

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

DECISIONS OF 94TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 05-08-2025 (PART-I HARD FILES AGENDA)

94th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 5th August, 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.	Mr. Muzammal Waheed, Director, DTL, Health Department, Government of Punjab, Lahore.	Member (attended meeting through videolink)
3.	Dr. Ghazala Inayat, Deputy Director, Provincial Health Directorate, Government of Baluchistan	Member
4.	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)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
10.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)
11.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
12.	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. Zia Ullah	Deputy Director-V
6.	Mr. Muhammad Ashfaq	Deputy Director-VI
7.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
8.	Mr.Rana Ahsan-ul-Haq Athar	Deputy Director-VIII

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.

**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 Oxy-Med Private Limited, 509, Sheikh Yaseen Trade Center, Arbab Road Stop, University Road Peshawar.	Muhammad Imran Jan, Pharmacist Regn.No.7921-A/ 2022-PC CNIC:61101-8482184-5	Approved for storage of room temperature medical devices.
2.	M/s Fair Diagnostics & Scientific, House # 35/4, E-Block, Satellite Town, Rawalpindi.	Mr. Abdul Qayyum Khan, (CNIC No. 16102-9002261-1) B.Sc, Medical Laboratory Technology	Approved for storage of room temperature and <u>cold storage (2-8°C)</u> medical devices.
3.	M/s Vireon Lab, Office No 1 & 12, First Floor, Plaza 2D, Farooq Market, G-13/3, Islamabad.	Seyab Siddique Khan CNIC NO. 37405-7876927-1 BS Software Enginnering	Approved for storage of room temperature medical devices.
4.	M/s Lepustechex, Shop 03, Basement Abdul Rasheed Plaza, Near King Abdullah Teaching Hospital, Chanayi, Mansehra, KPK.	Mrs.Hurmat Malik, Pharm-D REgn.No.3441-A/2015 CNIC:13503-2711677-6	Approved for storage of room temperature medical devices.
5.	M/s Wali Medicine Company, 523-A, Faisal Town Lahore.	Ms. Sonia Shareef, Pharm-D REgn.No.36264-A/25	Approved for storage of room temperature medical devices, subject to submission of requisite fee for change of qualified person.
6.	Unique Dental Trading Corporation, Shop No. 45, Lower Grount Floor, 137-C Ibrar Centre, Main Wahdat Road, Lahore	Sayad Tariqullah Shah, Pharm-D, CNIC 35202-4435221-5 Reg.No.34322-A/24	Approved for storage of room temperature medical devices.
7.	M/s Unicare, Ground Floor, P-76, Street No.2, Officer Colony No.1, Susan Road Faisalabad.	Mr. Hamza Ali Adnan, Pharm-D CNIC 35201-8270173-5 Reg.No.33086-A/24	Approved for storage of room temperature medical devices.
8.	M/s Perform Leo, Office No. 708, 7 th Floor, Ashrafi Heights 2-E, Main Market Road Gulberg-II, Lahore.	Muhammad Hassan Butt CNIC 35202-6418561-9 Pharm-D Reg.No.32059-A/24	Approved for storage of room temperature medical devices.
9.	Lifar Pharma Services, Dean	Mst.Saleha Rehman	Approved for storage of

	Building #E22/11, B. Street # 3, Islam Nagar Walton Lahore.	Pharm-D Reg.No.28313-A/23	room temperature medical devices.
10.	M/s Biosurgico, Office # 103-104 first floor, Al Nafay Center, Sabzazar Lahore. Godown Address: Office 402, 4th Floor Sarwar Plaza, Main Boulevard Sabzazar Lahore.	Mr. Zeeshan Ali, Pharm-D REg.No.30088-A/23	Approved for storage of room temperature medical devices.
11.	M/s AF Global Logistics, Flat No.13, 1 st Floor, Sultana Arcade, Karim Block Market, Allama Iqbal Town, Lahore. Godown Address: Ground Floor, House No.38, Street No.3, Takbeer Home Barbanspura, Lahore.	Mr. Rizwan Bashir Pharm-D REg.No. 5431-A/09	Approved for storage of room temperature medical devices.
12.	AJ & Sons Trading SMC (PVT.) Ltd., Shops 15-20, Ground Floor, AL-Kareem Arcade, GT Road, Qaziabad, Wah Cantt.	Ms. Sannia Liaqat Ali (Pharm-D), CNIC No. 5229-42201-2945827-4, Reg.No. 5229	Approved for storage of room temperature medical devices.
13.	Diamond Eye Trading (SMC-Private) Limited, Flat No.03, Second Floor, Plot No. C-02, Block B, Gulshan e Millat, Bagh e Korangi, Korangi Town, Korangi, Karachi	Mr. Irfan Ali (Pharm. D) (CNIC No. 41102-7489381-7) Reg.No. 7069	Approved for storage of room temperature medical devices.

APPLICATIONS FOR SITE APPROVAL FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

Case No.01.

M/s Cotton Synergy International, Kasur has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed site for the construction of the Unit is located **at 4.5 KM, Kasur Bypass Road, Kasur**. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting of Establishment license to manufacture medical devices.

Accordingly, Mr. Ishtiaq Shafiq, Deputy Director, DRAP, Lahore was nominated for inspection of proposed site. Panel conducted the inspection and submitted recommendations/report as under: -

Location	The proposed site is located at 4.5 KM, Kasur Bypass Road, Kasur.
Surroundings	<ul style="list-style-type: none"> On the front side of the proposed site there was a main road (Kasur Bypass Road). On the left side of the site there was open plot. On the back side of the said site there was an open plot and about after 100 meters there was a village area On the right side of the said site there was an open plot. <p>Note: Within 1-KM surroundings of the site, there were numerous functional Brick Kilns.</p>
Size	The size of the total plot was 8K-0M in which front side 04 Kanal was dedicated for M/s Cotton Synergy International, 4.5 KM, Kasur Bypass Road, Kasur, for

	establishment of manufacturing unit of medical devices.
Recommendations	The above observations that within 1-KM surroundings of the site, there were numerous functional Brick Kilns led to the conclusion that the site was not suitable for establishment of manufacturing unit of medical device as on today.

Decision: Based on the observations of the inspector, the Board rejected the application of M/s Cotton Synergy International, Kasur for approval of site located at 4.5 KM, Kasur Bypass Road, Kasur.

REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER

Deferred cases

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19907 dated 04.07.2025 Approved Sections: 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso HBsAg (Hepatitis B surface antigen) RDT (Rapid Diagnostic Kit) Code: RDT-HBSAG Shelf Life: 18-24 months Class: D Fee Rs: 25000/- (Slip No. 111360383)	Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.
2.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19912 dated 04.07.2025 Approved Sections: 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso HCV RDT (Rapid Diagnostic Kit) Code: RDT-HCV Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 32694675387)	Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.
3.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19910 dated 04.07.2025 Approved Sections: 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso hCG Pregnancy RDT (Rapid Diagnostic Kit) Code: RDT-hCG Shelf Life: 18-24 months Class: B Fee Rs: 25000/- (Slip No. 1177730929)	Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.
4.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19911 dated 04.07.2025 Approved Sections: 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling)	Medsenso Dengue NS1 Antigen Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-Dengue-NS1 Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 6012706155)	Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.

	3. Laboratory Glass Slides (Production)		
5.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19913 dated 04.07.2025</p> <p>Approved Sections:</p> <p>1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso TP Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-SYP Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 333439176887)</p>	<p>Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.</p>
6.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19914 dated 04.07.2025</p> <p>Approved Sections:</p> <p>1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso Malaria Pf/Pv Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-MAL Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 946737563502)</p>	<p>Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.</p>
7.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19915 dated 04.07.2025</p> <p>Approved Sections:</p> <p>1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso HIV ½ Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-HIV Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 7476247817)</p>	<p>Approved for Assembling, Labelling, Sealing and Packing with shelf-life of 18 months.</p>
8.	<p>Paktex Industries 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]</p>	<p>NEOCARE CORD CLAMP Umbilical cord clamp-sterile Class-A Shelf Life: 5 Years Sizes & Codes Standard Size in different colors i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red vi)-Black Fee: 5000/- with slip No. 4370381754 dated 5-10-2021</p>	<p>Approved with shelf-life of 3 years.</p>
9.	<p>Paktex Industries 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]</p>	<p>Shoe guard Disposable shoe cover Class-A Shelf Life: 5 Years Sizes & Codes Standard Size in different colors i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red</p>	<p>Approved with shelf-life of 3 years.</p>

		vi)-Black Fee: 5000/- with slip No. 04324665659 dated 5-10-2021	
10.	Paktex Industries 2.5th KM Tatlay Road Saroya Abad, Kamoke. [ELM No.0025]	Pakband Disposable Surgeon/Operation Theatre Cap Class-A Shelf Life: 5 Years Sizes & Codes Standard Size in different colors i)-Pink ii)-White- iii)-Blue iv)-Green v)-Red vi)-Black Fee: 5000/- with slip No. 609659184849 dated 5-10-2021	Approved with shelf- life of 3 years.

REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.

New cases

S#	Importer Name	Manufacturer Details	Name of Medical Device/ Class / Shelf life / Codes / etc	Decision
1.	M/s. Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8 Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037) Date of R&I 14/12/2020 Fee Rs.25,000/-	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address:511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Address: 333 Coney Street East Walpole, MA, 02032, USA FSC UK Valid till: May-2023 LOA validity 08-01-2024 ISO 13485 validity 31-12-2027	Atellica IM Cortisol (Cor) Cluster for Immuno Chemistry Renal Metabolism assays Class B Shelf Life: 15 months Atellica IM Calibrator E (CAL E) (10995512 10995513) Shelf Life: 16 months Atellica IM Multi-Diluent 3 (10995645) Shelf Life: 12 months Atellica IM Cortisol (Cor) (10995537) (10995538)	Approved subject to submission of valid and original FSC and notarized LOA.
2.	M/S. Safe Health Pakistan Bizcon. Address: Office # 25, 2 nd Floor, Dilkusha	Legal Manufacturer: M/S. Tianchang City Anrui Medical Equipment Co. LTD. Renhe Industrial District, TianChang City, AnHui	Venous Sterile Surgical Gloves, powdered free Class-B	Approved

	<p>Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p>R&I details 20th May 2025</p> <p>Fee Rs. 30,000/ through slip no. 11554387690, dated 12-05-2025</p>	<p>Proviance, China.</p> <p>LOA: Issuance: 24-02-2025</p> <p>FSC: Validity: 23-02-2030</p> <p>ISO-13485: Validity: 19-07-2027</p> <p>CE certificate validity 26-05-2024 alongwith Extension notification letter</p>	<p>Shelf Life: 5 years</p> <p>Sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 & 9.5</p>	
3.	<p>M/S. Safe Health Pakistan Bizcon.</p> <p>Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p>R&I details 20th May 2025</p> <p>Fee Rs. 30,000.00 through slip no. 8618708376 Date 12-05-2025</p>	<p>Legal Manufacturer: M/S. Jiangsu Jianzhiyuan Medical Instrument Technology Co., Ltd. Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou City. China.</p> <p>LOA: Validity: 30-09-2029</p> <p>FSC: Validity: 20-09-2025</p> <p>ISO-13485: Validity: 20-10-2025</p> <p>CE validity 26-05-2024</p>	<p>Venous Disposable Thoracic Drain Catheter / Chest Drainage Catheter</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Models: WI, WII, WIII, WIV, ZI, ZII, ZIII and ZIV</p> <p>Code/ Sizes: FR-7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39 & 40</p>	<p>Deferred for the provision of valid CE marked and clarification of all models applied and fee challan</p>
4.	<p>M/S. Safe Health Pakistan Bizcon.</p> <p>Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p>R&I details 20th May 2025</p> <p>Fee Rs. 30,000.00 through slip no. 511522573 Date 12-05-2025</p>	<p>Legal Manufacturer: M/S. Gangzhou Shengwei Medical Devices Co., Ltd. No 126, Gangshao Road, Aotou Town, Conghua District, Guangzhou 510945, Guangdong Province, China.</p> <p>LOA: Validity: 08-05-2027</p> <p>FSC: Validity: 06-12-2025</p> <p>ISO-13485: Validity: 10-04-2027</p>	<p>Venous Biopsy Needle</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Sizes: G-14, 16, 18, 20 & 22</p> <p>Models: 121, 111, 112</p>	<p>Deffered for class and specific intended use and fee challan</p>
5.	<p>M/S. Safe Health Pakistan Bizcon.</p>	<p>Legal Manufacturer: M/S. Chamfond Biotech Co., Ltd.</p>	<p>Venous Disposable Biopsy Needle.</p>	<p>Deffered for class and specific intended use and fee</p>

