Validity Date: Issuing Authority: Staatliches Gewerbeaufsichtsamt Braunschweig Attestation Status: Embassy Attested FSC provided LOA: Submitted Issue Date: 2024-08-13 Validity Date: 2027-08-13 Notarization Status: Notarized		
6	Product Registration Number/Enlistment: Excel Corporation 435,BYJ Society Bahadurabad, Karachi Fee: Rs 15000 /- Challan No.: 89137691554 Date of submission: 23 August 2025 Tracking ID: MDMR-20250823- 00008	Legal Manufacturer (as per FSC) Hangzhou Superds Industry Co., Ltd Address: Taifeng Village, Zhongtai Township, Yuhang District, Hanzhou City, Zhejiang Province, China ISO 13485: Submitted Issue Date: 2025-03-21 Validity Date: 2028-03-30 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2024-04-02 Validity Date: 2026-04-01	Brand Name: Safety Inhale Generic Name: Nebulizer Mask Class B Device/Accessories Name: SAFETY-INHALE NEBULIZER MASK Shelf life/service life: 60 Months Codes/Sizes (if any): NA/S, M, L, XL Specify grouping: Family Storage condition: To be stored in a cool dry place in an insect free, rodent free area away from light	approved

		<p>Issuing Authority: CFDA</p> <p>Attestation Status: Apostille & Notarized</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2018-12-30</p> <p>Validity Date: 2028-12-29</p> <p>Notarization Status: Notarized & Apostille</p>	and dust.	
7	<p>Product Registration Number/Enlistment:</p> <p>Sadqain Healthcare Pvt Ltd</p> <p>Safari villas 2, commercial complex, 3rd floor, bahria town ph-7, Rawalpindi</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 008762889255</p> <p>Date of submission: 27 August 2025</p> <p>Tracking ID: MDMR-20250827-14367</p>	<p>Legal Manufacturer (as per FSC)</p> <p>M/s. Intersurgical Limited</p> <p>Address: CraneHouse,MollyMillarsLane ,Wokingham,Berkshire,</p> <p>Manufacturing Site (as per FSC)</p> <p>UAB Intersurgical</p> <p>Address: Arnioniu60,Pabrade,Lithuania, LT-18170</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-12-04</p> <p>Validity Date: 2026-11-26</p> <p>Notarization Status: VALID</p> <p>EC Certificate: Submitted</p>	<p>Brand Name:</p> <p>Cirrus2</p> <p>Generic Name:</p> <p>Nebuliser breathing system T-kit</p> <p>Class B</p> <p>Device/Accessories Name:</p> <p>Cirrus2nebuliser breathing system T-kit</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any):</p> <p>2605000/22mmandtube,1.8m</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temp (5-45oc)</p>	Deferred for differential fee for SYSTEM as prer applicable SRO

		<p>Issue Date: 2024-10-01</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: STATE HEALTH CARE ACCREDITATION AGENCY UNDER THE MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA</p> <p>Attestation Status: VERIFIED</p> <p>FSC provided</p> <p>LOA: Submitted</p> <p>Issue Date: 2021-03-01</p> <p>Validity Date: 2026-03-01</p> <p>Notarization Status: VALID</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-12-04</p> <p>Validity Date: 2026-11-26</p> <p>Notarization Status: VALID</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-10-01</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: STATE HEALTH CARE ACCREDITATION AGENCY UNDER THE MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA</p> <p>Attestation Status: VERIFIED</p> <p>FSC</p>		
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		LOA: Submitted Issue Date: 2021-03-01 Validity Date: 2026-03-01 Notarization Status: VALID		
8	Product Registration Number/Enlistment: Global Health Care Midway Commercial Plaza no 20 Backside Prism Arcade 2 Bahria Town Phase 7 Rawalpindi, Rawalpindi Fee: Rs 15000 /- Challan No.: 369538446827 Date of submission: 20 August 2025 Tracking ID: MDMR-20250820-00014	Legal Manufacturer (as per FSC) M/s Boditech Med Inc Address: 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang-won-do 24398, KOREA ISO 13485: Submitted Issue Date: 2022-11-01 Validity Date: 2025-10-31 Notarization Status: Apostille EC Certificate: Submitted Issue Date: 2025-03-20 Validity Date: Issuing Authority: National Institute of Medical Device Safety Information (NIDS) Attestation Status: Apostille FSC provided LOA: Submitted Issue Date: 2025-01-01 Validity Date: 2027-12-31 Notarization Status: Apostille	Brand Name: ichroma Cortisol Generic Name: Cortisol Class B Device/Accessories Name: ichroma™ Cortisol Shelf life/service life: 20 Months Codes/Sizes (if any): ichroma™ Cortisol /25 units/Pack Device/Accessories Name: Control Shelf life/service life: 12 Months Codes/Sizes (if any): N/A/1 Unit/Pack Specify grouping: IVD Kit Storage condition: 2°C~ 30°C	approved

Deferred renewal Applications

Evaluator Name: Sadaf Ahmad (Evaluator-III)

Sr.No.	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	K.M Enterprises KM Mansion 605-D block M.A Johar Town lahore, Lahore Fee: Rs 15700 /- Challan No.: 113037442 Date of submission: 01 September 2025 Tracking ID: MDMR-20250901-14624 - D-98	Legal Manufacturer (as per FSC) Euromed for Medical Industries Address: Area No. 10 Block(i) Free Zone, Nasr City, Cairo, Egypt. ISO 13485: Submitted Issue Date: 2025-07-17 Validity Date: 2028-07-16 Notarization Status: YES EC Certificate: Submitted Issue Date: 2022-02-07 Validity Date: 2028-12-31 Issuing Authority: EGYPTIAN DRUG AUTHORITY Attestation Status: YES FSC PROVIDED LOA: Submitted Issue Date: 2025-04-15 Validity Date: 2030-04-14 Notarization Status: YES	Brand Name: EURO FLOW Generic Name: SILICONE FOLEY CATHETER Class B Device/Accessories Name: EURO FLOW SILICONE FOLEY CATHETERS Shelf life/service life: 5 Years Codes/Sizes (if any): 2-Way/All Size Specify grouping: Single Storage condition: 30C	approved

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Abdul Qadir
Assistant Director-I (MIS)
(O/B Web Publisher)
Monday, 06 October, 2025, 2:42:39 PM

Abdul Qadir
Assistant Director-I (MIS)
(O/B Web Publisher)
Monday, 06 October, 2025, 2:42:39 PM

Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

DECISIONS OF 99TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 11-09-2025 (PART-II MANUAL FILES AGENDA)

99th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 11th September, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
11.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
12.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
13.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
14.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
15.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
16.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
17.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member

18.	Prof Dr M Nadeen Ahmed, Department of radiology, Agha Khan University Hospital,	Member (attended meeting through videolink)
19.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
20.	Asif Jalil, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
9.	Mr. Saadat Ali Khan	Deputy Director-I
10.	Mr. Waqar Ahmad	Deputy Director-II
11.	Mst. Sadaf Ahmad	Deputy Director-III
12.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
13.	Mr. Muhammad Ashfaq	Deputy Director-VI
14.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
15.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
16.	Mr. Muhammad Amin	Deputy Director-IX

Item No. I(A): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

FRESH CASES

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Accord Distributors, Room No. 706, 7 th Floor, Kashif Centre, Shahrah-e-Faisal Road,	Shehzady Uroosa	Approved

	Karachi South, Saddar Town, Karachi	Pharma D	
2.	M/s Bio Safe Lab Technologies, House No. 1220, Street No. 52, I-11/2, Islamabad	Usman Jawad MS Biotechnology	Approved
3.	M/s Fast Medical, Plot No. A-10, Flat No. G-5, Basement, Shamsi Cooperative Housing Society Near Wireless Gate, Karachi	Kiran Jawed Pharm-D	Approved
4.	M/s MNM Traders (Pvt) Ltd., Opposite House No. B2-B, Gul e Latif Near Sonahri Bookland, Hyderabad	Engr. Sanwal Khan Bio Medical Engineer	Approved
5.	M/s Musani Pharmaceuticals Ltd., Unit No. 503, Al-Amin Tower, Plot E-2, Block 10, Gulshan e Iqbal, Karachi	Uroosa Fatima Pharm D	Approved
6.	M/s Newline Empire Pvt. Ltd., Office No. 5, Block B 5 th Floor Marina One Building Near Gulberg Green Islamabad	Dildar Khan Bio-Medical Engineer	Approved
7.	M/s M Zakaria & Sons, Head Office: House No. 372, Street 59, G-11/2, Islamabad Godown: First Floor House No. 372, Street 59, G-11/2, Islamabad	Babar Ali BSC Biomedical Engineering	Approved
8.	M/s Biolife Surgical, Office No. 4, Basement Makkah Tower, Namak Madni, Peshawar Godown: Godown No. 506, 5 th Floor, Makkah Tower, Namak Mandi, Peshawar	Muhammad Asim Pharmacist	Approved
9.	M/s Biotelic Traders, Office NO. 37-E, 5 th Floor, Karachi Market, Khyber Bazar, Peshawar Godown: WareHouse No. 17-E, 05 th Floor, Karachi Market, Khyber Bazar Peshawar	Himayat Said Microbiologist	Approved

10.	M/s Rose Orthoplant, Dir Medical Center, 3 rd Floor, Room No. 13-C & 14-C Infront of LRH Emergency Gate, Peshawar	Miss. Shahzadi Mahnoor Medical Lab Technologist	Approved
11.	M/s Riz Traders, Office No. 2A, 2 nd Floor, Plot No. B-133, Ghazali Plaza, Main Murree Road, Rawalpindi	M. Aarish Hashmi Pharma D	Approved
12.	M/s Vista Enterprises, 125-Ferozepour Road, 2 nd Floor, Imran Building Lahore	Zaira Yasir Pharm –D	Approved
13.	M/s Arizona Healthcare Proudcts, Arizona House 279, Rewaz Garden, Chauburji, Lahore	Seher Muskan Pharm- D	Approved
14.	M/s Synergy Medics, 18, Edward Road, Lahore	Noor Shahid BS Biomedical Engineering	Approved
15.	M/s Vision Technologies, 1 st Floor, 36-Kamran Block, Allama Iqbal Town, Lahore	Muhammad Asad Ullah, Biomedical Engineering	Approved
16.	M/s Samco International, Bungalow No. F-57, Block-B, North Nazimabad Near KDA Chowrangi, Karachi	Fauzia Navid, M.Sc Microbiology	Approved
17.	M/s Expert Medical Services, B-313 B-Block, Satellite Town, Rawalpindi	M. Mumtaz Ali, BS Microbiology	Approved
18.	M/s MB Traders, House No. 928/26, Lane No. 6-A, near McDonalds, Peshawar Road, Rawalpindi	Farhat ul Ain Pharm-D	Approved
19.	M/s Synes International, Office No. 1, Abu Al Qasim Street, Near Hascol Pump, Shoukat Heights Plaza, Sohan, Islamabad	Zoma Irfan Pharm-D	Approved
20.	M/s MEDZAH OEM (Private) Limited, Plot No. E/11, SITE Phase-II Super Highway, Karachi	Hani Siddiqui Pharm-D	Approved
21.	M/s Technology Management Services & Solution, Hill View Plaza, Office No. 12-A, Mezzanine Floor, Blue Area, Islamabad	Maira Sehar (Pharmacist)	Approved

22.	M/s Pharma Point (Pvt) Ltd., Office No. 5, 3 rd Floor, Al-Hasan Plaza, Tarlai, Islamabad	Nosheen Ilyas (Pharmacist)	Approved
23.	M/s Medicare Impex Private Limited, Plot No. 17-D, Commercial Market, 4 th Floor, Phase-XII, DHA EME Sector, Multan Road, Lahore	Muhammad Umar Farooq BS in Microbiology and Biotechnology	Approved
24.	M/s Audiology Consultants, Office No. 214, Second Floor, Ali Tower, M M Alam Road, Gulberg-III, Lahore	Atif Tahir Pharm-D	Approved
25.	M/s AS Diagnostics, Building No. 7/14 Ittehad Park Lytton Road, Lahore	Zain Akram Pharm-D	Approved
26.	M/s Enamel Innovations (Smc-Pvt) Limited, Office No. 02, 3 rd Floor Chaudhary Arcade, Plaza NO. 352, National Police Foundation, Sector O-9, Islamabad	Amjad Sajjad Pharm-D	Approved
27.	M/s Medical Solutions, Shop No. 1, 1 st Floor, TM Plaza, DAV College Road, Rawalpindi Cantt. Rawalpindi	Ms. Muneem Fatima (Pharmacist)	Approved
28.	M/s Trade International Private Limited, 269-D, St. No. 53, Sector F-10/4, Islamabad	Amed Umar B.E. Electrical	Deferred for appointment of technical staff as per medical devices rules 2017.
29.	M/s KB Enterprises, 1 st Floor, Hamza House, Dhoke Raja Muhammad Khan, Old Airport Service Road, Rawalpindi		Rejected as the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
30.	M/s Technotra, House No. 86-B Street No. 7, Chaklala Scheme 3 Rawalpindi		Rejected. The board decided to reject the application of the firm as the applicant decided to withdraw its application for the grant of an establishment license to import medical devices.
31.	M/s Eman Traders, F-3, Fazal Centre, 11 Faiz Road, Old Muslim Town, Lahore		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI,

			therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
32.	M/s Akhtar Saeed Medical & Dental College (Private) Limited, 1 st & 2 nd Floor Plaza No. 169 G Block DHA, Phase 1, Lahore		Rejected. The board decided to reject the application of the firm as the applicant decided to withdraw its application for the grant of an establishment license to import medical devices.
33.	M/s Quasars Private Limited, House no. 26A, Street No. 1, Shah Jahan Park, Behind Pakistan Mint, Lahore Godown: Aun Muhammad Plaza , Main GT Road, Near Islam Park Orange Train station, Lahore		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
34.	M/s Askari Enterprises Pvt. Ltd., AWT Plaza, 6 th Floor, Shahra-e-Quaid-e-Azam, Rawalpindi		Deferred. The board considered the request of the firm, being a genuine request due to catastrophic rains.
35.	M/s Talha Brothers, 6 Jamal U Din Afghani Road, Lahore		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
36.	M/s Joun Healthcare Enterprises, Near Joun Hospital, Kot Sultan District Layyah.		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.