	<p>Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p>R&I details 9th May 2025</p> <p>Fee Rs. 30,000.00 through slip no. 851977932085 Date 12-05-2025</p>	<p>2/F Building E, Sino Danish Eco Life Science Pak, Jiangbei, New Area, Nanjing Jiangsu, CN 21032, China.</p> <p>LOA: Issuance: 01-03-2025</p> <p>FSC: Validity: 11-05-2025</p> <p>ISO-13485: Validity: 12-07-2027</p>	<p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Sizes: G-8, 9, 11, 13, 15, 16, 18</p> <p>Models: BN, MAB, CF, CB, MA</p>	challan
6.	<p>M/s La-Vie (Pvt) Ltd. 450, G-III. Johar Town, Lahore.</p> <p>Fee: Rs. 62000/ through slip no. 7973105474</p>	<p>Legal Manufacturer: M/s Jiangsu Yenssen Biotech. Co.,Ltd. No.10, Dingshan Road, Binjiang Development Zone, Jiangyin, Jiangsu, China, Jiangsu Province, 214431, China.</p> <p>LOA: 11.12.2024 up to 03.11.2027</p> <p>ISO: 11-11.2024 to 14.11.2027</p> <p>FSC China 07.09.2025</p> <p>EC DoC Valid up to 07.09.2025</p> <p>CE Mark & Audit Report 31.12.2028</p>	<p>Dermlin Wound Healing Dressings</p> <p>Class C</p> <p>Shelf Life 3 years</p> <p>Specification/ Model 10cmx4cm, 10cmx6cm, 10cmx10cm 15cmx2.5cm, 15cmx4cm, 15cmx6cm. 15cmx10cm, 20cmx2.5cm, 20cmx4cm, 20cmx6cm, 20cmx8cm, 20cmx10cm, 20cmx15cm</p>	Approved
7.	<p>M/s La-Vie (Pvt) Ltd. 450, G-III. Johar Town, Lahore</p> <p>Fee: Rs: 62000/ through slip no. 94042772605</p>	<p>Legal Manufacturer: M/s Jiangsu Yenssen Biotech. Co.,Ltd. No.10, Dingshan Road, Binjiang Development Zone, Jiangyin, Jiangsu, China, Jiangsu Province, 214431, China.</p> <p>LOA: 11.12.2024 up to 03.11.2027</p> <p>ISO: 11-11.2024 to 14.11.2027</p> <p>FSC China 07.09.2025</p> <p>EC DoC Valid up to 07.09.2025</p> <p>CE Mark & Audit Report 31.12.2028</p>	<p>Dermlin Wound Healing Paste</p> <p>Class C</p> <p>Shelf Life 3 years</p> <p>Specifications/sizes: 0.5g, 1g, 2g, 3g, 5g, 7.5g, 10g, 20g, 50g</p>	Approved
8.	<p>M/s La-Vie (Pvt) Ltd. 450, G-III. Johar</p>	<p>Legal Manufacturer: M/s Jiangsu Yenssen Biotech.</p>	<p>Dermlin Wound Healing Powder</p>	Approved

	<p>Town, Lahore</p> <p>Fee: Rs: 62000/ through slip no. 13674078660</p>	<p>Co.,Ltd. No.10, Dingshan Road, Binjiang Development Zone, Jiangyin, Jiangsu, China, Jiangsu Province, 214431, China.</p> <p>LOA: 11.12.2024 up to 03.11.2027</p> <p>ISO: 11-11.2024 to 14.11.2027</p> <p>FSC China 07.09.2025</p> <p>EC DoC Valid up to 07.09.2025</p> <p>CE Mark & Audit Report 31.12.2028</p>	<p>Class C</p> <p>Shelf Life 3 years</p> <p>Specification/ Model 0.5g, 1g, 2g, 3g, 5g, 7.5g, 10g, 20g, 50g</p>	
9.	<p>M/s La-Vie (Pvt) Ltd. 450, G-III. Johar Town, Lahore</p> <p>Fee: Rs. 62000/ through slip no. 6192350059</p>	<p><u>Legal Manufacturer:</u> M/s Jiangsu Yenssen Biotech. Co.,Ltd. No.10, Dingshan Road, Binjiang Development Zone, Jiangyin, Jiangsu, China, Jiangsu Province, 214431, China.</p> <p>LOA: 11.12.2024 up to 03.11.2027</p> <p>ISO: 11-11.2024 to 14.11.2027</p> <p>FSC China 07.09.2025</p> <p>EC DoC Valid up to 07.09.2025</p> <p>CE Mark & Audit Report 31.12.2028</p>	<p>Dermlin Wound Healing Powder Spray</p> <p>Class C</p> <p>Shelf Life 3 years</p> <p>Specification/Model 0.5g, 1g, 2g, 3g, 5g, 7.5g, 10g, 20g, 50g</p>	Approved
10.	<p>M/s Elate CC Pvt. Ltd., Suite No. 1, 2, 3, St-3, Block -3, Gulshan-e-Iqbal, Karachi</p> <p>ELI-00294.</p> <p>Date of R& I 16-05-2025</p> <p>Fee: Rs.62000/ through slip no. 8586341454</p>	<p><u>Legal Manufacturer:</u> M/s Beijing Kellymed Co., Ltd., Room 115 4th Building No. 2 Ti Yuan West Road, Haidian District, Beijing, 100084, P.R. China</p> <p><u>Manufacturing Site:</u> 2nd Floor, No. 1 Building, No. 2 Jingshegnan Street No. 15, Jinqiao Industrial Base, Zhongguancun Science Park Tongzhou Sub-Park, Tongzhou District, Beijing 101102 PR China</p> <p>LOA: Valid till: 12-03-2030 (Original)</p>	<p>Kelly Med KL-605T Syringe Pump</p> <p>Class C</p> <p>Shelf Life: N/A</p> <p>KL-605T</p>	Approved

		<p>FSC: China Validity: 23-04-2026 (Original)</p> <p>ISO - Validity Date: 23-09-2026 (Original)</p> <p>EU QMS Certificate MDR Valid till: 09-07-2029 (Original)</p>		
11.	<p>M/s Global Biotech Medical Devices (Pvt) Ltd., First Floor, Plot No. 35-N/3, PECHS Block -6, Near Rohail Khund Society Karachi</p> <p>ELI-01292</p> <p>Date of R& I 20-05-2025</p> <p>Fee: Rs.62000/ through slip no. 223235619455</p>	<p><u>Legal Manufacturer:</u> Quanta System Spa vid Acquedotto, 109 21017 - Samarate (VA) - Italy</p> <p>Market Authorization Holder: AngioDynamics, 603 Queensbury Ave QBY NY USA</p> <p>LOA: Valid till: 09-04-2027</p> <p>FSC: Italy Issue Date: 29-04-2022 (Copy)</p> <p>ISO - Validity Date: 09-03-2027 (Copy)</p> <p>EC Certificate Valid till: 26-05-2024 (Copy)</p>	<p>Venacure 1470 Pro Laser Diode Laser System</p> <p>Class C</p> <p>Shelf Life: 5 Years</p>	<p>Deferred for the provision of original documents including notarized LOA, legalized FSC, notarized ISO 13485 and notarized FQA certificate.</p> <p>Submit the fee for System as per revised SRO.</p>
12.	<p>M/s Radiant Medical (Pvt) Ltd,</p> <p>06 Sher Shah Block, New Garden Town, Lahore.</p> <p>ELI-00135</p> <p>Date of R& I 20-05-2025</p> <p>Fee: Rs.62000/ through slip no. 069883869</p>	<p><u>Legal Manufacturer:</u> M/s Ken Hygeine System A/S Bøgebjergvej 60, 5672 Broby, Denmark</p> <p>Supplier: Antonio Matachana S.A, Carrer de Copernic, 8, 08860 Castelldefels, Barcelona Spain</p> <p>LOA: Valid till: 31-12-2026 (Original)</p> <p>FSC: Denmark Validity: 08-05-2026 (Original)</p>	<p>MAT LD 1000 Washer Disinfectant</p> <p>Class C</p> <p>Shelf Life: 10-15 Years</p> <p>Code/sizes: IQ6/MAT LD1000</p>	<p>Approved</p>

		ISO - Validity Date: 12-06-2026 (Original) EC Certificate Valid till: 01-03-2024 (Original)		
13.	M/s Radiant Medical (Pvt) Ltd, 06 Sher Shah Block, New Garden Town, Lahore. ELI-00135 Date of R& I 20-05-2025 Fee: Rs.62000/ through slip no. 75149553	<u>Legal Manufacturer:</u> M/s Ken Hygeine System A/S Bogebjergvej 60, 5672 Broby, Denmark Supplier: Antonio Matachana S.A, Carrer de Copernic, 8, 08860 Castelldefels, Barcelona Spain LOA: Valid till: 31-12-2026 (Original) FSC: Denmark Validity: 08-05-2026(Original) ISO - Validity Date: 12-06-2026 (Original) EC Certificate Valid till: 01-03-2024 (Original)	MAT LD 500 Washer Disinfector Class C Shelf Life: 10-15 Years Code/sizes: IQ5/MAT LD500	Approved
14.	Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 16/05/2025 Fees: 62,000/- Challan No. 438114885977	<u>Legal Manufacturer:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany <u>Manufacturing Site:</u> Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA FSC: 02-11-2027 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485:	VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody Class: C Product Name: 1. VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody CAT #: 09365575001 Pack size: 50 Tests Shelf life: 24 months at 2-8°C 1. VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody	Deferred for the provision of original documents including notarized LOA, legalized FSC, notarized ISO 13485 and notarized EU QMS certificate.

		RDG ISO Validity: 29-06-2027 Ventana ISO Validity: 19-08-2027	CAT #: 08404160001 Pack size: 50 Tests Shelf life: 08 months at 2-8°C	
15.	Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 16/05/2025 Fees: 62,000/- Challan No.317702431211	<u>Legal Manufacturer:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany <u>Manufacturing Site:</u> Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: 11-02-2030 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027	Tina-quant Hemoglobin A1CX4 Class: C Product Name: 1. A1CX4 CAT #: 09529721190 Pack size: 500 Tests Shelf life: 15 months at 2-8°C 1. A1CX4 CAT #: 09529705190 Pack size: 200 Tests Shelf life: 15 months at 2-8°C 1. A1CX4 CAT #: 09529713190 Pack size: 500 Tests Shelf life: 15 months at 2-8°C	Deferred for the provision of original documents including notarized LOA, attested FSC, notarized ISO 13485 and notarized EU QMS certificate.
16.	M/s Jawad Surgical, Office No. 13, Naz Medicine Market Namak Mandi, Peshawar ELI-00913 Date of R& I 20-05-2025 Fee: Rs.62000/ through slip no. 45456101	<u>Legal Manufacturer:</u> M/s Huaian Angel Medical Instruments Co. Ltd., NO. 19, East Zhuhai Road Huaian Jiangsu, China LOA: Valid till: 31-03-2030 (Original) FSC: China Validity: 24-10-2026(Original) ISO - Validity Date: 26-04-2026(Original) EC Certificate Valid till: 30-08-2023 with extension notification.	Neo Medical Non-Absorbable Suture Braided Silk Class C Shelf Life: 3 Years Code/sizes: 6-0, 5-0, 4-0, 3-0, 2-0, 2-0/T, 0, 1, 2	Approved subject to submission of notarized ISO 13485 certificate issued by CAB.
17.	M/s Jawad Surgical, Office No. 13, Naz Medicine Market Namak Mandi, Peshawar	Manufacturer: M/s Huaian Angel Medical Instruments Co. Ltd., NO. 19, East Zhuhai Road Huaian Jiangsu, China	Neo Medical Non-Absorbable Suture Polypropylene Class C	Approved subject to submission of notarized ISO 13485 certificate issued by CAB.