37.	M/s V2 Traders International Pvt. Ltd., Office No. 208, 2 nd Floor, Wall Street Plaza, G-15 Markaz, Islamabad		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
38.	M/s Skin Flex Pvt. Ltd., 205 Street 12, E-11/4, Islamabad Godown: Pind Bari Shahdra Road, Bara Kahu, Plot No. 22 Islamabad		Rejected. The board observed that the firm was not ready for inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
39.	M/s Slosch AI-Solutions, 341-F, Street A1, NPF Society, 0-9, Islamabad Godown: P64-65, Pak Town, PH-1, Islamabad		Rejected. The board decided to reject the application of the firm as the applicant decided to withdraw its application for the grant of an establishment license to import medical devices. The firm may apply afresh with details of new management
40.	M/s MED-O-GEN Pak Services, Office No. 16, GF, Muneer Plaza, Khayaban-e-Sir Sayyad, Sector III, Rawalpindi Godown: Unit No. 8&9, GF, Muneer Plaza, Khayaban-e-Sir Sayyed, Sector-II, Rawalpindi		Rejected. The board decided to reject the application based upon the findings and recommendations of inspector for being not compliant to medical devices rules 2017.
41.	M/s Pearle Associates, Plot No. 311, Sector K-6, Phase 11, Hayatabad, Peshawar Godown: House No. 295, Street No. 27, F-11/2, Islamabad		Rejected. The board decided to reject the application based upon the findings and recommendations of inspector for being not compliant to medical devices rules 2017.
42.	M/s New Pak Surgical, 2 nd Floor, 30 Syed Mauj Darya Road (Edward Road), Lahore		Rejected. The board observed that the firm was not ready for

			inspection despite making application for grant of ELI, therefore decided to reject the application for grant of ELI. However, the firm may apply afresh once ready for inspection.
43.	M/s Lab Master, 113 A Block A Gulshan Ravi, Lahore		Rejected. The board decided to reject the application based upon the findings and recommendations of inspector for being not compliant to medical devices rules 2017.

Item No. I(B): APPLICATIONS FOR GRANT OF RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Essity Pakistan Limited, A-69, SITE, Manghopir Road, Karachi (ELI-00011)	Miss Zarqa Saqi Pharm-D	Approved
2.	M/s Popular International, A-141, Justice Inamullah Road, Block 7&8, KMCHS, Karachi (ELI-00091)	Dr. Shehyaar Ahmed Basha, Pharm-D	Approved
3.	M/s Vida Laboratories, Plot No. 225, Sector 23, Korangi Industrial Area, Karachi	Miss Nimra Nasir Pharm-D	Approved

Item No. I(C): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision of MDB
1.	M/s Revive Meditech Pvt, Ltd., Plot No. 2-A, Street No. W-1, Industrial Area, Rawat Islamabad	Fateh Muhamamd	Asad Abdullah	The Board approved grant of Establishment licence to manufacture medical devices for following sections: <ul style="list-style-type: none"> • Angiographic Catheter • Microspheres

Item No. I(D): APPLICATIONS FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	decision OF mdb
1.	M/s Atco Laboratories Limited, B-18, S.I.T.E, Karachi (ELM-0010)	Ali Mustafa	Miss Nimrah Kamal	Renewal of establishment license No. ELM-0010 Approved.

Item No. II: DEFERRED APPLICATION FOR REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<p>Name: Fresenius Medical Care Pakistan Pvt. Ltd</p> <p>Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore</p> <p>Warehouse Address: Al-Madina Warehouse, 28-Km, Multan Road, Lahore</p> <p>Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi</p>	<p>Legal Manufacturer: Name: Nipro Corporation</p> <p>Address: 3-26, Senriokashinmachi, Settsu, Osaka, 566-8510, JAPAN</p> <p><u>Manufacturing Site:</u> Name: Nipro (Thailand) Corporation Limited</p> <p>Address: 10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayutthaya 13110 THAILAND</p>	<p>Brand Name: Fistula Needle</p> <p>Class B</p> <p>Shelf Life: 05 Years after the date of sterilization</p> <p>Codes/Sizes: 14GA-R25L-R (F00012655) 15GA-R25L-R (F00012656) 16GA-R25L-R (F00012657) 17GA-R25L-R (F00012658) 14GV-R25L-R (F00012665) 15GV-R25L-R (F00012666) 16GV-R25L-R (F00012667) 17GV-R25L-R (F00012668)</p>	<p>Deferred the case for submission (last opportunity) of;</p> <ol style="list-style-type: none"> 1. fee for family as per SRO1399(I)/2025 dated 1st August 2025. 2. valid notarized CE certificate on which manufacturing site is mentioned or legalized FSC of RRA. 3. legalized FSC of country of origin.
2.	<p>Applicant Name:</p> <p>M/s. Fresenius Medical Care Pakistan Pvt. Ltd</p>	<p>Name of Manufacturer:</p> <p>M/s. Ningbo Tianyi Medical Appliance Co., Ltd</p> <p>Address: No.788, Mozhi North Road, Tourism Resort,</p>	<p>Brand Name:</p> <p>FRESLINE</p> <p>(Extra-corporeal Blood Circuit for Haemodialysers,</p>	<p>Deferred for subject to submission of fee for system/family as per SRO1399(I)2025 dated 1st August 2025 and valid original FSC of Germany.</p>

<p>Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore</p> <p>Warehouse Address: 1. Al-Madina Warehouse, 28-Km, Multan Road, Lahore</p> <p>2. Plot No. A6 A7, Northwestern Industrial Zone, Port Qasim, Karachi</p> <p>(ELI-000315)</p> <p>R&I Date: 30-01-2024</p>	<p>Dongqian Lake 315121 Ningbo, People's Republic of China Manufacturing Site: Name: Ningbo Tianyi Medical Appliance Co., Ltd Address: No.788, Mozhi North Road, Tourism Resort, Dongqian Lake 315121 Ningbo, People's Republic of China & No.1 Xinye Road, Tourism Resort, Dongqian Lake 310021 Ningbo, China.</p> <p>LOA Validity: 21-04-2026</p> <p>FSC Validity: 13-06-2025</p> <p>Iso Certificate validity 30-06-2024.</p>	<p>Haemodiafilters and Haemofilters)</p> <p>Class B</p> <p>Shelf Life: 03 Years</p> <p>Codes/Sizes: TX-JB-10 TX-KA-13 TX-KA-14 TX-KB-15 TX-KB-16 TX-HA-17</p>	
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	<p>Fee Details: November 2022 Fee Challan No.: 52047421</p> <p>PKR: 25,000</p> <p>Dated: 24-01-2024</p> <p>Tracking ID RQA-1H8-GEDZ</p>			
3.	<p>Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore.</p> <p>ELI-00045</p> <p>5152-P</p>	<p><u>Legal Manufacturer:</u> M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China.</p> <p>FSC China validity 06-07-2025</p> <p>FSC: Germany. Issuance 27-10-2021</p>	<p>Simedice Hydrophobic Aspheric Foldable IOL's Class-C</p> <p>Shelf Life: 5 years</p> <p>Models: SM60AS SM60AS1 SM60AS2 SM60AS3</p>	<p>Deferred the case for submission (Last opportunity) of;</p> <ol style="list-style-type: none"> valid, notarized CE marking certificate or legalized FSC of RRA and DOC. fee for family as per SRO 1399(I)/2025 dated 1st August 2025. justification that Codes ST8, ST 9, ST10, STF1, STF2, STF3, SV1 not mentioned on FSC and LoA, clarification that Manufacturing site in USA not mentioned in any document. Justification of applying multiple products in single application. submission of link b/w manufacturing site and legal manufacturer. clarification that name of Mfg site on manufacturer credential is <u>Henan Simedice Biotechnologies</u> and on audit report is <u>Simedice Biotechnologies</u>

4.	<p>Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore.</p> <p>ELI-00045</p> <p>5163-P</p> <p>Copy of Fee challan Rs 50,000 submitted vide slip no. 71858435572 dated 30.08.2024</p>	<p><u>Legal Manufacturer:</u></p> <p>Simedice Biotechnologies Inc., 251 Little Falls, Drive, Wilmington, Delaware 19808, USA.</p> <p>FSC: Germany issuance 27-10-2021</p> <p>Manufacturing site</p> <p>M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China.</p>	<p>Simedice (Hydrophobic Aspheric Preloaded Foldable IOL's)</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Models: AS-P22, AS1-P22, AS2-P22, AS3-P22</p>	<p>Deferred the case for submission (Last opportunity) of;</p> <ol style="list-style-type: none"> valid, notarized CE marking certificate or legalized FSC of RRA and DOC. fee for family as per SRO 1399(I)/2025 dated 1st August 2025. justification that Codes ST8, ST 9, ST10, STF1, STF2, STF3, SV1 not mentioned on FSC and LoA, clarification that Manufacturing site in USA not mentioned in any document. Justification of applying multiple products in single application. submission of link b/w manufacturing site and legal manufacturer. clarification that name of Mfg site on manufacturer credential is <u>Henan Simedice Biotechnologies</u> and on audit report is <u>Simedice Biotechnologies</u>
5.	<p>Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore.</p> <p>ELI-00133</p> <p>5410-P</p> <p>62,000/-</p>	<p><u>Legal Manufacturer:</u></p> <p>Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin, People's Republic of China.</p> <p>FSC: China.</p>	<p>TPRI Disposable Extra Corporeal Circuit Tube - Cardioplegia Delivery System</p> <p>Class-D</p> <p>Shelf Life: 3 Year</p> <p>Codes as per FSC</p>	<p>Deferred the case for clarification (last opportunity);</p> <ol style="list-style-type: none"> that as per revised Form 7-A according to which product is of class C but as per DoC its class IIa product while initially applied in class D. that how product falls under the definition of system. Submission of separate applications for adult, baby, pediatric and infant TPRI

		Issuance: 13-05-2024 valid for 2 years.		Disposable Extra Corporeal Circuit Tube - Cardioplegia Delivery System 4. submission of notarized copy of CE marking certificate or SC or RRA.
6.	Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore. ELI-00133 5130-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin, People's Republic of China. FSC: China. Issuance: 13-05-2024 valid for 2 years.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Adult) Class-D Shelf Life: 3 Year Codes as per FSC	Deferred the case for clarification (last opportunity); 1. that as per revised Form 7-A according to which product is of class C but as per DoC its class IIa product while initially applied in class D. 2. Fee not submitted for family as per MDB decision. 3. Separate applications not submitted as per body location where implant is to be applied. 4. submission of notarized copy of CE marking certificate or SC or RRA.
7.	Cardiac Care 848-C Shadman -1, Lahore ELI-00070 R&I 14-11-22 Fee Challan No 2376701207 dated 08-11-22	Company: 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.c om FSC VALID: 06-07- 2026	Brand Name Connecting tube with Yankauer handle (Oropharyngeal secretions suction) Class : B Shelf Life: 05 years	Deferred the case (last opportunity) to submit; 1. original, legalized FSC of country of origin issued by relevant Health Regulatory Authority. 2. Notarized CE marking certificate or legalized FSC of country of origin.

		LOA VALID: 09-10-2026 ISO 13485 VALID: 31-03-24		
8.	Cardio Life House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi ELI: 00984 [3645-P]	Legal Manufacturer: M/s CPT Sutures Co., Ltd 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam. Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam. Legalized FSC Vietnam valid upto 25-09-2023. Notarized Copy of ISO 13485 valid upto 30-09-2024. LOA valid upto 31-12-2024	Protibond Polyester Non-Absorbable Surgical Suture Codes & Sizes: Class-D Shelf Life :5 years Fee: 50,000/- Date of Application: 15-02-2023	Rejected the case due to following reasons; 1. Firm submitted the Medical Devices Import Licence issued to Advance Medical Thai Co. Lts mentioning it as Free sale certificate. 2. Firm has failed to submit; a. valid, legalized FSC of RRA or CE marking certificate. b. Design Examination Certificate.
9.	Cardio Life House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi	Legal Manufacturer: M/s CPT Sutures Co., Ltd	Caresteel Surgical Stainless Steels-Non-absorbable Surgical Suture	Rejected the due to following reasons; 1. false declaration that FSC is enclosed while no document was attached with

	<p>ELI: 00984 [3645-P]</p>	<p>83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility</p> <p>8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p> <p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO 13485 valid upto 30-09-2024.</p> <p>LOA valid upto 31-12-2024</p>	<p>Codes & Sizes: Class-C</p> <p>Shelf Life :5 years</p> <p>Fee: 50,000/-</p> <p>Date of Application: 15-02-2023</p>	<p>reply letter.</p> <p>2. failed to submit FSC of RRA or CE certificate as per MDB decision.</p> <p>3. has applied Surgical Stainless Steels-Non-absorbable Surgical Suture used in whole body as single medical device.</p>
10.	<p>Cardio Life House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi</p> <p>ELI: 00984 [3645-P]</p>	<p>Legal Manufacturer: M/s CPT Sutures Co., Ltd</p> <p>83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility</p> <p>8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p>	<p>Carecel Absorbable Hemostats</p> <p>Codes & Sizes: Class-D</p> <p>Shelf Life :5 years</p> <p>Fee: 50,000/-</p>	<p>Rejected the case due to following reasons;</p> <p>1. Firm submitted the Medical Devices Import Licence issued to Advance Medical Thai Co. Lts mentioning it as Free sale certificate.</p> <p>2. Firm has failed to submit;</p> <p>a. valid, legalized FSC of RRA or CE marking certificate.</p> <p>b. Design Examination Certificate.</p>

		<p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO 13485 valid upto 30-09-2024.</p> <p>LOA valid upto 31-12- 2024</p>	Date of Application: 15-02-2023	
11.	<p>Cardio Life House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi</p> <p>ELI: 00984 [3645-P]</p>	<p>Legal Manufacturer: M/s CPT Sutures Co., Ltd 83 Hai Ba Trung, Ben Nghe Ward District 1, No Chi Minh City, Vietnam.</p> <p>Manufacturing Facility 8 Dao Tri, Phu Thuan Ward District 7, Ho Chi Minh City, Vietnam.</p> <p>Legalized FSC Vietnam valid upto 25-09-2023.</p> <p>Notarized Copy of ISO 13485 valid upto 30-09-2024.</p>	<p>Trustilent Polypropylene Non-Absorbable Surgical Suture Codes & Sizes: Class-D Shelf Life :5 years Fee: 50,000/- Date of Application: 15-02-2023</p>	<p>Rejected the case due to following reasons;</p> <ol style="list-style-type: none"> 1. Firm submitted the Medical Devices Import Licence issued to Advance Medical Thai Co. Lts mentioning it as Free sale certificate. 2. Firm has failed to submit; a. valid, legalized FSC of RRA or CE marking certificate. b. Design Examination Certificate.

		LOA valid upto 31-12-2024		
12.	<p>M/S Future Scientific Address: FS House, Opposite Street # 04, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Post Code 46330, Rawalpindi, Pakistan.</p> <p>(ELI-00209) Date of R&I 09-09-2024</p>	<p><u>Legal Manufacturer:</u> DIESSE Diagnostica Senese SPA Address: Viale Decumano 36 - 20157 Milano - Italy Operational Headquarters: Strada dei Laghi, 39 - 53035 Monteriggioni (SI) - Italy</p> <p>FSC: Country of Origin-Italy Validity: 22-10-2025 FSC: FSC of Reference Country-ITALY Validity: 22-10-2025</p> <p>LOA Validity: 31-12-2024 EC Certificate Validity: 26-05-2025 ISO 13485 Validity: 26-06-2027</p>	<p>CHORUS Virology Cluster</p> <p>Class-B</p> <p>Shelf life: 12 Months</p> <p>CODE PACK SIZE CHORUS CHIKUNGUNYA IgG (36) 81133 36 test</p> <p>CHORUS CHIKUNGUNYA IgM (36) 81134 36 Test</p> <p>CHORUS DENGUE IgG (36) 81154 36Test</p> <p>CHORUS DENGUE IgM capture(36) 81157 36 Test</p>	<p>Approved subject to submission of requisite Fee as per SRO 1399(I)/2025 dated 1st August, 2025.</p>
13.	<p>M/S Future Scientific Address: FS House, Opposite Street # 04, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Post Code 46330, Rawalpindi, Pakistan.</p> <p>(ELI-00209) Date of R&I 09-09-2024</p>	<p><u>Legal Manufacturer:</u> DIESSE Diagnostica Senese SPA Address: Viale Decumano 36 - 20157 Milano - Italy Operational Headquarters: Strada dei Laghi, 39 - 53035 Monteriggioni (SI) -</p>	<p>CHORUS Bacteriology Cluster</p> <p>Class-B</p> <p>Shelf Life: 12 months</p>	<p>Approved subject to submission of requisite Fee as per SRO 1399(I)/2025 dated 1st August, 2025.</p>

		<p>Italy</p> <p>FSC: Country of Origin-Italy Validity: 22-10-2025 FSC: FSC of Reference Country-ITALY Validity: 22-10-2025</p> <p>LOA Validity: 31-12-2024 EC Certificate Validity: 26-05-2025 ISO 13485 Validity: 26-06-2027</p>	<p>Codes/Sizes:</p> <p>Products Description Code Pack Size CHORUS CLOSTRIDIUM DIFFICILE GDH(12) 81168 12 CHORUS CLOSTRIDIUM DIFFICILE A/B TOXINS(12) 81170 12</p>	
14.	<p>Cardiac Care, 848-C, Shadman-1, Lahore.</p> <p>ELI: 00070</p>	<p><u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany.</p> <p>FSC Germany Issuance 29-03-2019</p>	<p>Lifecath Brovaic (Silicone central venous catheter with subcutaneous cuff for long-term venous access)</p> <p>Class-D</p> <p>Shelf life: 05 years</p> <p>Art. No. 2191</p>	Approved subject to submission of original FSC
15.	<p>Cardiac Care, 848-C, Shadman-1, Lahore.</p> <p>ELI: 00070</p>	<p><u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany.</p>	<p>Lifecath Hickman (Silicone central venous catheter with subcutaneous cuff for long-term venous access)</p>	Approved subject to submission of original FSC

		FSC Germany Issuance 29-03-2019	Class-D Shelf life: 05 years Art. No. 2193	
16.	Cardiac Care, 848-C, Shadman-1, Lahore. ELI: 00070	<u>Legal Manufacturer:</u> M/s VYGON GmbH & Co. KG Prager Ring 100, 52070, Aachen, Germany. FSC Germany Issuance 29-03-2019	Lifecath Biflux (Radiopaque Double-lumen Silicone catheter with subcutaneous cuff for long-term venous access) Class-D Shelf life: 05 years Art. No. 2293	Approved subject to submission of original FSC
17.	Hakimsons House, A-58/B S.I.T.E Manghopir Road, Karachi- 75700, Pakistan. ELI_00396	TMT Tibbi Medical Malz San. Ve Tic. A.S Add: Faith Mah.1188 Sok. No 14 PK 35414 Sarnic Gaziemirizmir/Turkiy e. FSC Country valid until (22-10-2024) ISO Valid until 09-02-2024 FQA Valid untill	Life Control Disposable Mechanical Ventilator Claimed shelf life: 05 Class: C	Deferred for submission of Form 7A along with annexures, valid and legalized, notarized documents.

		EC Certificate (12-12-2023) LOA Valid until (22-19-2024)		
18.	Tech Zone, Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore. ELI- 00040 Submission Date 14.11.2024	<u>Legal Manufacturer:</u> GUILIN HBM HEALTH PROTECTION NO.1-2, SHUIJING EAST ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT AREA, GUILIN, CHINA LOA: Validity 20-08-2027 FSC: COUNTRY OF ORIGIN: CHINA Validity: 22-09-2025 EC	MEDISPO Surgical Gloves (POWDERED) Class-B Shelf Life 5 Years Codes/ Sizes: 6, 6.5, 7, 7.5, 8, 8.5,9	Deferred for personal hearing to M/s Assuza Corporation, Lahore and M/s Tech Zone along with valid notarized authorization letter with brand name.
19.	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 Fanrong Road, Binhai	Brand Name: Undis-Catheter Mount Class: B MD group: Single	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.

	(ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 5627218377 PKR: 31,000/-	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		
20.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated:	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	Brand Name: Undis-Closed Suction System Class: B MD group: Set	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly. Clarify applied product is as set or sytem with justification.

	09/August/2024 Fee Challan No: 9916977914 PKR: 31,000/-	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		
21.	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	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/	Brand Name: Disposable Anesthesia Breathing Circuit Class: B MD group: Set	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.

	PKR: 31,000/-	LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31		
22.	<p>Applicant Name:</p> <p>Total Technologies (Pvt) Ltd.</p> <p>696, J-2 Johar Town, District Lahore, Pakistan</p> <p>(ELI- 00129).</p> <p>R&I Dated: 09/August/2024</p> <p>Fee Challan No: 164878026701</p> <p>PKR: 31,000/-</p>	<p>Name of Manufacturer:</p> <p>Brand name LEO LIFE</p> <p>SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD</p> <p>No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China</p> <p>Tel: 0086-575-8521 5008</p> <p>Fax: 0086-575-8521 5007</p> <p>Website: http://www.undis.cn/</p> <p>LOA Validity: 23/05/2027</p> <p>FSC Validity:</p>	<p>Brand Name:</p> <p>Disposable Anesthesia Mask</p> <p>Class: B</p> <p>MD group: Single</p>	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.

		30/05/2026 DOC Validity: 2028-12-31		
23.	<p>Applicant Name:</p> <p>Total Technologies (Pvt) Ltd.</p> <p>696, J-2 Johar Town, District Lahore, Pakistan</p> <p>(ELI- 00129).</p> <p>R&I Dated: 09/August/2024</p> <p>Fee Challan No: 7508062254</p> <p>PKR: 31,000/-</p>	<p>Name of Manufacturer:</p> <p>Brand name LEO LIFE</p> <p>SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD</p> <p>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/</p> <p>LOA Validity: 23/05/2027</p> <p>FSC Validity: 30/05/2026</p> <p>DOC Validity: 2028-12-31</p>	<p>Brand Name:</p> <p>Disposable Breathing Filter</p> <p>Class: B</p> <p>MD group: Single</p>	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.