	<p>ELI-00913</p> <p>Date of R& I 20-05-2025</p> <p>Fee: Rs.62000/ through slip no. 8692381696</p>	<p>LOA: Valid till: 31-03-2030 (Original)</p> <p>FSC: China Validity: 24-10-2026(Original)</p> <p>ISO - Validity Date: 26-04-2026(Original)</p> <p>EC Certificate Valid till:</p>	<p>Shelf Life: 3 Years</p> <p>Code/sizes: 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 2-0/T, 0, 1, 2</p>	
18.	<p>M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK)-Pakistan.</p> <p>ELI-00120</p> <p>Fee: Rs 195000 Challan # 7000318435</p> <p>Date of R& I 05-05-2025</p>	<p>Legal Manufacturer: M/s Boston Scientific Corporation. 4100 Hamline Ave North Saint Paul, MN 55112 USA</p> <p>Manufacturing site: M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN 55112 USA.</p> <p>LOA: Sole Agency Agreement Validity date: 31-12-2025 (Copy)</p> <p>FSC: USA Valid Until: 05-12-2025(Original apostile)</p> <p>EC Certificate valid until:26-05-2024 (Original Notarized)</p> <p>ISO: Valid till: 06-02-2025 (Original Notarized)</p>	<p>AMS 700 Inflatable Penile Prosthesis and AMS 700 Accessory Kit AMS 700-36250-Inflatable Penile Prosthesis AMS 700 Accessory Kit-60787-Penile Prosthesis Implantation Kit Accessories disposable Dilators-58389-Corpus Cavernosum Dilator, Single-use</p> <p>Class C</p> <p>Shelf Life: 60 months</p> <p>Codes/Sizes:</p>	<p>Deferred for clarification as multiple products applied in single application .Which product for this application</p>
19.	<p>Shirazi Trading Comoany Pvt Ktd, 114 -C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi 75500</p> <p>Godown: 2nd Floor, Nadir House, I.I. Chandrigar Road, Karachi Pakistan</p>	<p>Legal Manufacturer: Nihon Kohden Corporation, 1-31-4 Nishiochiai, Shinjuku-Ku 161-8560 Tokyo, Japan</p> <p>LOA: Sole Agency Agreement Validity date: 31-03-2026 (Copy Notarized)</p> <p>FSC: Japan Issue date: 12-07-2018(Original</p>	<p>MEB-2300K Electromyography (EMG)/Nerve Conduction Velocity (NCV)/Evoked Potential (EP) Measuring system</p> <p>Class C</p> <p>Applied as: System</p> <p>Shelf Life: Service life 10 years</p>	<p>Approved</p>

	(ELI-00263) Fees: Rs 100000 Challan # 397441896 Date of R& I 15-05-2025	Notarized) EC Certificate valid until: ISO: Valid till: 05-04-2027(Copy Notarized)		
20.	Shirazi Trading Comoany Pvt Ktd, 114 -C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi 75500 Godown: 2nd Floor, Nadir House, I.I. Chandrigar Road, Karachi Pakistan (ELI-00263) Fees: Rs 100000 Challan # 9881553066 Date of R& I 15-05-2025	Legal Manufacturer: Nihon Kohden Corporation, 1- 31-4 Nishiochiai, Shinjuku-Ku 161-8560 Tokyo, Japan LOA: Sole Agency Agreement Validity date: 31-03-2026 (Copy Notarized) FSC: Japan Issue date: 12-07-2018(Original Notarized) EC Certificate valid until: ISO: Valid till: 05-04-2027(Copy Notarized)	MEB-9600 Electromyography (EMG)/Nerve Conduction Velocity (NCV)/Evoked Potential (EP) Measuring system Class C Applied as: System Shelf Life/service: 10 years	Approved
21.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi (ELI-00691) Date of R& I 14-05.2025 Fee: Rs. `62000/ through slip no. 576556922057	Legal Manufacturer: Shenzhen Antmed Co., Ltd., 18 Jinhul Ave., Pingshan New District, Shenzhen 518122, China LOA: Valid till: 25-02-2030(Copy) FSC: Validity Date: 06-03-2026 (Copy) ISO - Validity Date: EC Certificate Valid till: 26-05- 2024 Copy	V Cure Sterile Peripheral Vascular Radiofrequency Electrosurgical Ablation Catheters Applied as: Single Class C Shelf Life: 2 Years Codes/sizes: VC77100Y, VC7760Y, VC77100N, VC7760N	approved

22.	<p>Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi</p> <p>(ELI-00691)</p> <p>Date of R& I 14-05.2025</p> <p>Fee: Rs.100000/ through slip no. 45781923</p>	<p><u>Legal Manufacturer:</u> Resonant Medical Technology Co.Ltd., Floor No. 4, West G4, 999 Qujia RD, Kunshan, Jiangsu, PR. China</p> <p><u>LOA:</u> Valid till: 25-02-2030(Copy)</p> <p><u>FSC:</u> Validity Date: 06-03-2026 (Copy)</p> <p>ISO - Validity Date: 17-01-2026 Copy</p> <p>EC Certificate Valid till: 26-05-2024 Copy</p>	<p>V Cure Radiofrequency Electrosurgical Ablation System Generators</p> <p>Applied as: System</p> <p>Class C</p> <p>Shelf Life: 5 Years</p> <p>Model: Genesis-V01</p>	<p>Deferred for Clarification for applied product whether system or otherwise</p>
23.	<p>Shirazi Trading Comoany Pvt Ktd, 114 -C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi 75500</p> <p>Godown: 2nd Floor, Nadir House, I.I. Chandrigar Road, Karachi Pakistan</p> <p>(ELI-00263)</p> <p>Fees: Rs 145000 Challan # 472299630577</p> <p>Date of R& I 15-05-2025</p>	<p><u>Legal Manufacturer:</u> Progetti S.R.L, Strada Del Rondello, 5-10028 Trofarello (TO), Italy</p> <p><u>LOA:</u> Sole Agency Agreement Validity date: 31-12-2026 (Original Notarized)</p> <p><u>FSC: Italy</u> Issue date: 22-04-2022(attested)</p> <p>EC Certificate valid until: 26-05-2024(Original Notarized with extension notification)</p> <p><u>ISO:</u> Valid till: 06-06-2026(Copy Notarized)</p>	<p>PG Vent Lung Ventilator</p> <p>Class C</p> <p>Applied as: System</p> <p>Service Life: 10 years</p>	<p>Defereed for clarification of model Number</p>
24.	<p>Combined Engineers, Plot No. 300, Sector No.27, Near National Flour Mills, Korangi Industrial Area,</p>	<p><u>Legal Manufacturer:</u> LargeV Instrument Corp. Limited, A-800B, Tongfang Building QIngHua Yuan, Haidian District Beijing 100084</p>	<p>Dental X-Ray Tomographic System (Smart3D-X)</p> <p>Class C</p>	<p>Deferred for the provision of original documents including notarized LOA, attested FSC,</p>

	Karachi ELI-00377 Fees: Rs 62000 Challan # 4977732964 Date of R& I 15-05-2025	P.R. China <u>LOA:</u> Sole Agency Agreement Validity date: 10-04-2026 (Copy) <u>FSC: China</u> Valid Until: 07-07-2025 (Copy) EU QMS Certificate valid until: 22-09-2029 (Copy) <u>ISO:</u> Valid till: 05-06-2024 (Copy)	Shelf Life: 15 years Model: Smart3D-X	notarized ISO 13485 and notarized CE certificate.
25.	M/s Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi ELI-00019 Date of R& I 13-05-2025 Fee: Rs. 62,000/ through slip no. 0311072476	<u>Legal Manufacturer:</u> M/s Abbott Diabetes Care Ltd., Range Road, Witney, Oxon, OX29 0YL, United Kingdom LOA: Valid till: 30-03-2028 FSC: UK Validity: 12-02-2031 ISO - Validity Date: 28-04-2027 EC Certificate Valid till: 12-02-2030	FreeStyle Libre 2 Plus Flash Glucose Monitoring System (Sensor Kit) Applied as: Lit Class C Shelf Life: 18 months	Approved
26.	M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi ELI-01280 Date of R& I 19-04-2025 Fee: Rs. 62000/ through slip no. 20508/02823	M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea LOA: Valid till: 09-02-2027(Copy) FSC: Korea Issue Date: 27-02-2025 (ORIGINAL) ISO - Validity Date: 28-07-2027 Copy	Biocredit – Dengue NS1 Ag+Ab Duo Test Kit Class C Shelf Life: 24 months Code/sizes: D30RHA10 D30RHA25	Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document.

		EC Certificate Valid till:		
27.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 36988807782</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit – HAV IgG Test Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: A10RHA25</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and attested FSC of country of origin.</p> <p>Original, valid and attested FSC of ref country or valid and notarized CE marked document.</p> <p>Declaration of Conformity.</p> <p>Manufacturing details and stability studies data for the claimed shelf life.</p>
28.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 1975664419</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date: 27-02-2025(Copy)</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit – H. pylori Ag Test Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: 111RHA20</p>	<p>Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document, stability studies data for the claimed shelf life.</p>
29.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea</p>	<p>Biocredit – HIV1/2 Ab Test Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and attested FSC of country of origin.</p> <p>Original, valid and attested FSC of ref</p>

	Date of R& I 19-04-2025 Fee: Rs.62000/ through slip no. 4562116096	ISO - Validity Date: 28-07-2027 Copy EC Certificate Valid till:	Code/sizes: B10RHA25 B10RHA100	country or valid and notarized CE marked document. Declaration of Conformity. Manufacturing details and stability studies data for the claimed shelf life.
30.	M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi ELI-01280 Date of R& I 19-04-2025 Fee: Rs.62000/ through slip no. 09339877048	M/s Rapigen, Inc. 161, Saneop- ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea LOA: Valid till: 09-02-2027(Copy) FSC: Korea Issue Date: 27-02-2025) ISO - Validity Date: 28-07-2027 Copy EC Certificate Valid till:	Biocredit – Malaria Ag Pf (pLDH) Test Kit Class C Shelf Life: 24 months Code/sizes: C14RHA25 C14RHG25 C14RHH25	Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document.
31.	M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi ELI-01280 Date of R& I 19-04-2025 Fee: Rs.62000/ through slip no. 4424081870	M/s Rapigen, Inc. 161, Saneop- ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea LOA: Valid till: 09-02-2027(Copy) FSC: Korea Issue Date ISO - Validity Date: 28-07-2027 Copy EC Certificate Valid till:	Biocredit – HBs Ag Test Kit Generic Name: HBs Ag Test Applied as: Kit Class C Shelf Life: 24 months Code/sizes: A20RHA25 A20RHB100	Deferred for the provision of following: Original, valid and attested FSC of country of origin. Original, valid and attested FSC of ref country or valid and notarized CE marked document. Declaration of Conformity. Manufacturing details and stability studies data for the claimed shelf life.
32.	M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C,	M/s Rapigen, Inc. 161, Saneop- ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do,	Biocredit – Malaria Ag Pf/Pv (Pldh/Pldh) Test Kit	Approved subject to submission of Original, valid and

	<p>Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 8193672742</p>	<p>Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date: 27-02-2025)</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: C61RHA25 C61RHG25 C61RHH25</p>	<p>attested FSC of ref country OR valid and notarized CE marked document.</p>
33.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 77527874027</p>	<p>M/s Rapigen, Inc. 161, Saneop- ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date: 27-02-2025)</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit – Dengue NS1 Ag Test Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: D20RHA25</p>	<p>Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document. .</p>
34.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 00158335392</p>	<p>M/s Rapigen, Inc. 161, Saneop- ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date: 27-02-2025)</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit – Dengue IgG/IgM Test kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: D10RHA25 D10RHG25</p>	<p>Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document. .</p>

35.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 977408515286</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit Anti Hbs Test Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: A21RHA25 A21RHB100</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and attested FSC of country of origin.</p> <p>Original, valid and attested FSC of ref country or valid and notarized CE marked document.</p> <p>Declaration of Conformity.</p> <p>Manufacturing details and stability studies data for the claimed shelf life.</p>
36.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I 19-04-2025</p> <p>Fee: Rs.62000/ through slip no. 157545120</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC:</p> <p>ISO - Validity Date: 28-07-2027 Copy</p> <p>EC Certificate Valid till:</p>	<p>Biocredit – HCV Ab Test Kit</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: A30RHA25 A30RHB100</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and attested FSC of country of origin.</p> <p>Original, valid and attested FSC of ref country or valid and notarized CE marked document.</p> <p>Declaration of Conformity.</p> <p>Manufacturing details and stability studies data for the claimed shelf life.</p>
37.	<p>M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi</p> <p>ELI-01280</p> <p>Date of R& I</p>	<p>M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea</p> <p>LOA: Valid till: 09-02-2027(Copy)</p> <p>FSC: Korea Issue Date: 27-02-2025)</p>	<p>Biocredit – Malaria Ag Pf (Pldh/HRPII) Test kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: C13RHA25 C13RHG25 C13RHH25</p>	<p>Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document.</p>

	19-04-2025 Fee: Rs.62000/ through slip no. 6271887731	ISO - Validity Date: 28-07-2027 Copy EC Certificate Valid till:		
38.	M/s Rosaceae Pharma Pvt. Ltd., Altimi House, Plot No. 21-C, Suite No. 301-A, Khalid Commercial Street No. 4 - Phase 7 Ext., DHA, Karachi ELI-01280 Date of R& I 19-04-2025 Fee: Rs.62000/ through slip no. 8101771310	M/s Rapigen, Inc. 161, Saneop-ro 155 beon-gil, Gwonseon-Gu, Suwon-SI, Gyeonggi-do, Republic of Korea LOA: Valid till: 09-02-2027(Copy) FSC: Korea Issue Date: 27-02-2025) ISO - Validity Date: 28-07-2027 Copy	Biocredit – H. pylori Ab Test Kit Class C Shelf Life: 24 months Code/sizes: I10RHA25 I10RHB100	Approved subject to submission of Original, valid and attested FSC of ref country OR valid and notarized CE marked document.
39.	M/s JAWAD SURGICAL Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913 R&I details 20 MAY 2025 Fee Rs. 31000/ through slip no.3548376389, dated 30-04-2025	Legal Manufacturer: Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA LOA: Validity: 06-MARCH-2030 FSC: Validity: 23-MARCH-2027 ISO-13485: Validity: 28-12-2025 CE (PQA certificate) validity 26-05-2024 with extension notification	NEO MEDICAL Yankauer Handle with Connecting Tube Class-B Shelf Life :5 years Sizes: Tube Length (1.8M, 2.0M, 2.5M, 3M, 3.6M, customized length)	Deferred for the provision of following: FSC of country of origin must be issued by the concerned Regulatory body.
40.	M/s JAWAD SURGICAL Address: Office 13 Naz Medicine Market Namak Mandi	Legal Manufacturer: Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S	NEO MEDICAL (URINE BAG) Class-B Shelf Life :5 years	Deferred for the provision of following: FSC of country of origin must be

	<p>Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no.5469353573, dated 30-04-2025</p>	<p>REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>	<p>Code/ Sizes: 100ML, 500ML, 750ML 1000ML, 2000ML, 2000ml+2600ml+200ml/ 400ml/500ml</p>	<p>issued by the concerned Regulatory body. Fee needs to be revised for Family.</p> <p>The subject device falls in Class-A. Revise the application on prescribed Form-6A.</p>
41.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no.83287069847, dated 30-04-2025</p>	<p>Legal Manufacturer: Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>	<p>NEO MEDICAL Infusion Set</p> <p>Class-B</p> <p>Shelf Life :5 years</p> <p>Code/ Sizes: IV Burette 100ML/150ML</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body. The applied product is not mentioned in the CE certificate, clarification is required.</p>
42.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no. 919932555504, dated 30-04-2025</p>	<p>Legal Manufacturer: Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension</p>	<p>NEO MEDICAL (Infusion Set with Barrette)</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Code/ Sizes: IV burette 100ML/150ML</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body. The applied product is not mentioned in the CE certificate, clarification is required. The same is also not clear in the FSC.</p>

		notification		
43.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no. 385734274904, dated 30-04-2025</p>	<p><u>Legal Manufacturer:</u> Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>	<p>NEO MEDICAL Oxygen Mask</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Models: Oxygen Mask, Venturi Mask, Non-rebreathing Mask</p> <p>Sizes: XL, L, M, S</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body. The applied product includes Simple oxygen mask, Venturi mask and Non-rebreathing mask, specify your priority in this application and apply separately for others.</p>
44.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no. 686730580799, dated 30-04-2025</p>	<p><u>Legal Manufacturer:</u> Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>	<p>NEO MEDICAL Nasal Oxygen Cannula</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Sizes: L, S, XS, XXS</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body.</p>
45.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p>	<p><u>Legal Manufacturer:</u> Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p>	<p>NEO MEDICAL Nebulizer Mask</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Sizes: XL, L, M, S</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body.</p>

	<p>Fee Rs. 31000/ through slip no. 66238651458, dated 30-04-2025</p>	<p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>		
46.	<p>M/s JAWAD SURGICAL</p> <p>Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 20 MAY 2025</p> <p>Fee Rs. 31000/ through slip no. 195593070437, dated 30-04-2025</p>	<p>Legal Manufacturer: Ningbo Great Mountain Medical Instruments Co.,Ltd No.309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA: Validity: 06-MARCH-2030</p> <p>FSC: Validity: 23-MARCH-2027</p> <p>ISO-13485: Validity: 28-12-2025</p> <p>CE (PQA certificate) validity 26-05-2024 with extension notification</p>	<p>NEO MEDICAL HME Filter/ Respiratory Filter</p> <p>Class-B</p> <p>Shelf Life :5 years</p> <p>Models & Sizes: Silicone/Latex, Fr8-FR26 Models:</p>	<p>Deferred for the provision of following:</p> <p>FSC of country of origin must be issued by the concerned Regulatory body. The applied product includes both Silicon and Latex types. specify your priority in this application and apply separately for other.</p>
47.	<p>Microport Scientific Pakistan Pvt. Ltd., Office No. 02/03, 2nd Floor, Hive Gizri Road, Block 9, Clifton Karachi</p> <p>ELI-01182</p> <p>Date of R& I 06-05.2025</p> <p>Fee: Rs.100000/ through slip no. 33190092746</p>	<p>Legal Manufacturer: Hemovent GmbH, Pascalstrasse 59, 52076, Aachen, Germany.</p> <p>LOA: Valid till: 31-12-2025 (Copy)</p> <p>FSC: Not Provided</p> <p>ISO - Validity Date: 17-09-2027(Copy)</p> <p>EU Quality Management Certificate: 22-06-2027 (Copy)</p>	<p>MobyBox Systems ECMO System</p> <p>Class C</p> <p>Shelf Life 24 months</p> <p>Part number as per the EU/CE and DoC provided: HVEU-009</p> <p>Component: MOBYBOX Part number: HVEL-006</p> <p>Component: MOBYBOX Runner, analog Part number: HVCEU-003</p> <p>Component:</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, ISO 13485 and EU certificates.</p> <p>Original, valid and attested FSC of Germany.</p>

			MOBYBOX Runner, digital Part number: HVCEU-005	
48.	<p>Microport Scientific Pakistan Pvt. Ltd., Office No. 02/03, 2nd Floor, Hive Gizri Road, Block 9, Clifton Karachi</p> <p>ELI-01182</p> <p>Date of R& I 06-05.2025</p> <p>Fee: Rs.100000/ through slip no. 33190092746</p>	<p><u>Legal Manufacturer:</u> Hemovent GmbH, Pascalstrasse 59, 52076, Aachen, Germany.</p> <p><u>LOA:</u> Valid till: 31-12-2025 (Copy)</p> <p><u>FSC:</u> Not Provided</p> <p>ISO - Validity Date: 17-09-2027(Copy)</p> <p>EU Quality Management Certificate: 22-06-2027 (Copy)</p> <p>EC Certificate Valid till:</p>	<p>MobyBox System ECMO System</p> <p>Applied as: System Class C Shelf Life 24 months</p> <p>Code/sizes/ model: Not mentioned</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, ISO 13485 and EU certificates.</p> <p>Original, valid and attested FSC of Germany.</p>
49.	<p>Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore.</p> <p>ELI-00130</p> <p>Fees: Rs 62000 Challan 341787471002</p> <p>Date of R& I 05-05-2025</p>	<p><u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd</p> <p>Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China.</p> <p><u>LOA:</u> Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized)</p> <p><u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) <u>FSC: Spain</u> Issue date:12-03-2024 (Original Notarized)</p> <p>EC Certificate valid until:05-08-2029 (Original Notarized)</p>	<p>BIOSKY DISPOSABLE HEMOPERFUSION CARTRIDGE -</p> <p>Class C</p> <p>Shelf Life: 3 years</p> <p>Codes/Sizes: MG80, MG100, MG120, MG130, MG150, MG180, MG200, MG230, MG250, MG280, MG300, MG330, MG350, MG380, MG400</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA.</p> <p>Fee as per revised SRO for Family.</p>

		<u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)		
50.	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 Fees: Rs 62000 Challan # 287678899 Date of R& I 05-05-2025	<u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China. <u>LOA:</u> Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized) <u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) FSC: Spain Issue date:12-03-2024 (Original Notarized) EC Certificate valid until:05-08-2029 (Original Notarized) <u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)	Biosky-Disposable Bilirubin Adsorption Column Class C Shelf Life: 3 years Codes/Sizes: DX100, DX150, DX250, DX350, DX400	Deferred for the provision of following: Original, valid and notarized LOA. Fee as per revised SRO for Family.
51.	Medzntech Pvt.Ltd., D-21 Sector 16-A Govt. Teachers CO-operative Housing Society, KDA Scheme 33, Karachi (ELI-00657) Fees: Rs 62000 Challan # 99957955755 Date of R& I	<u>Legal Manufacturer:</u> Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX, USA 76134 Other Sites: PT CIBA Vision Batam, JI. Berinjin Lot # 204, Batamindo Industrial Park, Muka Kuning, Batam Islamabd, Indonesia <u>LOA:</u> Sole Agency Agreement Issue date: 09-01-2024 (Original notarized)	Laser Probes 8065750978-25 GA Straight Laser Probe w/RFID 8065750985-20 GA Curved Illuminated Laser Probe w/RFID SMA/RFID-ACMI 8065750989 – 20 GA Curved Laser Probe w/RFID 8065750990 – 20 GA Straight Laser Probe w/RFID	Deferred for the provision of following: Description of the applied Laser probes is not provided. Clarification/ justification of applying the subject product in Set. Shelf life of the product.