24.	<p>Applicant Name:</p> <p>Total Technologies (Pvt) Ltd.</p> <p>696, J-2 Johar Town, District Lahore, Pakistan</p> <p>(ELI- 00129).</p> <p>R&I Dated: 09/August/2024</p> <p>Fee Challan No: 65313147163</p> <p>PKR: 31,000/-</p>	<p>Name of Manufacturer:</p> <p>Brand name LEO LIFE</p> <p>SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD</p> <p>No.12 Yuexing Technology Park, No.11 Fanrong Road, Binhai New Area,312366 Shaoxing, Zhejiang Province, the People's Republic of China</p> <p>Tel: 0086-575-8521 5008</p> <p>Fax: 0086-575-8521 5007</p> <p>Website: http://www.undis.cn/</p> <p>LOA Validity: 23/05/2027</p> <p>FSC Validity: 30/05/2026</p> <p>DOC Validity: 2028-12-31</p>	<p>Brand Name:</p> <p>Disposble Heated Wire Circuit</p> <p>Class: B</p> <p>MD group: Set</p>	<p>Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly. Justify for applying as set</p>
25.	<p>Applicant Name:</p> <p>Total</p>	<p>Name of Manufacturer:</p> <p>Brand name LEO LIFE</p>	<p>Brand Name:</p> <p>Heat And Moisture</p>	<p>Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.</p>

	<p>Technologies (Pvt) Ltd.</p> <p>696, J-2 Johar Town, District Lahore, Pakistan</p> <p>(ELI- 00129).</p> <p>R&I Dated: 09/August/2024</p> <p>Fee Challan No: 285643559988</p> <p>PKR: 31,000/-</p>	<p>SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD</p> <p>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/</p> <p>LOA Validity: 23/05/2027</p> <p>FSC Validity: 30/05/2026</p> <p>DOC Validity: 2028-12-31</p>	<p>Exchanger</p> <p>Class: B</p> <p>MD group: Single</p>	
26.	<p>Applicant Name:</p> <p>Total Technologies (Pvt) Ltd.</p>	<p>Name of Manufacturer:</p> <p>Brand name LEO LIFE</p> <p>SHAOXING UNDIS MEDICAL TECHNOLOGY CO., LTD</p>	<p>Brand Name:</p> <p>High Flow Nasal Cannula</p> <p>Class: B</p>	<p>Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.</p>

	696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 63631796733 PKR: 31,000/-	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	MD group: System	
27.	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 Fanrong Road, Binhai	Brand Name: Nasal Oxygen Cannula Class: B MD group: Single	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly.

	(ELI- 00129). R&I Dated: 09/August/2024 Fee Challan No: 158351075 PKR: 31,000/-	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		
28.	Applicant Name: Total Technologies (Pvt) Ltd. 696, J-2 Johar Town, District Lahore, Pakistan (ELI- 00129).	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	Brand Name: Nebulizer Tube Class: B MD group: Set	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly. Clarify applied product is as set with justification.

	R&I Dated: 09/August/2024 Fee Challan No: 9677848547 PKR: 31,000/-	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		
29.	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: 01559847379	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/	Brand Name: Oxygen Mask Class: B MD group: Set	Deferred for submission of valid CE certificate and codes as per FSC along with differential fee accordingly. Clarify applied product is as set with justification.

	PKR: 31,000/-	LOA Validity: 23/05/2027 FSC Validity: 30/05/2026 DOC Validity: 2028-12-31		
30.	SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland. <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547-USA. <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland. FSC Switzerland	ANTIBODY IDENTIFICATION PANEL REAGENT RED BLOOD CELL IVD, KIT, AGGLUTINATION, (FAMILY) Class – C	Approved ID-Diapanel (45161) and ID-Diapanel-P (45171) subject to submission of valid original FSC.

		Valid Till (18.10.2022) ISO 13485:2016 Certificate Valid till (30.10.2021) LOA Valid until (31.12.2020)		
31.	M/s. Moon Enterprises Address: 5/6 Rabani Road, Old Anarkali Lahore (ELI:000356) R&I Details: 07-06-2023 Fee: PKR 5000/- Slip: 5598479629 Dated:	<u>Legal Manufacturer:</u> M/S AYSET TIBBİ ÜRÜNLER VE PLASTİK ELEKTRONİK GIDA TEMİZLİK MADDELERİ SAN. A.Ş Sarıhamzalı Mah. 47007 Sk No:36/A Seyhan Turkey. <u>LOA</u> Validity: 16-10-2027 <u>FSC validity:</u> <u>EC Certificate</u> Validity:	Brand: AYEST Generic: VACCUM BLOOD COLLECTION TUBE Models: <i>as per FSC</i> Class A Shelf Life: 48 months Storage condition: Store in cool and dry place.	Deferred (last opportunity) for; 1. clarification for submission of expired fee challan with initial application. 2. Legalized, valid FSC with codes applied. 3. valid. Notarized ISO 13485:2016.
32.	IRTEQA BIOTEK (ELI-00218)	<u>Legal Manufacturer:</u> M/S PRECISION	EXDIA Vitamin D Kits Exdia Heating Block	Approved EXDIA Vitamin D kit only subject to submission of valid original

		<p>BIOSENSOR INC. South Korea Manufacturing Site: 306, Techno 2-ro, Yuseong-gu, Daejeon, South Korea</p> <p>Date of R&I 30th Nov 2022</p> <p>FSC: Country of Origin: South Korea Valid &</p> <p>FSC: FSC of Reference Country: Germany Valid LOA Validity: 15-02-2025 Attached EC Certificate Valid</p> <p>ISO 13485 Validity: 04-04-2025</p>	<p>Vitamin D Test Heating Incubator</p> <p>Class-B</p> <p>Shelf Life: 01 years</p> <p>Codes/Sizes: Single Packed Test Box of 20 Tests & Box of 10 Tests.</p>	<p>FSC of country of origin and valid CE.</p> <p>MDB also acceded the request of the firm to apply separately for Exdia Heating Block</p> <p>Vitamin D Test Heating Incubator.</p>
33.	<p>M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore</p> <p>ELI-00314</p> <p>Evaluator AD-IV [2753-P]</p>	<p>Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujiyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China</p> <p>FSC China valid till 17.09.2022 (product not it)</p>	<p>Trugut Chromic (Catgut Chromic Absorbable suture)</p> <p>Codes & Sizes: Not mentioned in FSC</p> <p>Class D</p> <p>Shelf Life: 5 years (studies not provided)</p>	<p>Deferred (last opportunity) the case and directed firm to reply as per MDB decision taken in its 47th meeting.</p>

34.	<p>M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 00090)</p> <p>Track ID: JQ9-ZAP-NHSW Fee: PKR 5000/- Slip: 3236434012 Dated: 12-10-2022 Date of R&I 12-10-2022</p>	<p>Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD 80 Fuzhong Road, Lijiang Street, Changsha, Hunan, China. FSC Spain: DOI : 15-10-2021 LOA LOA Valid till 31-12-2024 EC Certificate Validity: 26-05-2024 With CE Extension letter ISO 13485 Validity: 13-05-2021 Expired at submission</p>	<p>Brand Name: Gel And Clot Activator Tube. Class-B Letter of authorization: Validity date: 31-12-2024 Shelf life: 24 Months. Storage Conditions: Room temperature</p>	<p>Deferred for submission of original, notarized LOA and Sizes/codes of applied product.</p>
35.	<p>Name Radiant Medical (Pvt) Ltd., Address of Importer 06-Sher Shah Block New Garden Town, Lahore</p>	<p>Legal Manufacteurer) Gemss Healthcare Co., Ltd., (Manufacturing site) 1F, 822, Bogwang-ro, Gwangtan-myeon, Paju-si, Gyeonggi-do, 10952, Republic of Korea</p>	<p>HORIZON X-Ray Machine</p>	<p>Deferred for submission original, legalized statement of president GEMSS and LOA and valid FSC and CE certificate .</p>

36.	<p>Khan trading agency Data Complex, Mouj darya Road, Lahore.</p> <p>EL100592</p> <p>5861-P</p> <p>R&I 4.02.21</p>	<p>Legal Manufacturer: Pro-Lab Diagnostics 3 Bassendale road, PL 6250 Shigella Bromborough, Wirral, CH62 3QL, U.K. Tel: +44 (0) 151 353 1613 Fax: +44 (0) 151 353 1614 www.pro-lab.co.uk.</p> <p>LOA issuance 23-10-2024</p> <p>FSC Canada issuance 12-04-2023</p> <p>LOA issuance 24-08-2021</p> <p>FSC USFDA 28-01-2026</p> <p>ISO 13485 31.05.23</p>	<p>Dehydrated culture media VVD kits applied in single application.</p> <p>Agglutinating sera are prepared for use in slide agglutination screening procedures to serologically identify cultures for epidemiological and diagnostic purposes.</p> <p>Antisera provide serological identification only; full identification of an organism can only be made in conjunction with biochemical testing.</p> <p>Shigella Agglutination sera are prepared for use in serological identification of organisms belonging to the genus Shigella</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. Establishment of Link b/w manufacturer and Pro-Lab diagnostic. 2. submission of Fee Challan of the product.
37.	<p>Name</p> <p>M/s Raffay Associates, Office NO, 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi</p>	<p>LEGAL MANUFACTURER</p> <p>M/s STARmed Co., Ltd, B-dong, 4F&12F,</p>	<p>VIVA RF Generator (VRS01)</p>	<p>Approved subject to provision of DoC for class..</p>

		158, Haneulmaeul-ro, IlsanDong-gu, Goyang-si, Gyeonggi- do, Korea		
38.	M/s Endoaid Biomedica 185-C DHA EME Lahore ELI: 00169. 342 (P) <u>Evaluator:</u> AD-VI	Legal Manufacturer Raysen (Tianjin) Health Care Product Co. Ltd No. 3 Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin China FSC: China Date of Issue: 15.05.2021	FEE- BREATH Disposable Nebulizers Class: A Shelf Life: 2 years Rs.5,000/-	Deferred for submission of; 1 stability data as per shelf life claim. 2. clarification of link b/w Raysen (Tianjin) Health Care Product Co. Ltd and M/s Taian Dalu Medical Instrument Co. 3. valid FSC nad CE certificate
39.	Shafia Enterprises, 2nd Floor, Nigra Center Patiala Ground Link Mcleod Road Lahore. ELI-00766 5638-P Fee-62,000/-	<u>Legal Manufacturer:</u> Laboratorios SL SA Curupayti 2611 B1644GDC, San Fernando 1644- Buenos Aires Argentina. FSC: France. Date of Issuance: 04- 08-2023.	Subiton Quirurgico RO 40g Subiton Quirurgico RO 20g Subiton Quirurgico Gun 60g (Bone Cement) Class-D Shelf Life: 36 Month Codes: 880000 (RO 40g) 880020 (RO 20g) 880300 (Gun 60g)	Deferred for; Submission of 1. DOC having name and codes of the products. 2. Notarized DEC. 3. Notarized ISO13485 4. Justification for applying as cluster. 5. Clarification of shipping, storage and distribution of product with storage condition -10°C to -60°C.
40.	Shafia Enterprises, 2nd Floor, Nigra Center Patiala Ground Link Mcleod Road Lahore.	<u>Legal Manufacturer:</u> Laboratorios SL SA Curupayti 2611 B1644GDC, San	Subiton Quirurgico G 40g Subiton Quirurgico G 20g Subiton Quirurgico GUN G 60g (Bone Cement with Gentamycin)	Deferred for; Submission of 1. Notarized, original DEC.

	<p>ELI-00766</p> <p>5637-P</p> <p>Fee-62,000/-</p>	<p>Fernando 1644- Buenos Aires Argentina.</p> <p>FSC: France. Date of Issuance: 04-08-2023.</p>	<p>Class-D</p> <p>Shelf Life: 36 Month</p> <p>Codes: 880200 (G 40g) 880220 (G 20g) 880400 (Gun G 60g)</p>	<p>2. Original Notarized ISO13485:2016.</p> <p>3. Clarification for applying as cluster.</p> <p>4. Clarification of shipping, storage and distribution of product with storage condition -10°C to -60°C.</p>
41.	<p>M/s HealthBee Projects Private Limited.</p> <p>Ground floor, Momi Plaza, Plot # 43, Business Square Phase 7, Bahria Town, District Rawalpindi.</p> <p>(ELI-00814)</p> <p>D.O.I: 24-11-2021</p> <p>Dy. No.: 13072 DRAP (R&I)</p> <p>Dated: 09-08-2024</p> <p>Fee Challan No.: 9427036167</p> <p>PKR: 50000/-</p> <p>Dated: 09-08-2024</p>	<p>Legal Manufacturer: Name: M/s Maxigen Biotech Inc.</p> <p><i>(Main Manufacturer, design, development, manufacture, aseptic filling, Moist heat sterilization & distribution)</i></p> <p>Address 01: No. 88, Keji 1st Road, Guishan District, Taoyuan City 33383, Taiwan (R.O.C).</p> <p><i>(Contract Sterilization-Gamma Sterilization)</i></p> <p>China Biotech Corporation</p> <p>Address 02: No. 10, 33rd road, Taichung Industrial Park, Taichung,</p>	<p>ArtiBest Intra-Articular Injection</p> <p>Catalogue No.: AB-305</p> <p>Product Specification: 3.0 ml containing 2.0% Sodium Hyaluronate</p> <p>Class: D</p> <p>MD group: not a group type Medical device.</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity: 13-10-2026</p> <p>Shelf life: 03 years</p> <p>Storage Conditions: 2°C – 25°C</p>	<p>Deferred for submission valid FSC of RRA or Design examination certificate.</p>

		<p>Taiwan.</p> <p>(Contract Sterilizer- Ethylene Oxide Sterilization)</p> <p>Taiwan Advanced Sterilization Technology Inc.</p> <p>Address 03:</p> <p>No. 17-1, Chien Kuo Road, Tan Tze, Taichung City, 427, Taiwan.</p>		
42.	<p>Medequips SMC Pvt Ltd, 30-Shahrah E Quaid E Azam, Lahore, 54000, Pakistan.</p> <p>ELI-00362</p> <p>7023-P</p>	<p><u>Legal Manufacturer:</u> MEDISONO LLC. 3016 NW 82nd Avenue, Doral, FL 33122, USA.</p> <p>FSC: USA. Date of Validity: 23- 10-2026.</p> <p>LOA issuance 05-12- 2024</p> <p>ISO 13485 missing.</p> <p>510k No. K231659 for P11 Plus</p>	<p>MS12 Digital Color Doppler Ultrasound System and P11 Plus Digital Color Doppler Ultrasound System (Digital Color Doppler Ultrasound System)</p> <p>Class-B</p> <p>Service life: 7 years</p> <p>Model as per FSC</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. notarized ISO13485 valid Original FSC.</p> <p>2. Clarification and justification for applying Two systems in single application.</p>
43.	<p>M/s COR-MED 2ND FLOOR 38/62 REHMAN PLAZA BANK ROAD SADDAR RAWALPINDI</p> <p>(ELI-00226)</p>	<p><u>Legal Manufacturer:</u> M/s MERIT MEDICAL SYSTEM, Inc.</p> <p>1600 West Merit</p>	<p>Merit Achieve Biopsy System II</p> <p>Class: B</p> <p>MD group: Single</p> <p>LOA Validity: 02/22/2026</p>	<p>Deferred (last opportunity) for;</p> <p>1. Clarification for grouping of the device.</p> <p>2. Justification for applying in class B while device will be used to take biopsy</p>

	<p>R&I Dated: 24-5-2024</p> <p>Fee Challan No.: 49926622</p> <p>PKR: 25000/-</p>	<p>Parkway, South Jordan, Utah 84095, USA</p> <p>Manufacturing Site: Merit Maquiladora Mexico, S.DE R.L DE C.V Avenda Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California MEXICO 22630</p>	<p>FSC Validity: 04/24/2025</p> <p>CA2011, CA2015, CA2020, CA1811, CA1815, CA1820, CA1611, CA1615, CA1620, CA1411, CA1415, CA1420, A206, A209, A2011, A2015, A2020, A186, A189, A1811, A1815, A1820, BA149, BA1411, BCA1411, BA129, BA1211, BA1215, BCA1211, BCA1215</p>	<p>samples from soft tissues such as kidney, liver, prostate, spleen, lymph node and various soft tissues masses.</p> <p>3. submission of product catalogue.</p>
44.	<p>M/s Haji S. Ameer Din & Sons 305-A Upper Mall Lahore.</p> <p>(ELI-00059)</p> <p>Fee-6,000/-</p>	<p><u>Legal Manufacturer:</u> UNICOS Co., Ltd (282-30, Munji-ro, Yuseonj-Gu, Deajeon, Korea)</p>	<p>UNICOS</p> <p>AUTO CHART PROJECTOR ACP 900</p> <p>Class-A</p> <p>Shelf Life: 10 years</p> <p>Model: (ACP 900)</p>	<p>Deferred for submission of ;</p> <ol style="list-style-type: none"> 1. samples of the product. 2. Product brochure and catalogue. 3. FSC of country of origin or reference regulatory authority where product has been registered as medical device.
45.	<p>M/s Haji S. Ameer Din & Sons 305-A Upper Mall Lahore.</p> <p>(ELI-00059)</p>	<p><u>Legal Manufacturer:</u> Good-Lite Company, 1155 Jansen Farm Drive Elgin, IL 60123,</p>	<p>Good-Lite</p> <p>Vision acuity screening items</p> <p>Class-A</p>	<p>Deferred for submission of;</p> <ol style="list-style-type: none"> 1. samples of the product. 2. Product brochure and catalogue. 3. clarification of grouping.

	<p>Fee-5,000/-</p> <p>April 2024 submission</p>	<p>USA.</p> <p>FSC: USA.</p> <p>Validity: 09-01-2025.</p>	<p>Shelf Life: N/A</p> <p>Articles:</p> <p>LEA SYMBOLS Single Symbol Book Set</p> <p>LEA SYMBOLS 2.5% Single Symbol Book Set</p> <p>LEA SYMBOLS Low Contrast Flipchart Set</p> <p>LEA SYMBOLS Near Screener Card</p> <p>LEA GRATINGS</p> <p>LEA GRATINGS Low Contrast Test</p> <p>HIDING HEIDI Low Contrast Face Test</p> <p>LEA SYMBOLS Distance Screener Book Set</p>	
46.	<p>Algene Medical Private Limited, 139-B, Commercial Zone, 2nd Floor, Jasmine Block Sector C, Bahria Town, Lahore</p> <p>ELI: 00142</p>	<p><u>Legal Manufacturer:</u></p> <p>Via Tito Schipa, 6 73020 Carpignano Salentino (LE), Italy</p> <p>FSC: Italy</p> <p>Date of Issue: 28/06/2019</p> <p>LOA validity 31-12-2026</p>	<p>Dermoxen Bactor (Vaginal Ovules)</p> <p>Class-B</p> <p>Shelf Life: 24 Months</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. opinion from 3 relevant Expert nominated by the Chairman MDB. 2. Firm will submit <ol style="list-style-type: none"> a. formulation and mode of action. b. product catalogue and brochure.

47.	<p>Algene Medical Private Limited, 139-B, Commercial Zone, 2nd Floor, Jasmine Block Sector C, Bahria Town, Lahore</p> <p>ELI: 00142</p>	<p><u>Legal Manufacturer:</u> Via Tito Schipa, 6 73020 Carpignano Salentino (LE), Italy</p> <p>FSC: Italy</p> <p>Date of Issue: 28/06/2019</p> <p>LOA validity 31-12-2026</p>	<p>Dermoxen Hydra (Vaginal Ovules)</p> <p>Class-B</p> <p>Shelf Life: 24 months</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. opinion from 3 relevant Experts nominated by the Chairman MDB. 2. Firm will submit <ol style="list-style-type: none"> a. formulation and mode of action. b. product catalogue and brochure.
48.	<p>Algene Medical Private Limited, 139-B, Commercial Zone, 2nd Floor, Jasmine Block Sector C, Bahria Town, Lahore</p> <p>ELI: 00142</p>	<p><u>Legal Manufacturer:</u> Via Tito Schipa, 6 73020 Carpignano Salentino (LE), Italy</p> <p>FSC: Italy</p> <p>Date of Issue: 28/06/2019</p> <p>LOA validity 31-12-2026</p>	<p>Dermoxen Florexil (Vaginal Douche)</p> <p>Class-B</p> <p>Shelf Life: 24 months</p> <p>Size: 140ml douches</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. opinion from 3 relevant Expert nominated by the Chairman MDB. 2. Firm will submit <ol style="list-style-type: none"> a. formulation and mode of action. b. product catalogue and brochure.
49.	<p>Muslim Scientific Corporation, 3 Syed Moj Darya Road 3rd Floor of Building</p> <p><u>Warehouse Address:</u> House # 57 PAF Colony Zarar Shaheed Road, Lahore</p> <p>ELI: 00431</p> <p>3036-P</p> <p>13-06-2022</p>	<p><u>Legal Manufacturer:</u> Taidoc Technology Corporation 127, Wugong 2nd Road, Wugu District, New Taipei City, Taiwan 248</p>	<p>CC TD-4116 (CC Advance Glucometer+ strips)</p> <p>Class-C</p> <p>Shelf life: AS per stability study</p>	<p>Deferred for following reasons;</p> <ol style="list-style-type: none"> 1. FQA is not notarized and valid. 2. copy of FSC and not valid. 3. product name not mentioned on FSC. 4. Strips not mentioned on FSC. 5. Name on label is CC advance blood glucose monitoring system. 6. product catalogue

50.	<p>M/s. Alfa Scientific Store, Lahore</p> <p>ELI:00148</p> <p>R&I Details: 01-June-2021</p>	<p>Legal Manufacturer: M/s. Weiner Laboratoris S.A.I.C</p> <p>Manufacturing Site: Maipu 2571 street (2000) - Rosario city, Santa Fe, Argentina.</p> <p>LOA Validity: 31-Dec-2026</p> <p>FSC: Country of Origin: Argentina Validity: 27-Feb-2026</p> <p>EC Certificate: Validity: 14-Dec-2026</p> <p>ISO 13485 Validity: 26-April- 2027</p>	<p>Brand Name: WEINER LAB</p> <p>Generic Name: IONS Cluster Name: IONS</p> <p>Class B</p> <p>Product Name: Ca color AA (Calcium) Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 45789 Product Registration No FSC: C-2529/98 Product Catalogue Codes: 1152002</p> <p>Product Name: Ca-color Arsenazo II AA (Calcium) Shelf Life: 19 Months</p> <p>Codes / Sizes (if any)</p>	<p>Deferred for;</p> <p>1. justification of grouping with Test methodology and cluster grouping as per schedule B of MDR 2017.</p> <p>2. verification of storage facility 2°C-10°C.</p> <p>3. As per DOC all are different products.</p>
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			<p>GMDN: 45789</p> <p>Product Registration No</p> <p>FSC: PM-1102-4209</p> <p>Product Catalogue</p> <p>Codes: 1009248, 1009606, 1009307, 1152004</p> <p>Product Name: Mg color AA (Magnesium)</p> <p>Shelf Life: 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 46795</p> <p>Product Registration No</p> <p>FSC: PM-1102-209</p> <p>Product Catalogue</p> <p>Codes:1009271, 1009337, 1580001</p> <p>Product Name:</p> <p>Fosfatemia UV AA (Phosphorus)</p>	
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			<p>Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 59123</p> <p>Product Registration No</p> <p>FSC: PM-1102-232</p> <p>Product Catalogue</p> <p>Codes: 1009614, 1009256, 1009311, 1382321</p> <p>Product Name: FER COLOR AA Liquida (IRON)</p> <p>Shelf Life: 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 54758</p> <p>Product Registration No</p> <p>FSC: PM-1102-27</p> <p>Product Catalogue</p>	
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			<p>Codes:1009285, 1009613, 1009336, 1492360</p> <p>Product Name: UIBC/TIBC AA Liquida</p> <p>Shelf Life: 24 months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 58196</p> <p>Product Registration No</p> <p>FSC: PM-1102-28</p> <p>Product Catalogue</p> <p>Codes: 1009286, 1009633, 1009340, 1492361</p>	
51.	<p>NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi</p> <p>(ELI-01117</p>	<p>Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuxing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China</p>	<p>KESYS OXYGEN MASKS</p> <p>Class B</p>	<p>Deferred the case for;</p> <ol style="list-style-type: none"> 1. submission of original legalized FSC from health regulatory authority of china. 2. Form 7A with all annexures. 3. original legalized FSC of RRA or CE marking certificate.

52.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Closed Suction System Class B	Deferred the case for; 1. submission of original legalized FSC from health regulatory authority of china. 2. Form 7A with all annexures. 3. original legalized FSC of RRA or CE marking certificate.
53.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Anesthesia Breathing Circuit System Class B	Deferred the case for; 1. submission of original legalized FSC from health regulatory authority of china. 2. Form 7A with all annexures. 3. original legalized FSC of RRA or CE marking certificate.
54.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Disposable Breathing Filter Class B	Deferred the case for; 1. submission of original legalized FSC from health regulatory authority of china. 2. Form 7A with all annexures. 3. original legalized FSC of RRA or CE marking certificate.
55.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS NEBULIZER MASK FOR SINGLE USE Class B	Deferred the case for; 1. submission of original legalized FSC from health regulatory authority of china. 2. Form 7A with all annexures. 3. original legalized FSC of RRA or CE marking certificate.
56.	NI Healthcare Proudcts (Pvt) Ltd.,	Tianck Medical Co.	Cestbien Pressure Transducer Kit	Deferred for submission of (Apostille)

	Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Ltd., 1-2 Floor, Building C, No. 16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119 Guangdong P.R. China	(Disposable Pressure Transducer) Class C	FSC, valid notarized CE certificate
57.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Tianck Medical Co. Ltd., 1-2 Floor, Building C, No. 16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119 Guangdong P.R. China	Cestbien Ureteral Stent Kit (Ureteral Stent Kit) Class C	Deferred for submission of (Apostille) FSC, valid notarized CE certificate.
58.	Name M/s ACP System, 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi ELI- 00001	LEGAL MANUFACTUREUR: R: CardioTek B.V., Dr. Nolenslaan 107B 6136 GL Sittard, The NETHERLAND	EP – TRACER 38	Approved subject to submission of original FSC and DoC for class .
59.	Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061) Date of R&I 18-04-2025 Rs.62000/- Slip# 6796855367	Legal Manufacturer: STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany Manufacturing Site Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16,	Stema HF-U Pro Touch Electrosurgical Unit Class C Apply as System	Deferred for; 1. clarification that name and codes applied on Form 7A are not mentioned on FSC and FQA. 2. clarification that the name of legal manufacturer not mentioned on FSC, FQA and ISO. 2. submission of fee as per 93 rd MDB meeting decision.