	05-05-2025	<p><u>FSC: USA</u> Valid Until: 08-05-2025 (Original Notarized)</p> <p>EC Certificate valid until:23-06-2027 (Original Notarized)</p> <p><u>ISO:</u> Valid till: 24-04-2025 (Original Notarized)</p>	<p>Applied as: Set</p> <p>Class C</p> <p>Shelf Life:</p> <p>Codes/Sizes: 8065750978-25 GA Straight Laser Probe w/RFID</p> <p>8065750985-20 GA Curved Illuminated Laser Probe w/RFID SMA/RFID-ACMI</p> <p>8065750989 - 20 GA Curved Laser Probe w/RFID</p> <p>8065750990 - 20 GA Straight Laser Probe w/RFID</p>	
52.	<p>Medzntech Pvt.Ltd., D-21 Sector 16-A Govt. Teachers CO- operative Housing Society, KDA Scheme 33, Karachi</p> <p>(ELI-00657)</p> <p>Fees: Rs 62000 Challan # 96250745</p> <p>Date of R& I 05-05-2025</p>	<p><u>Legal Manufacturer:</u> Kirwan Surgical Products LLC, 180 Enterpriser Dr., PO BOX 427, Marshfield, MA, USA</p> <p><u>LOA:</u> Sole Agency Agreement Issue date: 21-02-2024 (Original notarized)</p> <p><u>FSC: USA</u> Valid Until: 03-12-2025(Original Notarized)</p> <p>EC Certificate valid until:24-05- 2024 (Original Notarized)</p> <p><u>ISO:</u> Valid till: 30-03-2024 (Original Notarized)</p>	<p>Bipolar Products Generic Name: 8065128402 - Reusable Bi-Polar Cable, 3.66M (12 Feet) Silicone</p> <p>8065127501 - 102mm (4") Straight Jewelers, 0.4mm Tip</p> <p>8065129101 - Curved Jewelers / Iris Bipolar Forceps</p> <p>Applied as : Set</p> <p>Class C</p> <p>Shelf Life:</p> <p>Codes/Sizes: 8065128402 - Reusable Bi-Polar Cable, 3.66M (12 Feet) Silicone</p>	<p>Deferred for the provision of following:</p> <p>Description of the applied products is not provided.</p> <p>Clarification/ justification of applying the subject product in Set as per FSC.</p> <p>Shelf life of the product.</p>

			8065127501 - 102mm (4") Straight Jewelers, 0.4mm Tip 8065129101 - Curved Jewelers / Iris Bipolar Forceps	
53.	M/s Medco, 19-Khyber Bazar Peshawar ELI-00686 Date of R& I 19-05-2025 Fee: Rs.31000/ through slip no. 09271620709 and Rs. 31000 70206399529	<u>Legal Manufacturer:</u> M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro, Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea LOA: Valid till: 31-12-2030 FSC: Validity: ISO - Validity Date: 22-01-2026 EC Certificate Valid till: 05-06-2024	GEMSS Stationary X-Ray System XVision-525 Digital X-Ray Machine Applied as: Single Class-C Shelf Life: Model: XVision-525	Deferred for the provision of following: Original and notarized LOA. Notarized CE/FQA/Production QA certificate.
54.	M/s Medco, 19-Khyber Bazar Peshawar ELI-00686 Date of R& I 19-05-2025 Fee: Rs.50000/ through slip no. 20521777101 and Rs. 62000 7607854166	<u>Legal Manufacturer:</u> M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro, Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea LOA: Valid till: 31-12-2030 FSC: Validity: Not provided ISO - Validity Date: 22-01-2026 EC Certificate Valid till: 05-06-2024	GEMSS Image Intensified Fluoroscopic X-Ray System (Mobile C-Arm) Class-C Shelf Life: Code/sizes: XPLUS 35 XPLUS 35FD	Deferred for the provision of following: Original and notarized LOA. Notarized CE/FQA/Production QA certificate.
55.	Applicant Name:	<u>Legal Manufacturer:</u> M/s Ecotron Co. Ltd., 505Ho,	Ecotron Image Intensified Fluoroscopic X-Ray	Deferred for the provision of

	<p>M/s Medco, 19-Kyber Bazar, Peshawar</p> <p>ELI-00686</p> <p>Date of R&I 19-05-2025</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 7170434627</p>	<p>Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-gu, Seoul, 08511, Korea.</p> <p>LOA Validity: 14-05-2029</p> <p>FSC: missing</p> <p>ISO Validity: 18-02-2028</p> <p>EC Certificate Validity: N/A</p>	<p>System (Mobile C-Arm) Anyview Series Anyview 500DR, Anyview 500R, Anyview 240DR & Anyview 320DR</p> <p>Mobile C-Arm</p> <p>Class-B</p> <p>Shelf life: 10 Years</p> <p>Models/specifications: Anyview 500DR, Anyview 500R, Anyview 240DR Anyview 320DR</p>	<p>following:</p> <p>Original and notarized LOA.</p> <p>Notarized CE/FQA/Production QA certificate.</p>
56.	<p>Name of Importer M/s Mian Scientific Corporation (PVT) Ltd Address of Importer: 534-Jinnah Colony Faisalabad, 38030, Pakistan.</p> <p>(ELI-00442)</p> <p>R&I Dated: 28 JAN 2021</p> <p>Fee Challan No.: 2070371 PKR: 50,000/-</p>	<p>Legal Manufacturer: Name: Wuxi BioHerms Bio & Medical Technology CO., Ltd. Address : No.136, Mashan Meiliang Road Binhu, Wuxi 214092, Jiangsu china.</p> <p>LOA Validity: February 28, 2026</p> <p>FSC China Validity: 26-04-2025</p>	<p>Name of Medical device BioHermes A1c Chek Pro Glycohemoglobin Analyzer</p> <p>Class: C</p> <p>Shelf life: 5 Year</p> <p>Model: A1c EZ Auto 4,A1c EZ Auto 4W,A1c EZ Auto 4G,A1c Auto 4GW</p>	<p>Deferred for the provision of following:</p> <p>Original and attested FSC.</p> <p>Notarized ISO 13485 certificate</p> <p>Notarized FQA certificate.</p> <p>Specify the model required in this application and apply separately for others.</p>
57.	<p>Name of Importer M/s Mian Scientific Corporation (PVT) Ltd Address of Importer: 534-Jinnah Colony Faisalabad, 38030, Pakistan.</p> <p>(ELI-00442)</p> <p>R&I Dated: 28 JAN 2021</p> <p>Fee Challan No.: 2070372 PKR: 50,000/-</p>	<p>Legal Manufacturer: Name: Wuxi BioHerms Bio & Medical Technology CO., Ltd. Address : No.136, Mashan Meiliang Road Binhu, Wuxi 214092, Jiangsu china.</p> <p>LOA Validity: February 28, 2026</p> <p>FSC China Validity: 04-08-2026</p> <p>ISO 13485 validity 10-06-2028</p> <p>CE extension notification.</p>	<p>Name of Medical device BioHermes A1c Chek Pro Glycohemoglobin Test Kit</p> <p>Class: C</p> <p>Shelf life: 24 Month</p> <p>Sizes: 50 tests,100 tests,200 tests</p>	<p>Deferred for the provision of following:</p> <p>Original and attested FSC.</p> <p>Notarized ISO 13485 certificate</p> <p>Notarized FQA certificate.</p>

58.	<p>Name of Importer M/s Mian Scientific Corporation (PVT) Ltd Address of Importer: 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442)</p> <p>R&I Dated: 22 FEB 2021</p> <p>Fee Challan No.: 2107656 PKR: 50,000/-</p>	<p>Legal Manufacturer: Name: YASEE Biomedical, Inc.</p> <p>Address: No.9, Xiuyuan Road, High-tech Industrial Development Zone, Qingdao City, Shandong Province, China.</p> <p>LOA Validity: February 28th 2027</p> <p>FSC China Validity: 19-01-2026</p> <p>ISO 13485 validity 25-04-2026</p> <p>CE extension notification</p>	<p>Name of Medical device True Answer Blood Glucose Test Strip</p> <p>Class: C</p> <p>Shelf life: 24 Month</p> <p>Model: GLS-78</p>	Approved
59.	<p>Name of Importer M/s Mian Scientific Corporation (PVT) Ltd Address of Importer: 534-Jinnah Colony Faisalabad, 38030, Pakistan. (ELI-00442)</p> <p>R&I Dated: 11 JAN 2021</p> <p>Fee Challan No.: 2077471 PKR: 25,000/-</p>	<p>Legal Manufacturer: Name: Getein Biotech, Inc</p> <p>Address: No.9 Bofu Road, Luhe District, Nanjing,211505 China.</p> <p>LOA Validity: 20 April, 2026</p> <p>FSC Spain (issuance 27-08-2024)</p> <p>ISO 13485 validity 25-07-2026</p>	<p>Name of Medical device Getein CEA Fast Test Kit</p> <p>Class: C</p> <p>Shelf life: 24 Month</p> <p>Sizes: 1TEST/KIT, 3TEST/KIT, 5TEST/KIT, 10TEST/KIT, 25TEST/KIT, 50TEST/KIT,100TEST/K IT</p>	Approved
60.	<p>Applicant Name:</p> <p>Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes)</p> <p>ELI-01186 (yes)</p> <p>Date of R&I</p>	<p>Name of Manufacturer:</p> <p>GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes)</p> <p>Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes)</p> <p>LOA Validity: 30-12-2029 (Copy) (yes)</p> <p>FSC: Turkey</p>	<p>Brand name:</p> <p>S&J PA Sterile Surgical Suture (yes)</p> <p>Generic Name: Non-Absorbable Polypropylene Surgical Suture (yes)</p> <p>Class:D</p> <p>Shelf life: 5 years</p>	Deferred for clarification of the brand name since the brand name applied and the name in the FSC is not similar.

	26-05-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 86456446	Validity: 1-03-2027 (yes) APOSTILLE ATTACHED ISO Validity: 24-08-2025 (yes) notarized EU QA/ EC Certificate Validity: 27-05-2024 notarized EU Design examination Certificate notarized Validity: 27-05-2024 Extension letter given	Models/ Specification	
61.	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 (yes) Fee Details: Paid Fee: 62,000/- 6670451321 (yes)	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes) Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China LOA Validity: 30-12-2029 (Copy) (yes) FSC: Turkey Validity: 1-03-2027 (Copy) (yes) APOSTILLE ATTACHED(copy) ISO Validity: 24-08-2025 (Copy) (yes) EU QA/ EC Certificate Validity: 27-05-2024 (yes)	Brand name: S&J PDO Sterile Surgical Suture Generic Name: Absorbable Polydioxanone Monofilament Surgical Suture (yes) Class-D (yes) Shelf life: 5 years Models/ Specification	Deferred for clarification of the brand name since the applied name and the name in the FSC is not similar. Clarify the shelf life as well since the submitted studies is of three years not five years.
62.	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 (yes)	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes) Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China LOA Validity:	Brand name: S&J PE Sterile Surgical Suture Generic Name: Non- Absorbable Polyester Surgical Suture (yes) Class-D Shelf life: 5 year Models/ Specification	Deferred for clarification of the brand name since the applied name and the name in the FSC is not similar.