		<p>400 13 Castel Maggiore (BO) Italy</p> <p>Critical suppliers for production: _ RS ELETTRONICA SRL -Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN)</p> <p>FSC (Italy) No. DGDMF/3/P/1.51.e.1/2 024/2347: Dated 19-11-2024 (Apostille)</p> <p>LOA Validity: 31-12-2027 (Original Notarized)</p> <p>CE Certificate (FQA) Validity: 26-05-2024 with Extension letter (Notarized)</p> <p>ISO 13485 for legal manufacturer Validity: 28-01-2025 (Notarized) & copy of ISO 13485 valid up to 17-11-2027.</p> <p>ISO 13485 for manufacturing site</p>	<p>Shelf Life: N/A</p> <p>Codes/Sizes (if any) as mentioned in the remarks</p>	<p>4. submission of original legalized/notarized documents.</p>
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		Validity: 19-12-2025 (Notarized)		
60.	<p>Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061)</p> <p>Date of R&I 18-04-2025 Rs.62,000/- Slip# 17374570547</p>	<p><u>Legal Manufacturer:</u> STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany</p> <p><u>Manufacturing Site</u> Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16, 400 13 Castel Maggiore (BO) Italy</p> <p>Critical suppliers for production: _ RS ELETTRONICA SRL -Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN)</p> <p>FSC (Italy) No. DGDMF/3/P/I.51.e.I/2 024/2347:</p> <p>Dated 19-11-2024 (Apostille)</p> <p>LOA Validity: 31-12-2027 (Original Notarized)</p>	<p>Stema HF-U PRO</p> <p>Electrosurgical Unit</p> <p>Class C</p> <p>Apply as System</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes (if any) as mentioned in the remarks</p>	<p>Deferred for;</p> <p>1. clarification that name and codes applied on Form 7A are not mentioned on FSC and FQA.</p> <p>2. clarification that the name of legal manufacturer not mentioned on FSC, FQA and ISO.</p> <p>2. submission of fee as per 93rd MDB meeting decision.</p> <p>4. submission of original legalized/notarized documents.</p>

		<p>CE Certificate (FQA)</p> <p>Validity: 26-05-2024 with Extension letter (Notarized)</p> <p>ISO 13485 for legal manufacturer Validity: 28-01-2025 (Notarized) & copy of ISO 13485 valid up to 17-11-2027.</p> <p>ISO 13485 for manufacturing site Validity: 19-12-2025 (Notarized)</p>		
61.	<p>Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240)</p> <p>R&I Date 12th March 2025</p> <p>Fee Rs. 31,000/ Dated 10/03/2025</p> <p>Challan No. Slip no. 2622643894</p>	<p>Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhonghtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA)</p> <p>Documents submitted:</p> <p>Copy of Sole Agency Agreement validity: 10-02-2028</p> <p>Copy of FSC (MHRA)</p>	<p>DispoPlus 3way Stopcock (with and without Tube)</p> <p>Apply as Single</p> <p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes N/A</p>	<p>Deferred for submission of;</p> <ol style="list-style-type: none"> 1. Revised, original, notarized LOA with correct address. 2. Revised Form 7A for 3-way Stopcock (without tube). 3. original, valid, legalized FSC of country of origin for relevant health regulatory authority. 4. FSC of MHRA on which applied product 3-way Stopcock (without tube) is mentioned. 5. clarification that factory is present in 5 rooms only. 6. other valid documents.

		Valid till: 26-05-2025 EC Certificate: Not provided Copy of ISO-13485 Validity 2025-05-31		
62.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi (ELI-00078) R&I Date: 08-4-2025 Fee Rs 62,000/- vide Challan no. 4764746874	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain. LOA validity: 30-09-2026 (Notarized copy) FSC Issued on 10-01- 2025(Original Apostille FSC) EU QMS Certificate Validity:28-09-2026 (Notarized Copy) ISO-13485 Validity:	DG Gel DC Scan Class: C Shelf life: 25 months Codes/Sizes: 210345	Approved.

		23-09-2025(Notarized copy)		
63.	<p>S. Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi</p> <p>(ELI-00078)</p> <p>R&I Date: 08-4-2025</p> <p>Fee Rs 62,000/- vide Challan no. 1707745877</p>	<p>Diagnostic Grifols, S.A.</p> <p>Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain.</p> <p>LOA validity: 30-09-2026 (Notarized copy)</p> <p>FSC</p> <p>Issued on 10-01-2025(Original Apostille FSC)</p> <p>EU QMS Certificate Validity:28-09-2026 (Notarized Copy)</p> <p>ISO-13485 Validity: 23-09-2025(Notarized copy)</p>	<p>DG Gel Anti-IgG</p> <p>Gel card for gel technique for Direct and Indirect antiglobulin test.</p> <p>Applied as : Not Mentioned</p> <p>Class: C</p> <p>Shelf life: 13 months</p> <p>Codes/Sizes: 210344</p>	Approved.
64.	M/s Ejazuddin & Co., 237-B, Block II,	<u>Legal Manufacturer</u>	SIEMENS Hemostasis Coagulation	Approved

	<p>PECHS, Shahrahe-Quaideen, Karachi, Pakistan</p> <p>(ELI-00078)</p> <p>R & I Date: 16.03.2020</p> <p>Fee details: Amount paid: PKR 25000/- Paid Slip No: 1945881 Dt: 04.03.2020</p>	<p>Siemens Healthcare Diagnostics Products GmbH Emil-von- Behring-Straße 76 35041 Marburg Germany</p> <p>ISO 13485 Certificate: Valid till: 15.08.2027</p> <p>FSC: Germany Issue Date: February 2023 (No Expiry date)</p> <p>LOA Validity: 13.12 2025 DoC: No Expiry date</p>	<p>kits with controls & diluent</p> <p>Class-B</p> <p>1. Berichroma2- Antiplasmin Code: OUBU15 Shelf Life: 24 months</p> <p>2. Berichrom C1- Inhibitor Code: OUIA15 Shelf Life: 24 months</p> <p>3. Berichrom Plasminogen Code: OUCA17 Shelf Life: 24 months</p> <p>4. Berichrom Protein C Code: OUVV15 Shelf Life: 24 months</p> <p>5. Coagulation Factor XII Deficient Plasma Code: B4233-15Y Shelf Life: 24 months</p> <p>6. Dade Fibrinogen Determination Reagent Code: B4233-15Y Shelf Life: 24 months</p> <p>7. Dade Thrombin Reagent Code: B4233-25, B4233-27 Shelf Life: 24 months</p> <p>8. Innovance VWF Ac Code: OPHL035 Shelf Life: 24 months</p> <p>9. LA 1 Screening Reagent Code: OQGP17 Shelf Life: 18</p>	
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			<p>months</p> <p>10. LA 2 Confirmation Reagent</p> <p>Code: OQGR17 Shelf Life: 18 months</p> <p>11.LA Control High</p> <p>Code: OPWD11 Shelf Life: 24 months</p> <p>12. LA Control Low</p> <p>Code: OQWE11 Shelf Life: 24 months</p> <p>13. Multifibren U Code: OWZG19, OWZG23</p> <p>Shelf Life: 24 months</p> <p>14. ProC Global Code: OQLS13</p> <p>Shelf Life: 18 months</p> <p>15.Von Willebrand Reagent</p> <p>Code: OUBD23 Shelf Life: 24 months</p> <p>16. ProC Control Plasma</p> <p>Code: OQKE17 Shelf Life: 24 months</p> <p>17. Fibrinogen Calibrator Kit Code: OQVK11 Shelf Life: 24 months</p> <p>18. Berichrom PAI Code: OWOA15</p> <p>Shelf Life: 12 months</p> <p>19. Kaolin Suspension</p> <p>Code: OQAB45 Shelf Life: 30 months</p> <p>20.Control Plasma N Code: ORKE41 Shelf Life: 30 months</p>	
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			<p>21. Control Plasma P Code: OUPZ17 Shelf Life: 24 months</p> <p>22. Standard Human Plasma Code: ORKL17 Shelf Life: 24 months</p> <p>23. Dade Owren's Veronal Buffer Code: B4234-25 Shelf Life: 24 months</p> <p>24. Imidazole Buffer Solution Code: OQAA33 Shelf Life: 30 months</p> <p>25. Calcium Chloride Solution Code: ORHO37 Shelf Life: 60 months</p> <p>26. Dade Ci-Trol 1 Code: 291070 Shelf Life: 36 months</p>	
65.	<p>Oasis Medical Systems, Bangalow No. A-86, block C, Gulshan-e- Jamal, Karachi, 75360, Pakistan.</p> <p>(ELI-00495)</p> <p>Dossier#1448-C</p> <p>Date:04-04-23</p>	<p>Legal Manufacturer: UTAS technologies S.R.O., 1, Stavitel'ska st., Bratislava,83104, Slovakia</p> <p>FSC: Slovakia</p> <p>Issued: 26-04-2021</p>	<p>UTAS (Patient Monitor UM-300S)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 05 years</p> <p>Patient Monitor UM-300S represents standard portable bedside device for continuous monitoring of basic hemodynamic parameters as well as other vital signs using optional modules.</p>	<p>Approved Patient Monitor UM-300S) , Codes (UM-300-15-S subject to valid original FSC and valid CE Certificate.</p>
66.	<p>M/s EV Solutions (Private) Limited, Apartment # 307, 3rd Floor, Gulberg Empire, Civic Center, Gulberg Greens, Islamabad.</p>	<p>M/S Jiangsu Guanchuang Medical Technology Co., Ltd. 2D, Wujin Science &</p>	<p>Disposable Trocar for Laparoscope</p>	<p>Deferred (last opportunity) for;</p> <p>1. clarification that product is of class B (IIa) as per DOC but has been applied as Class D.</p>

	<p>ELI-01382</p> <p>R& I dated 26-03-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 716429844983: Dated: (24/03/2025)</p>	<p>Technology Park No 256, Mingxin Middle Road, Hutang, Changzhou, Jiangsu Peoples Republic of China.</p> <p>Free Sale Certificate valid upto 17/02/2026 issued by Peoples Republic of China (apostille)</p> <p>ISO 13485 valid up to 15/03/2027.(Notarized)</p> <p>Letter of authorization valid upto 13/01/2028 (Notarized)</p>	<p>Class-D</p> <p>Shelf life:</p> <p>Storage Conditions: 36 Months (Room temperature)</p>	<p>2. submission of original, notarized CE marking certificate.</p>
67.	<p>M/s EV Solutions (Private) Limited, Apartment # 307, 3rd Floor, Gulberg Empire, Civic Center, Gulberg Greens, Islamabad.</p> <p>ELI-01382</p> <p>R& I dated 28-03-2025</p>	<p>M/S Jiangsu Guanchuang Medical Technology Co., Ltd. 2D, Wujin Science & Technology Park No 256, Mingxin Middle Road, Hutang, Changzhou, Jiangsu Peoples Republic of China.</p>	<p>Disposable Endoscopic Cutting Stapler and Reload.</p> <p>Class-D</p> <p>Shelf life:</p> <p>Storage Conditions: 36 Months (Room temperature)</p>	<p>Deferred (last opportunity) for;</p> <p>1. clarification that product has been applied as class D but as per DOC class IIb (C).</p> <p>2. submission of original, notarized EC certificate.</p>

	<p>Fee details:</p> <p>Amount paid: PKR 62,000 /-</p> <p>Paid Slip/ challan No. 1515188633:</p> <p>Dated: (24/03/2025</p>	<p>Free Sale Certificate valid upto 17/02/2026 issued by</p> <p>ISO 13485 valid up to 15/03/2027. Copy</p> <p>Letter of authorization valid up to 13/01/2028 copy</p>		
68.	<p>The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore.</p> <p>ELI-00567</p> <p>5816-P</p> <p>62,000/-</p>	<p><u>Legal Manufacturer:</u></p> <p>Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.</p> <p>Address:</p> <p>Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey.</p> <p>FSC: Turkey.</p> <p>Date of Issuance: 06-03-2024.</p> <p>LOA validity 01-01-2029</p> <p>GMP certificate</p>	<p>Biorad Liquid PA 5L (High Level Medical instruments-devices and endoscopes disinfectant)</p> <p>Class-C</p> <p>Shelf Life: 2 Years</p> <p>Codes/sizes: 5557</p>	<p>Deferred (last opportunity) for submission of;</p> <ol style="list-style-type: none"> 1. original, notarized, CE marking certificate, notarized manufacturer details, notarized ISO 13485:2016 and legalized FSC of country of origin. 2. Submission of stability studies.