	<p>Fee Details: Paid Fee: 62,000/- 7587015702 (yes)</p>	<p>30-12-2029 (Original) (yes)</p> <p>FSC: Turkey Validity: 1-03-2027 (Original) (yes) not original APOSTILLE ATTACHED(copy)</p> <p>ISO Validity: 24-08-2025 (Copy) (yes)</p> <p>EU QA/ EC Certificate Validity: 27-05-2024 (yes) copy</p>		
63.	<p>Applicant Name:</p> <p>Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes)</p> <p>ELI-01186 (yes)</p> <p>Date of R&I 26-05-2025 (yes)</p> <p>Fee Details: Paid Fee: 62,000/- 7587015702 (no)</p>	<p>Name of Manufacturer:</p> <p>GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi</p> <p>Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes)</p> <p>GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China</p> <p>LOA Validity: 30-12-2029 (Copy) (yes)</p> <p>FSC: Turkey Validity: 1-03-2027 (Copy) (yes) APOSTILLE ATTACHED(copy)</p> <p>ISO Validity: 24-08-2025 (Copy) (yes)</p> <p>EU QA/ EC Certificate Validity: 27-05-2024 (yes) copy</p>	<p>Brand name:</p> <p>S&J PGLA Rapid Sterile Surgical Suture (yes)</p> <p>Generic Name: Absorbable Polyglactin 910 Rapid Surgical Suture (yes)</p> <p>Class-D (yes)</p> <p>Shelf life: 5 years</p> <p>Models/ Specification</p>	<p>Deferred for clarification of the brand name since the applied name and the name in the FSC is not similar.</p>
64.	<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 26-05- 2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No.</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. As per fsc</p> <p>Free Sale Certificate valid upto 17/02/2026 issued by Peoples Republic of China (copy) (apostille attached)</p> <p>ISO 13485 valid up to 15/03/2027. (apostille aattached) (copy)</p>	<p>Disposable Linear Cutting Staplers & Reloads.</p> <p>Class D</p> <p>Shelf life: Storage Conditions: 36 Months (Room temperature)</p>	<p>Deferred for submission of the Valid and notarized FQA. The firm shall separately apply for the reloads along with the fee.</p>

	4632704052: Dated: (21/05/2025)	Declaration of conformity: Issuance date:(26/05/2021) Letter of authorization valid up to 13/01/2028 (Notarized) (copy)		
65.	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. (yes) ELI-01011</p> <p>R& I dated 08-05- 2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 328440652458</p>	<p>Legal Manufacturer: Cochlear Limited</p> <p>Address: 1 University Avenue, Macquarie University, NSW 2109, Australia.</p> <p>Manufacturing Site: Cochlear Malaysia Sdn Bhd, Kuala Lumpur Malaysia,</p> <p>Unit UG-1, Upper Ground Floor, Vertical Podium, the Vertical, Avenue 3, Bangsar South, No. 8 Jalan Kerinchi, 59200 Kuala Lumpur, Malaysia.</p> <p>LOA Validity: 30-11-2026(Apostilled)</p> <p>FSC: Australia Issue date: 17-12-2024 APOSTILLE Attached (original) ISO Validity: 14-07-2026 (Original)</p> <p>EU QA/ EC Certificate Validity: 05-08-2026 (Original)</p> <p>EU Tech doc assessment cert valididty 09.02.2028</p>	<p>Brand name: Kanso CP950</p> <p>Generic Name: Cochlear Implant system sound processor (yes)</p> <p>Class-D (yes) Shelf life: N/a (yes)</p> <p>Models/ Specification</p>	<p>Approved subject to submission of the differential fee of RS 38000/- since the product is applied as system</p>
66.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI</p> <p>(ELI-01292) (yes)</p> <p>R& I dated 22-05- 2025</p>	<p>Legal Manufacturer: M/s Vascular Innovations Co., LTd., 88/38 Moo 1, 345 Road, Bangtanai Sup-District, Pakkret District, Nonthaburi 11120 Thailand.</p> <p>Site 2: (Sterilization Process): Siam Steri Service Co., Ltd., (SIS) Address 700/644, Amata city Chonburi, Moo 3 Tambol Bankao, Amphur Pantong, Chonburi 20160, Thailand.</p>	<p>Brand name: Hydra Aortic Valve Loading System</p> <p>Generic Name: Aortic Valve Loading System HYDRA 18VLS</p> <p>Class-D</p> <p>Shelf life: 2 Years</p> <p>Models/ Specification</p>	<p>Already addressed in 77 meeting</p>

	<p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 5971544804</p>	<p>LOA Validity: 28-08-2026(copy)</p> <p>FSC: Thailand Validity: 13-11-2026 Embassy attested (copy)</p>		
67.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (yes)</p> <p>(ELI-01292) (yes)</p> <p>R& I dated 22-05-2025 (yes)</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 7035422885 (yes)</p>	<p>Legal Manufacturer: M/s Vascular Innovations Co., LTd., 88/38 Moo 1, 345 Road, Bangtanai Sup-District, Pakkret District, Nonthaburi 11120 Thailand</p> <p>Site 2: (Sterilization Process): Siam Steri Service Co., Ltd., (SIS) Address 700/644, Amata city Chonburi, Moo 3 Tambol Bankao, Amphur Pantong, Chonburi 20160</p> <p>LOA Validity: 08-08-2026(copy)</p> <p>FSC: Thailand Validity: 13-11-2026(copy))</p>	<p>Brand name: Hydra Aortic Valve Delivery Catheter (yes)</p> <p>Generic Name: Aortic Valve Delivery Catheter (yes)</p> <p>Class-D (yes)</p> <p>Shelf life: 2 Years (yes)</p> <p>Models/ Specification</p>	<p>Already addressed in 77 meeting</p>
68.	<p>M/s E-Dental Mart, 38/B Street No. 26, Block-D, Phase 1, DHA, Lahore (yes)</p> <p>ELI-00968</p> <p>R& I dated 19-05-2025</p> <p>Fee details: Amount paid: PKR 31,000 /- Paid Slip/ challan No. 2188649960</p>	<p>Legal Manufacturer: M/s Diadent Group International., 16, Osongsaengmyeong 4-ro, Osongjeup, Heungdeok-Gu, Chongju-si, Chungcheongbuk-do, 28161, Republic of Korea.</p> <p>LOA Issue Date: 17-04-2025 (copy) (yes)</p> <p>FSC: Korea Issue date: 16-04-2025(copy) (yes) (APOSTILLE ATTACHED)</p> <p>ISO Validity: NA</p> <p>EU QA/ EC Certificate Validity: 26-05-2024</p>	<p>Brand name: Gutta Percha Point (Yes)</p> <p>Generic Name: Gutta Percha Point (yes)</p> <p>Class-D (yes)</p> <p>Shelf life:</p> <p>Models/ Specification</p>	<p>Deferred for submission of the following documents.</p> <p>1. Notarized and valid ISO 13485, Design examination, LOA. 2. Apostilled / embassy attested valid FSC Clarify the shelf life and the class of the Device</p>

69.	<p>M/s Cardiac Care, 848-C Shadman-1, Lahore, Pakistan (yes)</p> <p>ELI-00070 (yes)</p> <p>R& I dated 23-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 22528084315</p>	<p>Legal Manufacturer:</p> <p>M/s Royal Fornia Medical Equipment Co., LTd., Fornia Tech Park, No. 18 Kejiyi Road, Hi-Tech Innovation Coast Tangjia Bay, Zhuhai, Guangdong, 519085, China (yes)</p> <p>LOA Validity: 30-03-2028 (original) (yes)</p> <p>FSC: China Validity: 13-11-2026 (Apostilled) (yes)</p> <p>ISO Validity: 27-04-2028 (Original) (yes)</p> <p>EU QA/ EC Certificate Validity: 10-10-2027 (Original) (yes)</p> <p>EU Tech docum asses Certificate Validity: 10-10-2027 (Original) (yes)</p>	<p>Brand name:</p> <p>Disposable Central Venous Catheter Kit</p> <p>Generic Name: Central Venous Catheter Kit</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Approved subject to submission of the stability studies</p>
70.	<p>M/s M.A Traders. Khan g Archade main Gul Bahar Road back side Gul bahar Police Station, Peshawar.</p> <p>ELI-00601</p> <p>R& I dated 20-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 56029411766</p>	<p>Legal Manufacturer:</p> <p>M/s Gundong baihe medical Technology CO ,ltd No 89,TA O yal –east road, NANhai,fushan gundong province , china.</p> <p>LOA Validity: 31-01-2029 (Copy)</p> <p>FSC: China Validity: 16-07-2026 (Copy) (APOSTILLE ATTACHED)(copy)</p> <p>ISO Validity:</p> <p>EU QA/ EC Certificate Validity: 27.05.2024 (Copy)</p>	<p>Brand name:</p> <p>Med Surg</p> <p>Generic Name: Central Venous Catheter Kit (Quad Lumen) Class-D (yes)</p> <p>Shelf life: 5 years</p> <p>Models/ Specification</p>	<p>Deferred for submission of the following documents.</p> <p>1.Notarized and valid ISO 13485, Design examination, LOA. 2.Apostilled / embassy attested valid FSC</p>
71.	<p>M/s Cor-Med, 2nd Floor , 38-62 Rehman</p>	<p>Legal Manufacturer:</p>	<p>Brand name:</p>	<p>Deferred for submission of the</p>

	<p>Plaza Bank Road, Saddar, Rawalpindi</p> <p>ELI-00226</p> <p>R& I dated 19-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 309334770</p>	<p>M/s Life Tech Scientific (Shenzhen) Co., Ltd., 8F, Life Tech Scientific Building No. 22, Keji 12th Road South, High-Tech Industrial Park, Yuehai Sub District, Nanshan District, Shenzhen 518063 China</p> <p>LOA Validity: 31-12-2026 (Copy) Notarized</p> <p>FSC: China Validity: 18-12-2024 (Copy)</p> <p>ISO Validity: 03-08-2026 (Copy)</p> <p>EU QA/ EC Certificate Validity: 26-05-2024 (Copy)</p>	<p>Cera PFO Occluder</p> <p>Generic Name: CERA PFO Occluder</p> <p>Class-D</p> <p>Shelf life:</p> <p>Models/ Specification</p>	<p>following documents.</p> <p>1. Notarized and valid ISO 13485, Design examination, LOA.</p> <p>2. Apostilled / embassy attested valid FSC issued by the regulatory authority, reflecting the applied product on free sale. Also Clarify the shelf life and submit stability studies .</p>
72.	<p>M/s KASBN International, (yes)</p> <p>42-A1 Gulberg III Lahore. (yes)</p> <p>ELI-00434</p> <p>R& I dated 20-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 393214462</p>	<p>Legal Manufacturer:</p> <p>M/s Iberhospitex S.A. Av. Catalunya, 4, 08185 Llica de Vall, Barcelona, Spain (yes)</p> <p>LOA Validity: 31-12-2029 (Original)</p> <p>FSC: 3 Spain FSC (embassy attested)</p> <p>1. Issue date: 23.11.2022 FSC no CFYTTSQDEA 18 pages</p> <p>2. Issue date: 25.4.2024 FSC no 7WX8V7L533</p> <p>3. Issuance date : 14.06.2023 FSC no. CE67GAX82D</p> <p>ISO Validity: 16-02-2027 copy</p> <p>EU QA/ EC Certificate Validity: 16.2.2024 Extension letter provided</p> <p>Design exam valid till 16.2.2024 Extension letter provided</p> <p>LOA valid till 31-12-2029. Notarized</p>	<p>Brand name:</p> <p>Coronary Stent System Dilation Catheter Guiding catheter extension thrombus extension catheter</p> <p>Generic Name: Heart Stents and Catheter (yes)</p> <p>Class-D (yes)</p> <p>Shelf life: N/A</p> <p>Models/ Specification</p>	<p>Deferred for submission of the following documents.</p> <p>Multiple application submitted in one applications justify under the MDR 2017 or apply separately as per name in the FSC with applicable fee, since the name in the fee challan is not similar with the applied name.</p> <p>Clarify the shelf life with stability studies.</p>
73.	<p>M/s Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough MA 01752, USA</p>	<p>Brand name:</p> <p>Watchman FXD Curve Access System Access</p>	<p>Approved subject to submission of the differential fee of RS 38000/- since the</p>