		<p>validity</p> <p>01-03-2024</p> <p>CE certificate validity</p> <p>26-05-2024 issued by</p> <p>SZUTEST (2195-MED-2004501)</p>		
69.	<p>The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore.</p> <p>ELI-00567</p> <p>5817-P</p> <p>62,000/-</p>	<p><u>Legal Manufacturer:</u></p> <p>Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.</p> <p>Address:</p> <p>Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey.</p> <p>FSC: Turkey.</p> <p>Date of Issuance: 06-03-2024.</p> <p>LOA validity 01-01-2029</p> <p>GMP certificate validity</p> <p>01-03-2024</p> <p>CE certificate validity</p> <p>26-05-2024 issued by</p> <p>SZUTEST (2195-MED-2004501)</p>	<p>Biorad Clean Ak Spray (Surface disinfectant for medical devices)</p> <p>Class-C</p> <p>Shelf Life: 2 Years</p> <p>Codes/sizes:</p> <p>5001 (1L)</p> <p>5003 (5L)</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. original, notarized, CE marking certificate, notarized manufacturer details, notarized ISO 13485:2016 and legalized FSC of country of origin.</p> <p>2. Submission of stability studies.</p>

70.	<p>The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore.</p> <p>ELI-00567</p> <p>5818-P</p> <p>62,000/-</p>	<p><u>Legal Manufacturer:</u></p> <p>Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.</p> <p>Address:</p> <p>Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey.</p> <p>FSC: Turkey.</p> <p>Date of Issuance: 06-03-2024.</p> <p>LOA validity 01-01-2029</p> <p>GMP certificate validity 01-03-2024</p> <p>CE certificate validity 26-05-2024 issued by SZUTEST (2195-MED-2004501)</p>	<p>Biorad Thermo Clean 50% (Hemodialysis disinfectant) machines</p> <p>Class-C</p> <p>Shelf Life: 2 Years</p> <p>Codes/sizes: 5314 (5L)</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. original, notarized, CE marking certificate, notarized manufacturer details, notarized ISO 13485:2016 and legalized FSC of country of origin.</p> <p>2. Submission of stability studies.</p>
71.	<p>The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore.</p> <p>ELI-00567</p> <p>5819-P</p>	<p><u>Legal Manufacturer:</u></p> <p>Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.</p>	<p>Biorad Thermo Clean 21% (Hemodialysis disinfectant) machines</p> <p>Class-C</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. original, notarized, CE marking certificate, notarized manufacturer details, notarized ISO 13485:2016 and legalized FSC of country of origin.</p> <p>2. Submission of stability studies.</p>

	62,000/-	<p>Address:</p> <p>Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey.</p> <p>FSC: Turkey.</p> <p>Date of Issuance: 06-03-2024.</p> <p>LOA validity 01-01-2029</p> <p>GMP certificate validity 01-03-2024</p> <p>CE certificate validity 26-05-2024 issued by SZUTEST (2195-MED-2004501)</p>	<p>Shelf Life: 2 Years</p> <p>Codes/sizes: 5442 (5L)</p>	
72.	<p>The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore.</p> <p>ELI-00567</p> <p>5820-P</p> <p>62,000/-</p>	<p><u>Legal Manufacturer:</u></p> <p>Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.</p> <p>Address:</p> <p>Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey.</p>	<p>Biorad GDA 2% (High Level Medical instruments-devices and endoscopes disinfectant)</p> <p>Class-C</p> <p>Shelf Life: 2 Years</p> <p>Codes/sizes: 5401 (5L)</p>	<p>Deferred (last opportunity) for submission of;</p> <ol style="list-style-type: none"> 1. original, notarized, CE marking certificate, notarized manufacturer details, notarized ISO 13485:2016 and legalized FSC of country of origin. 2. Submission of stability studies.

		<p>FSC: Turkey.</p> <p>Date of Issuance: 06-03-2024.</p> <p>LOA validity 01-01-2029</p> <p>GMP certificate validity 01-03-2024</p> <p>CE certificate validity 26-05-2024 issued by SZUTEST (2195-MED-2004501)</p>		
73.	<p>Name</p> <p>Gulfam Brothers</p> <p>Address of Importer</p> <p>Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore</p> <p>H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore</p>	<p>(Legal Manufacturer)</p> <p>Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI.</p> <p>(Manufacturing site)</p> <p>Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.</p>	<p>CONFORT Vacuum Assisted Wound Closure Set with Silver</p> <p>Vacuum Assisted Wound Closure Set with Silver</p>	<p>Deferred for submission of:</p> <ol style="list-style-type: none"> 1. revised form 7A duly signed and stamped. 2. notarized CE marking certificate or legalized valid FSC of RRA. 3. notarized valid design examination certificate.
74.	<p>Name</p> <p>Gulfam Brothers</p> <p>Address of Importer</p> <p>Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore</p> <p>H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore</p>	<p>(Legal Manufacturer)</p> <p>Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI.</p> <p>(Manufacturing site)</p> <p>Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.</p>	<p>CONFORT Vacuum Assisted Wound Closure Set Spiral</p> <p>Vacuum Assisted Wound Closure Spiral</p>	<p>Deferred for submission of:</p> <ol style="list-style-type: none"> 1. revised form 7A duly signed and stamped. 2. notarized CE marking certificate or legalized valid FSC of RRA. 3. notarized valid design examination certificate.
75.	Name	(Legal	CONFORT Vacuum Assisted	Deferred for submission of:

	<p>Gulfam Brothers</p> <p>Address of Importer</p> <p>Office No. 702, 7th Floor, Land Mark Plaza Jail Road, Lahore</p> <p>H.No. 1-C, Zaildar Park, 97-Ferozpur Road, Lahore</p>	<p>Manufacturer)</p> <p>Konfort Ozel Saglik Hizmetleri Tibbi Malzemeler San. Ve Tic. Ltd. STI.</p> <p>(Manufacturing site)</p> <p>Organize Sanayi Bolgesi 9.Cad No. 32, Eskisehir, Turkey.</p>	<p>Wound Closure Set Hydrophobic</p> <p>Vacuum Assisted Wound Closure Set Hydrophobic</p>	<p>1. revised form 7A duly signed and stamped.</p> <p>2. notarized CE marking certificate or legalized valid FSC of RRA.</p> <p>3. notarized valid design examination certificate.</p>
76.	<p>Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi.</p> <p>ELI-00267</p> <p>5915-P</p> <p>62,000/-</p>	<p>Legal Manufacturer:</p> <p>INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy.</p> <p>FSC Italy issuance 25-02-2025 LOA: missing</p> <p>ISO 1348507-05-2026</p> <p>CE and CED certificates validity 27-05-2024 with extension notification.</p>	<p>PROMVIA HYDRO BALANCE 100mg 2,5% of Sodium Hyaluronate salt and trehalose)</p> <p>Class-D</p> <p>Shelf Life: 36 Months</p> <p>Code/size as per FSC</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. valid, notarized LOA.</p> <p>2. notarized, valid CE marking certificate or legalized FSC of RRA.</p> <p>3. Design Examination certificate.</p>
77.	<p>Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi.</p> <p>ELI-00267</p> <p>5912-P</p> <p>62,000/-</p>	<p>Legal Manufacturer:</p> <p>INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy.</p> <p>FSC Italy issuance 25-02-2025</p>	<p>INN61V INNEA AQUA Pre-filled syringe of 2ml, with 2.5% Sodium Hyaluronate (50mg/2ml)</p> <p>Class-D</p> <p>Shelf Life: 36 Months</p>	<p>Deferred (last opportunity) for submission of;</p> <p>1. valid, notarized LOA.</p> <p>2. notarized, valid CE marking certificate or legalized FSC of RRA.</p> <p>3. Design Examination certificate.</p>

		LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	Code/size as per FSC	
78.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5913-P 62,000/-	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy. FSC Italy issuance 25- 02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	INN03V INNEA (2% Hyaluronic acid sodium salt) 40mg Class-D Shelf Life: 36 Months Code/size as per FSC	Deferred (last opportunity) for submission of; 1. valid, notarized LOA. 2. notarized, valid CE marking certificate or legalized FSC of RRA. 3. Design Examination certificate.
79.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5914-P 62,000/-	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy. FSC Italy issuance 25- 02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	INN62V INNEA EVIDENCE PRAECLA 2ml, 40mg/2ml (2ml, 2% of High molecular weight Sodium Hyaluronate) Class-D Shelf Life: 36 Months Code/size as per FSC	Deferred (last opportunity) for submission of; 1. valid, notarized LOA. 2. notarized, valid CE marking certificate or legalized FSC of RRA. 3. Design Examination certificate.
80.	Radiant Medical (Pvt) Ltd 06-Sher	<u>Legal Manufacturer:</u>	Ardo Master/Ardo Senator/ Ardo	Approved Ardo Master Suction pump

	<p>Shah Block, New Garden Town, Lahore.</p> <p>ELI: 00135</p> <p>Date of application received along with Fee Date of R& I 16-Aug-2023</p> <p>Fee Rs. 25,000/ through slip no: 050215823</p>	<p>Ardo medical AG, Gewerbestrasse 1, CH-6314 Unterageri, Switzerland</p> <p>FSC: Switzerland</p> <p>Valid till: 23/03/2026</p> <p>LOA validity 31-12-2025</p>	<p>Calypso/Ardo (Carum/Ardo Alyssa/Ardo Bellis) (Suction Pump)</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Codes as per FSC</p>	only.
81.	<p>Radiant medical Pvt ltd</p> <p>06 sher shah block, new garden town lahore</p> <p>(ELI-00135)</p>	<p>TRUMPF MEDIZIN SYSTEME GMBH</p> <p>CO, KG, CARL - ZEISS- STRASSE 7-9, 07318 SAALFELD, GERMANY</p>	<p>CEILING MOUNED SUPPORT SYSTEM</p> <p>Class C</p>	<p>Deferred for clarification</p> <ol style="list-style-type: none"> 1. that medical device was initially applied as class C product nut now on as class A product. 2. that Form 6A is without its annexures. 3. that LOA is neither original nor notarized. 4. LOA with Hill-Rom instead of manufacturer.
82.	<p>Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E, PIA Housing Society, Johar Town, Lahore.</p> <p>ELI-01265</p> <p>5980-P</p> <p>62,000/-</p>	<p>Legal Manufacturer:</p> <p>Dongguan TT Medical, Inc. Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, PR China.</p> <p>FSC: Netherlands.</p> <p>Validity: 31-12-2027.</p>	<p>EverFlow (Paclitaxel Coated PTCA Balloon Catheter)</p> <p>Class-D</p> <p>Shelf life: 2 years</p> <p>Codes as per FSC</p>	<p>Deferred for submission of;</p> <ol style="list-style-type: none"> 1. original, notarized and valid declaration of manufacture for change of distributor. 2. original, legalized FSC of RRA mentioning product name and codes. 3. original, notarized design examination. 4. after completion of all documents, the Board will call both parties.