	<p>(KPK)-Pakistan.</p> <p>ELI-00120</p> <p>R& I dated 19-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 25029453808</p>	<p>Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA</p> <p>LOA Validity: 31-12-2025(Copy)</p> <p>FSC: Ireland Issue date: 13-05-2024(Original apostilled)</p> <p>ISO Validity: 23-03-2027(Copy)</p> <p>EU QA/ EC Certificate Validity: 21-04-2027</p> <p>EU tech docu assessment Certificate Validity: 21-04-2027</p>	<p>Sheath with Dilator</p> <p>Generic Name: Cardiac Occluder Delivery Kit</p> <p>Class-D</p> <p>Shelf life: 3 years (yes)</p> <p>Models/ Specification</p>	<p>product is applied as system.</p>
74.	<p>M/s Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK)-Pakistan.</p> <p>ELI-00120 (yes)</p> <p>R& I dated 19-05-2025 (yes)</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 25029453808</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough MA 01752, USA</p> <p>Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA</p> <p>FSC: Ireland Issue date: 13-05-2024 (Apostilled) LOA Validity: 31-12-2025(Copy)</p> <p>ISO Validity: 23-03-2027(Copy)</p> <p>EU QA/ EC Certificate Validity: 21-04-2027</p> <p>EU tech docu assessment Certificate Validity: 21-04-2027</p>	<p>Brand name:</p> <p>Stingray LP Catheter</p> <p>Generic Name: Vascular Guide-Catheter</p> <p>Class-D (yes)</p> <p>Shelf life: 24 months</p> <p>Models/ Specification</p>	<p>Approved</p>
75.	<p>M/s EV Solutions (Private) Limited, Apartment # 307, 3rd Floor, Gulberg Empire, Civic Center, Gulberg</p>	<p>M/S Jiangsu Guanchuang Medical Technology Co., Ltd. 2D, Wujin Science & Technology Park No 256, Mingxin Middle Road, Hutang,</p>	<p>Disposable Circular Staplers.</p> <p>Class-D</p>	<p>Deferred for submission of the FQA or FSC of reference regulatory authority and also</p>

	<p>Greens, Islamabad. (yes)</p> <p>ELI-01382(yes)</p> <p>R& I dated 23-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 359671276: Dated: (21/05/2025)</p>	<p>Changzhou, Jiangsu Peoples Republic of China.(yes)</p> <p>Free Sale Certificate valid upto 17/02/2026 issued by Peoples Republic of China(yes)</p> <p>ISO 13485 valid up to 15/03/2027.(yes)(copy)</p> <p>Declaration of conformity: Issuance date:(26/05/2021) (yes)(copy)</p> <p>Letter of authorization valid up to 13/01/2028 (yes)(copy)</p>	<p>Shelf life: Shelf life is 2 years from the date of sterility.</p> <p>Storage Conditions: 36 Months (Room temperature)</p>	<p>clarify the class of the product.</p>
76.	<p>Applicant Name:</p> <p>M/s PharmEvo Pvt. Ltd., Plot no. A-29, North Western Industrial Zone, Port Qasim, Karachi</p> <p>(ELI-00055)</p> <p>Date of R& I 16-05-2025</p> <p>Fee: PKR 62000/- + 38000/- Slip # 1787857387 & 58961061</p> <p>Total fee: 100,000.</p>	<p>Legal Manufacturer:</p> <p>MicroTech Medical (Hangzhou) Co., Ltd.,</p> <p>Manufacturing Site: No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang P.R. China.</p> <p>FSC (China): Validity: 17 Jan 2027</p> <p>CE Certificate Validity: 03 Sep 2029</p> <p>ISO 13485 Validity: 23-04-2026</p> <p>LOA Validity: 07-01-2028</p>	<p>Brand name:</p> <p>Evocheck Premium Linx (GX-01S)</p> <p>Generic Name: Continuous Glucose Monitoring System Sensor</p> <p>With LinX Continuous Glucose Monitoring App.</p> <p>Class-C</p> <p>Model: (GX-01S)</p> <p>Shelf Life: 16 months</p>	<p>Approved</p>
77.	<p>AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi</p>	<p>Shenzhen Dongdixin Technology Co., Ltd., Floor 1-2, No.3 Building, Fansheen Xusheng Industrial Estate Xilixiaobaimang, Nanshan District, 518108, Shenzhen,</p>	<p>Brand name:</p> <p>Nu-Tek</p> <p>Generic Name: Laser Therapy Device</p>	<p>Approved subject to submission of service life / shelf life.</p>

	ELI-01131 Date of R&I 19-05-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 5338947809	People's Republic of China LOA Validity: 27-11-2025 FSC: USA Validity: 11-11-2026 ISO Validity: 04-02-2028 EC Certificate / EU QA Certificate Validity: 26-05-2024	Class-B Shelf life: N/a Models/ Specification: LS2100	
78.	AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi ELI-01131 Date of R&I 19-05-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 03998864	Shenzhen Dongdixin Technology Co., Ltd., Floor 1- 2, No.3 Building, Fansheen Xusheng Industrial Estate Xilixiaobaimang, Nanshan District, 518108, Shenzhen, People's Republic of China LOA Validity: 27-11-2025 FSC: China Validity: 27-08-2025 ISO Validity: 04-02-2028 EU QA Certificate Validity: 26-05-2024	Brand name: Nu-Tek Generic Name: Ultrasound and Electrical Neuromuscular Stimulator Class-B Shelf life: N/a Models/ Specification UT2200 MT2200 CT2200	Deffered for following. Justification required for applying multiple models in single application. Service life / shelf life details.
79.	Business Medical International, Suite 101/102 Trade Centre, Plot 23/F Commercial Area M.A.C.H.S Karachi (ELI-00262) Date of R&I 06-05-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No. 9449475107	National Biological Corporation, 23700 Mercantile Rd, Beachwood, OH 44122, USA LOA Issuance: 17-02-2025 FSC: Not provided Validity: ISO Validity: 14-04-2025 EU QA Certificate Validity: Not Provided	Brand name: UV Phototherapy System Generic Name: UV Phototherapy System Class-B Shelf life / service life: Models/ Specification HOUVA 4, HOUVA II, PANASOL 6', PANASOL II 6', HANDISOL II, HAND/FOOT, DERMALUME, DERMALIGHT	Deffered for following. Firm shall submit Legalized / apostile FSC. Firm shall submit notarized copy of LOA, ISO 13485 Certificate, EC Certificate, Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.

				<p>Justification required for applying multiple models in single application.</p> <p>Service life / shelf life details.</p>
80.	<p>M/s Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar, Niaz Town Multan</p> <p>(ELI-00879)</p> <p>Date of R&I 08-05-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No. 09797077</p>	<p>M/s Anhui Deepblue Medical Technology Co. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei Anhui, China</p> <p>LOA Issuance: 23-03-2028</p> <p>FSC: China Validity: 28-10-2026</p> <p>ISO Validity: 21-06-2027</p> <p>EU QA Certificate Validity: 26-05-2025</p>	<p>Brand name: HCg Test Kit</p> <p>Generic Name: Human Chorionic Gonadotropin Test Kit</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Models/ Specification: Strip Type: 1. Copy/Bag, 2/3/5/10/20/50/100</p> <p>Midstream Type: 1. Copy/Box, 2. Copies/Box;</p> <p>Casset Type: 1. Copy/box 2. Copies /box</p>	<p>Deffered for following.</p> <p>Firm shall submit Valid EC Certificate / EU QA Certificate.</p> <p>Justification required for applying multiple models in single application and also product codes</p>
81.	<p>M/s Optical Palace, Hemani Mansion M.A Jinnah Road, Opp: KMC Karachi</p> <p>(ELI-00527)</p> <p>Date of R&I 02-05-2025</p> <p>Fee Details: Paid Fee: 31000 Fee Challan No. 2668393165 Dated: 18-04-25</p>	<p>M/s GN Resound A/S A.K.A GN Hearing A/S Address: Lautrupbjerg 7, DK-2750, Ballerup, Denmark</p> <p>M/s GN Resound (Malaysia) Sdn Bhd (P) No. 5 Jalan-i-park 1/1 Kawasan Perindustrian i-Park, 81000 Bandar Indapura, Kulai, Johor, Malaysia. (Manufacturing, Service, Repair and distribution of Hearing aids.</p> <p>M/s GN Resound China Ltd., No. 15, CHuang Xin Road, CTP Area 361006 Xiamen China. (Design and Development of Hearing Aids)</p>	<p>Brand name: Resound</p> <p>Generic Name: Hearing Aid</p> <p>Class-B</p> <p>Shelf life / service : N/A</p> <p>Models/ Specification: KE467-DW, KE367-DW, KE267-DW, KE477-DW, KE377-DW, KE277-DW, KE488-DWH, KE388-DWH, KE288-DWH, KE188-DWH, KE4ITC-</p>	<p>Deffered for following. Firm shall submit following details.</p> <p>Justification required for applying multiple models in single application.</p> <p>Service / shelf life details:</p>

		<p>LOA Issuance: Issuance and expiry date of the validity is not mentioned on letter.</p> <p>FSC: Denmark Validity: 07-06-2026</p> <p>ISO China Validity: 31-12-2026</p> <p>ISO Malaysia site: Validity: 21-06-26</p> <p>EU QA Certificate / EC Certificate: Valid till: 27-10-2026</p>	<p>DW-UP, KE3ITC-DW-UP, KE2ITC-DW-UP, KE4CIC-W-MP, KE4CIC-W-HP, KE3CIC-W-MP, KE3CIC-W-HP, KE498DW, KE398DW, KE298DW, KE461-DRWC, KE361-DRWC, KE261-DRW, KE361DRW, KE461-DRW, NX977-DWC, NX777-DWC, NX577-DWC, NX477-DWC, NX988-DWC, NX788-DWC, NX588-DWC, NX488-DWC, NX961-DRW, NX761-DRW, NX561-DRW, NX461-DRW, NX960S-DRWC, NX760S-DRWC, NX560S-DRWC, NX460S-DRWC, CX160S-DRWC, NX9CIC-MP, NX9CIC-HP, NX5CIC-MP, NX5CIC-HP, NC4CIC-MP, NX4CIC-HP, KE4CIC-MP, KE4CIC-HP, KE3CIC-MP, KE3CIC-HP, EQ988-DWHT, EQ788-DWHT, EQ588-DWHT, EQ998-DWT, EQ798-DWT, EQ598-DWT</p>	
82.	<p>Medequips SMC Pvt Ltd,</p> <p>30-Shahrah E Quaid E Azam, Lahore, 54000, Pakistan.</p> <p>ELI-00362</p> <p>Date of R& I 13-05-2025</p> <p>FEE: Not attached.</p>	<p>M/s Echo Nous, Inc. 8310 154th Ve. Ne., Building B, Suite 200 Redmond, WA 98052, USA</p> <p>LOA Validity: 02-09-2026</p> <p>FSC: USA Validity: 11-02-2027</p> <p>ISO Validity: 03-03-2028</p> <p>EU QA Certificate Validity: 28-11-2027</p>	<p>Brand name: Kosmos</p> <p>Generic Name: Diagnostic Ultrasound System with integrated electronic Stethoscope and electrocardiograph</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Models/ Specification: P006030 Kosmos Bridge P006025 Kosmos Torso</p>	<p>Deffered for following.</p> <p>Firm shall submit Paid fee details.</p> <p>Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.</p> <p>Justification required for</p>

			P006440 Kosmos Torso-One P006632 Kosmos Torso-One USB P006709 Kosmos Lexsa P006186 ECG Connector P007893 Kosmos OTS Android Ultrasound Application P008533 Kosmos OTS iOS ultrasound Application P006966 Kosmos Hub P007640 Kosmos Power Pack P006200 AI Station 2 P008392 Kosmos Link	applying multiple models in single application. Firm shall submit Legalized / apostiled FSC. Service / shelf life details:
83.	M/s Save on Health Care, House No. 06, Street NO. 02, Ibraheem Colony, Link Road, Aziz Bhatti Town, Lahore. ELI-00027 Date of R& I 08-05-2025 Fee: PKR 31,000/- Slip # 11094891288	M/s Hitec Medical Co., Ltd Address: 501, Building 2 Lane 1505, Lane Hang Road, Minhang District 201112 Shanghai, People Republic of China. LOA Validity: 30-12-2028 FSC: China Validity: 22-09-2026 ISO Validity: 02-11-2026 EU QA Certificate Validity:	Brand name: Hitecare Generic Name: Nasal Oxygen Cannula Class-B Shelf life / service life: 5 years Sizes: Infant, Pediatric, Adult	Deffered for following. Firm shall submit original copy of legalized/apostied FSC. Notarized copy of EC certificate.
84.	M/s United Brothers, Office No. 301, Mehrab Market Medicine Street No. 1, Marriot Road, Karachi ELI-00451 Date of R& I 12-05-2025 Fee: PKR 31,000/- Slip # 6577591847	M/s Tianchang City Anrui Medical Equipment Co., Ltd., Renhe Industrial District 239331 Tianchang city Anhui Province, China. LOA Validity: 12-03-2029 FSC: China Validity: 15-01-2026 ISO Validity: 19-07-2027 EU QA Certificate / EC Certificate Issue :03-06-2024	Brand name: UB Sterile Latex Surgical Gloves Powdered Generic Name: Latex Surgical Gloves Powdered Class-B Shelf life: 5 years Models/ Specification: 6, 6.5 7, 7.5, 8, 8.5, 9	Approved.