83.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273)</p> <p>Dated:06-03-2024</p> <p>Fee Challan No.: 28517201278 PKR: 50,000/-</p> <p>Dated: 07-12-2023</p>	<p>Name of Manufacturer: Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432</p> <p>Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432</p> <p>Manufacturing facilities:</p> <p>i. Medtronic Inc. 8200 Carol Sea Street NE Mounds View, Mn USA 55112</p> <p>ii. Medtronic Inc. 7000 Central Ave., N.E. USA 55432 Minneapolis, MN</p> <p>iii. Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II Bayan Lepas, Pulau Pinang Malaysia 11900</p> <p>iv. Medtronic Operations Puerto Co., Rico Villalba located at RD. 149, KM.56.3 Call Box 6001 Villalbba, PR USA 00766</p> <p>V. Medtronic Singapore Operations</p>	<p>Sprint Quattro Secure MRI SureScan</p> <p>Class: D Shelf life: 2 years Size & Model: 6947-65 6947-58 Storage conditions: No specific storage conditions</p> <p>ISO 13485 Validity: 31-03-2025 (Singapore) 12-02-2025 (Malaysia) 31-03-2025 (USA) 21-03-2025 (Puerto Rico)</p> <p>FQA Validity Date: 01-12-2025</p> <p>EC Design Examination Certificate Validity: 01-07-2027</p> <p>LOA Date: 21-10-2022</p> <p>FSC: USFDA Validity: 21-08-2024</p>	<p>Deferred for:</p> <p>valid FSC and ISO 13485 and product catalogue</p>
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		Pte Ltd located at 49 Changi South Avenue 2 Nasaco Tech Centre Singapore, Central Singapore Singapore 486057		
84.	<p>M/s Medtronic Pakistan Private Limited.</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>(ELI-00273)</p> <p>Dated:06-03-2024</p> <p>Fee Challan No.: 750299622757 PKR: 50,000/-</p> <p>Dated: 08-12-2023</p>	<p>Name of Manufacturer: Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432</p> <p>Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432</p> <p>Manufacturing facilities:</p> <p>i. Medtronic Inc. 8200 Carol Sea Street NE Mounds View, Mn USA 55112</p> <p>ii. Medtronic Inc. 7000 Central Ave., N.E. USA 55432 Minneapolis, MN</p> <p>iii. Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II Bayan Lepas, Pulau Pinang Malaysia 11900</p> <p>iv. Medtronic Operations Puerto Co., Rico Villalba located</p>	<p>CareLink SmartSync Device Manager Base</p> <p>Class: D</p> <p>Size & Model: 24970A</p> <p>Storage and Temperature conditions: No specific storage conditions</p> <p>Shelf life: N/A</p> <p>ISO 13485 Validity: 31-03-2025 (Singapore) 12-02-2025 (Malaysia) 31-03-2025 (USA) 21-03-2025 (Puerto Rico)</p> <p>FQA Validity Date: 01-12-2025</p> <p>EC Design Examination Certificate Validity: 01-07-2027</p> <p>LOA Date: 21-10-2022</p> <p>FSC: USFDA</p> <p>Validity: 21-08-2024</p>	Approved subject to valid FSC.

		at RD. 149, KM.56.3 Call Box 6001 Villalbba, PR USA 00766 V. Medtronic Singapore Operations Pte Ltd located at 49 Changi South Avenue 2 Nasaco Tech Centre Singapore, Central Singapore Singapore 486057		
85.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21 st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton. (ELI-00273) 16461 DRAP (R&I) Dated: 30-09-2024 Fee Challan No.: 830223488055 PKR: 50,000/- Dated: 09-09-2024	Name of Manufacturer: Medtronic Sofamor Danek USA, Inc, 1800 Pyramid Place Memphis, USA Medtronic Trading NL BC Earl Bakkenstraat 10 6422 PJ Herlen Netherlands Manufacturing facilities: i. Medtronic Medical Costa Rica S.R.L Coyol free, Zone Bldg B7 Multitenant 7-8, Module F Coyol, Alajuela Costa Rica. ii. Medtronic Sofamor Danek USA, INC 4340 Swinnea Road Memphis, TN USA 38118	Rialto™ SI Fusion System Class: C Size & Model: -74200001240 12mm x 40mm threaded device. -74200001245 12mm x 45mm threaded device. -74200001250 12mm x 50mm threaded device. -74200001250 12mm x 55mm threaded device. -74200001260 12mm x 60mm threaded device. Storage conditions: Corrosion free environment. Shelf life: 08 years ISO 13485 Validity: 20-09-2025 FQA Validity Date: 26-05-2024	Deferred for product catalogue and differential fee for system.

		iii. Warsaw ortho Inc, also known as M/s Medtronic Sofamor Danek manufacturing located at 2500 Silveus Crossing Warsaw, IN USA 46582	Design Examination Certificate: N/A LOA Date: 21-10-2022 FSC: USFDA Validity: 20-09-2025 EC Certificate validity: 20-09-2025	
86.	M/s Safeway Systems Pakistan, Flat No. 4, 2nd Floor, Amna Shopping Centre, Misrial Road, Rawalpindi. (ELI-00308) Evaluator: AD-IV [2739-P]	Legal Manufacturer: M/s CPT Sutures Co., LTD, 83 Hai Ba Trung, Ben Nghe Ward, District 1, Ho Chi Minh City, 700000, Vietnam FSC Vietnam issuance 25-09-2020 valid for 3 years (Original)	Carepace® Temporary Cardiac Pacing Lead (Wire) Class-D Shelf life: 5 years Codes & Sizes:	Rejected as the firm could not provide the FSC of any reference country or CE Certificate.
87.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5880-P 62,000/-	Legal Manufacturer: BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10-06-2024 LOA validity 31-03-2025 ISO 13485 validity 07-	VIDAS® β2 Microglobulin kit Class-C Shelf Life: 12 Months Code: 30420	Approved.

		11-2027		
88.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5881-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10- 06-2024 LOA validity 31-03- 2025 ISO 13485 validity 07- 11-2027 DEC: N/A	VIDAS® Anti-HBs Total II kit Class-D Shelf Life: 23 Month Code: 30318	Approved.
89.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5882-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10- 06-2024 LOA validity 31-03- 2025 ISO 13485 validity 07- 11-2027 DEC: N/A (Anex-II-A)	VIDAS® HBe/Anti-Hbe kit Class-D Shelf Life: 12 Months Code: 30305	Approved.

90.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5974-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10- 06-2024 LOA validity 31-03- 2025 ISO 13485 validity 07- 11-2027	VIDAS® Varicella-Zoster IgG kit Class-C Shelf Life: 10 Months Code: 30217	Approved.
91.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 6029-P 31,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile- France. Original FSC: France. Date of Issuance: 17- 01-2024. LOA validity 31-03- 2025 ISO 13485 validity 07- 11-2027	RAPIDEC® CARBA NP (10) test Class-B Shelf Life: 24 Months Code: 415418	Approved.
92.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 6028-P 31,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile- France. Original FSC: France. Date of Issuance: 17-	FB (FAST BLUE BB) 2AMP Class-B Shelf Life: 12 Months	Approved.

		01-2024. LOA validity 31-03-2025 ISO 13485 validity 07-11-2027	Code: 70562	
93.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 6027-P 31,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile-France. Original FSC: France. Date of Issuance: 09-10-2024. LOA validity 31-03-2025 ISO 13485 validity 07-11-2027	VIDAS® Vitamin B12 TOTAL Class-B Shelf Life: 12 Months Code: 424106	Approved.
94.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1542-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA.	VITEK® MI-TUBE Class-A Shelf Life: 20 Months Code: 424179	Approved.

		<p>Original FSC: France. Date of Issuance: 15-10-2024.</p> <p>LOA validity 31-03-2025</p> <p>ISO 13485 validity 17-12-2027</p>		
95.	<p>Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00109</p> <p>1566-P</p> <p>6,000/-</p>	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280 Marcy-l'Etoile - France.</p> <p><u>Manufacturing Site:</u> Biomerieux S.A. 5 rue des Aqueducs-69290 CRAPONNE, France</p> <p>Original FSC: France. Date of Issuance: 06-06-2024</p> <p>LOA validity 31-03-2025</p> <p>ISO 13485 validity 17-12-2027</p>	<p>Trypcase Soy Agar</p> <p>Class-A</p> <p>Shelf Life: 21 weeks</p> <p>Code: 43011</p>	Approved.
96.	<p>Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00109</p> <p>1567-P</p> <p>6,000/-</p>	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France.</p> <p><u>Manufacturing Site:</u> BIOMERIEUX S.A 5 rue des Aqueducs-69290 Craponne, France.</p>	<p>KOVACS Reagent</p> <p>Class-A</p> <p>Shelf Life: 2 years</p> <p>Code:</p>	Approved.

		FSC: France. Date of Issuance: 06-06-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	55631	
97.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1568-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> BIOMERIEUX S.A 5 rue des Aqueducs-69290 Craponne, France. FSC: France. Date of Issuance: 06-06-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	ID INDOLE TDA Class-A Shelf Life: 1 Year Code: 56541	Approved.
98.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1569-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA.	VITEK® 2 Pipetter/Diluter Accessory Kit Class-A Shelf Life: N/A Code:b21219	Approved.

		<p>Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA.</p> <p>FSC: France. Date of Issuance: 02-07-2024.</p> <p>LOA validity 31-03-2025</p> <p>ISO 13485 validity 17-12-2027</p>		
99.	<p>Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00109</p> <p>1569-P</p> <p>6,000/-</p>	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France.</p> <p><u>Manufacturing Site:</u> 3 route de Port Michaud-38390 LA BALME LES GROTTEs, France.</p> <p>Original FSC: France. Date of Issuance: 05-06-2024.</p> <p>LOA validity 31-03-2025</p> <p>ISO 13485 validity 17-12-2027</p>	<p>VITEK® MS SMARTCALIBRANT</p> <p>Class-A</p> <p>Shelf Life: 11 Months</p> <p>Code: 423710</p>	Approved.
100.	<p>Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00109</p>	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France.</p>	<p>BTL, 0.45% SALINE SOLUTION</p> <p>Class-A</p>	Approved.

	1571-P 6,000/-	<u>Manufacturing Site:</u> PiSA Farmaceutica, Calle 2676, Colon Industrial-44930 Guadalajara, Jalisco, Mexico. FSC: France. Date of Issuance: 03-07-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	Shelf Life: 24 Months Codes: 423718 (1 L x 12) 423719 (0.5 L x 18)	
101.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1572-P 6,000/-	<u>Legal Manufacturer:</u> BIOMERIEUX Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA. <u>Manufacturing Site:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA. FSC: France. Date of Issuance: 02-07-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	SCS UNIVERSAL 100/240V Class-A Shelf Life: N/A Code: 27209	Approved.
102.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280 Marcy-l'Etoile -	VITEK® COMPACT PRO Class-A	Approved.

	<p>ELI-00109</p> <p>1543-P</p> <p>6,000/-</p>	<p>France.</p> <p>Manufacturing Sites:</p> <p>Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA</p> <p>Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA.</p> <p>Original FSC: France. Date of Issuance: 15- 10-2024.</p> <p>LOA validity 31-03- 2025</p> <p>ISO 13485 validity 17- 12-2027</p>	<p>Shelf Life: N/A</p> <p>Model/code:</p> <p>423465 (Instrument)</p> <p>423737 (Software)</p>	
103.	<p>Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan</p> <p>ELI: 00120</p> <p>Dossier# 4049-KP</p> <p>Submission date: 02/08/2023</p> <p>Fee submitted: 50,000/-PKR</p>	<p>Legal Manufacturer:</p> <p>Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>Manufacturing Site:</p> <p>Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland.</p>	<p>Essentio MRI</p> <p>(Pulse Generator: Implantable Pacemaker)</p> <p>Codes & Sizes:</p> <p>Model: L131</p> <p>Class-D</p> <p>Shelf life: 2 years</p>	<p>Deferred for;</p> <p>1. Clarification of manufacturer name on ISO 13485:2016 i.e. Cardiac pacemakers, incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112-5798.</p> <p>3. Submission of notarized EU Quality Management System Certificate with manufacturing site mentioned on it.</p> <p>4. Submission of Design Examination certificate.</p> <p>5. DOC as EU Medical Device</p>

	Challan# 4307057199 Evaluator: DD-II	Original FSC: USA Valid till: 12/10/2024		Regulation (MDR) 2017/745 mentioning class of device.
104.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120	M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA M/s Boston Scientific Corporation 302 Parkway, Global Park, Heredia, Costa Rica Copy of FSC of USFDA valid till 05.11.2025. Copy of 3 FSC of Ireland two issued on 10.06.2024 Third FSC issued on 15.7.2024 EU technical documentation 2.09.2027 EU QMS valid till 2.09.2027 ISO 13485 Valid till 01.09.2026	Farapulse™ Pulsed Field Ablation System Pulse Field Ablation Catheter Connection Cable Class D 24 Months(2) N/A FARASTAR Pulsed Field Ablation Generator M004PFCE61M401 M004PFCE61M407 Electronic Components- Shelf Life Not Applicable FARAWAVE Catheter M004PFCE41M401 M004PFCE41M402 24 months	Deferred for: submission of original FSC, clarification/ justification for applying different products and inform which product to be considered for instant application as per FSC.

			<p>FARASTAR Connection Cable</p> <p>M004PF41M434</p> <p>24 months</p> <p>FARADRIIVE Steerable Sheath Clear.</p> <p>M004PFCE21M402</p> <p>Electronic Components- Shelf Life Not Applicable</p> <p>(Attached as annexure: 04)</p> <p>Fee 100000/-</p>	
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