85.	M/s E-Dental Mart, 38/B Street No. 26, Block-D, Phase 1, DHA, Lahore ELI-00968 Date of R& I 19-05-2025 Fee: PKR 31,000/- Slip # 1711368226	M/s Diadent Group International., 16, Osongsaengmyeong 4-ro, Osongeup, Heungdeok-Gu, Chongju-si, Chungcheongbuk- do, 28161, Republic of Korea LOA Issue date: 17-04-2025 FSC: Korea Issue date: 16-04-2025 ISO Validity: 01-06-2027 EU QA Certificate Issue :26-05-2024	Brand name: Sterile Paper Point Generic Name: Sterile Paper Point Class-B Shelf life: Models/ Specification:	Deferred for submission of following. Firm shall submit the sizes / codes details (if any). Provide Service life details.
86.	M/s SZ Surgical Supplier, Office #S, 12, 2nd Floor Ghulam Said Medicine Market Namak Mandi, Peshawar ELI-00662 Date of R& I 20-05-2025 Fee: PKR 25000/- Slip # 69256338410	M/s Taian Dalu Medical Instruments Co., Ltd., NO. 3988 Yitianmen Street, Hi-Tech Zone,Taian, Shandong, China 27100 LOA Issue date: FSC: China Validity: 05-02-2027 ISO Validity: 21-10-2027 EU QA Certificate Issue :20-04-2028	Brand name: Spacer for Aerosol Generic Name: Spacer for Aerosol Class-B Shelf life / service life: 5 Years Models/ Specification: DL-01. DL-01A, DL- 01B, DL-01C, DL-01D, DL-02, DL-02A. DL- 02B. DL-03B. DL-03C. DL-04, DL-05, DL-06, DL-06A, DL-06B. DL- 06C, DL-07. DL-08, DL- 03A DL-08B. DL-08C, DL-08D, DL-09, DL-10, DL-11, DL-12, DL-13, DL-14. DL-15. DL-16. DL-17.DL-18.DL-19, DL-20, DL-21, DL- 22,DL-23,DL-24,DL- 25,DL-26,DL-27.DL.DD petite. La grande, Tur bo, Aeroget, Maclife, Salbomatic. Intec, Aeromate Plus, Aerospacer zeolos. Esencia, Soldist. Farmasol. Instaspacer.	Deffered for following. Firm shall submit differential fee for class –B. Submit Legalized / apostiled FSC. Submit Notarized LOA. Justification required for applying multiple models in single application.

			Universal-Chamber. AS175. Transpacer VM	
87.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Chalan No. 498137388334 Dated: 09-04-25	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC (Germany) Issuance date: 06-11-2024 Valid till 05-11-29. LOA Validity: 17-01-2028 EU QMS Certificate: 14-12-25 ISO 13485: RDG ISO Validity: 29-06-2027 Suzhou ISO Validity: 20-10-2025	Cobas Phosphate (Inorganic) PHOS2 Class: B Product Name: 1. PHOS2 CAT #: 08058610214 Pack size: 750 Tests Shelf life: 18 months at 2 - 8°C	Deffered for following. Firm shall submit notarized EC Certificate. Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly. Clarification required regarding the class of the product. (Fee will be accordingly)
88.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan 0970518400 Dated. 11-04-25	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: Validity: 05-11-2029 LOA Validity: 17-01-2028 EU QMS Certificate: 14-12-25 ISO 13485: RDG ISO Validity: 29-06-2027 Suzhou ISO Validity: 20-10-2025	Cobas Triglycerides TRIGL Class: B Product Name: 1. TRIGL CAT #: 08058687214 Pack size: 1000 Tests Shelf life: 15 months at 2 - 8°C	Deffered for following. Firm shall submit notarized EC Certificate. Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly. Clarification required regarding the class of the product. (Fee will be accordingly)
89.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.	Legal Manufacturer: Buhlmann Laboratories AG Baselstrasse 55, 4124 Schonenbuch, Switzerland.	fCAL Turbo Test Kit Class: B Product Name:	Deffered for following. Firm shall submit notarized EC

	<p>(ELI-00009)</p> <p>R&I Date: 13-05-2025</p> <p>Fees: 31,000/- Challn No. 061815898110 Dated: 09-04-25</p>	<p>Manufacturing Site: Buhlmann Laboratories AG Baselstrasse 55, 4124 Schonenbuch. Switzerland.</p> <p>FSC: Validity: 12-12-2027</p> <p>LOA Validity: 31-12-2027</p> <p>EU QMS Certificate: Validity: 21-02-2027</p> <p>ISO 13485: Validity: 11-05-2027</p>	<p>1. fCAL Turbo CAT #: 08910332190 Pack size: 200 Tests Shelf life: 28 months at 2 - 8°C</p> <p>2. fCAL Turbo CAT #: 08910367190 Pack size: 200 Tests Shelf life: 28 months at 2 - 8°C</p> <p>3. fCAL Control Set CAT #: 08910502190 Pack size: 3 x 1 ml 3 x 1 ml Shelf life: 28 months at 2 - 8°C</p> <p>4. fCAL Calibrator Set CAT #: 08910499190 Pack size: 6 x 1 ml Shelf life: 28 months at 2 - 8°C</p>	<p>Certificate.</p> <p>Clarification required regarding the class of the product. (Fee will be accordingly)</p> <p>Justification required for applying multiple models / products in single application.</p>
90.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>R&I Date: 14-05-2025</p> <p>Fees: 31,000/- Challan No. 14894324125 Dated: 11-04-25</p>	<p>Legal Manufacturer: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA</p> <p>Manufacturing Site: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA</p> <p>FSC: Validity: 20-08-2026</p> <p>LOA Validity: 17-01-2028</p> <p>EU QMS Certificate: Validity: 03-11-2026</p> <p>ISO 13485: Validity: 19-08-2027</p>	<p>Confirm anti-Total cMET (SP44) Rabbit Monoclonal Primary Antibody</p> <p>Class: B</p> <p>Product Name: 1. Confirm anti-Total cMET (SP44) Rabbit Monoclonal Primary Antibody CAT #: 05571219001 Pack size: 50 Tests Shelf life: 24 months at 2-8°C</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized EC Certificate.</p> <p>Clarification required regarding the class of the product. (Fee will be accordingly)</p> <p>Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.</p>
91.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p>	<p>Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom</p> <p>Manufacturing Site:</p>	<p>LumiraDx NT-proBNP</p> <p>Class: B</p> <p>Product Name: 1. LumiraDx NT-proBNP Roche CAT #:</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized EC Certificate.</p>

	<p>R&I Date: 14-05-2025</p> <p>Fees: 31,000/- Challan No. 144385778263 Dated: 28-04-2025</p>	<p>LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & Cliniq Corporation. 495 Enterprise Street, San Marcos, CA 92078, USA</p> <p>FSC: Validity: 17-12-2029</p> <p>LOA Validity: 16-03-2030</p> <p>EU QMS Certificate: N/A</p> <p>ISO 13485: Lumira ISO Validity: 16-04-2026 Cliniq ISO Validity: 04-06—2025</p> <p>DOC: Issuance date. 25-05-2022.</p>	<p>10418320001 LumiraDx CAT #: L023000101012 Pack size: 12 Tests Shelf life: 40 weeks at 2 - 8°C</p> <p>2. LumiraDx NT-proBNP Quality Controls Roche CAT #: 10418354001 LumiraDx CAT #: L023080101002 Pack size: 2 Sets/pack Shelf life: 24 months at 2 - 8°C</p>	<p>Clarification required regarding the class of the product. (Fee will be accordingly)</p> <p>Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.</p> <p>Justification required for applying multiple models / products in single application.</p>
92.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>R&I Date: 14-05-2025</p> <p>Fees: 31,000/-</p>	<p>Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom</p> <p>Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & Cliniq Corporation. 495 Enterprise Street, San Marcos, CA 92078, USA & Hart Biologicals Ltd. 2 Rivergreen Business Centre, Queens Meadow, Hartlepool, TS25 2DL, United Kingdom</p> <p>FSC: Validity: 15-12-2029</p> <p>LOA Validity: 16-03-2030</p> <p>EU QMS Certificate:</p>	<p>LumiraDx Coagulation Markers</p> <p>Class: B</p> <p>Product Name: 1. LumiraDx D-Dimer Test Strips Roche CAT #: 10418087001 LumiraDx CAT #: L005000101012 Pack size: 12 Test Strips Shelf life: 52 weeks at 2 - 30°C</p> <p>2. LumiraDx Multi Quality Controls Roche CAT #: 10418281001 LumiraDx CAT #: L020080101003 Pack size: 3 sets/pack Shelf life: 52 weeks at 2 - 8°C</p> <p>3. LumiraDx INR Test Strips</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized EC Certificate.</p> <p>Clarification required regarding the class of the product. (Fee will be accordingly)</p> <p>Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.</p> <p>Justification required for applying multiple models / products in single application and consideration of</p>

		<p>N/A</p> <p>ISO 13485: Lumira ISO Validity: 16-04-2026 Cliniqa ISO Validity: 04-06—2025 Hart ISO Validity: 10-01-2027</p>	<p>Roche CAT #: 10418010001 LumiraDx CAT #: L003000101048 Pack size: 48 Test strips Shelf life: 12 months at 5 - 32°C</p> <p>4. LumiraDx INR Quality Controls Roche CAT #: 10418036001 LumiraDx CAT #: L003080101003 Pack size: 3 sets/pack Shelf life: 24 months at 2 - 8°C</p>	<p>which product for instant application.</p>
93.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>R&I Date: 14-05-2025</p> <p>Fees: 31,000/- Challan No. 0681274647 Dated: 28-04-25</p>	<p>Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom</p> <p>Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom</p> <p>FSC: Validity: 15-12-2029</p> <p>LOA Validity: 16-03-2030</p> <p>EU QMS Certificate: N/A</p> <p>ISO 13485: Lumira ISO Validity: 16-04-2026</p>	<p>LumiraDx CRP Test Strips</p> <p>Class: B</p> <p>Product Name: 1. LumiraDx CRP Roche CAT #: 10418044001 LumiraDx CAT #: L004000101024 Pack size: 24 Test Strips Shelf life: 36 weeks at 2 - 30°C</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized EC Certificate.</p> <p>Clarification required regarding the class of the product. (Fee will be accordingly)</p> <p>Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly.</p> <p>Justification required for applying multiple models / products in single application.</p>
94.	<p>Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009)</p> <p>R&I Date: 14-05-2025</p>	<p>Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom</p> <p>Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10</p>	<p>LumiraDx HbA1c Test Strips</p> <p>Class: B</p> <p>Product Name: 1. LumiraDx HbA1c Roche CAT #: 10418109001 LumiraDx CAT #:</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized EC Certificate.</p> <p>Clarification required regarding</p>

	Fees: 31,000/- Challan No. 9675535926 Dated: 28-04-25	2PB, United Kingdom & Aalto Scientific Ltd. 230 Technology Parkway, Eatonton, Georgia, 31024, USA FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 Aalto ISO Validity: 30-05-2026	L006000101024 Pack size: 24 Test Strips Shelf life: 39 weeks at 2 - 30°C 2. LumiraDx HbA1c Quality Controls Roche CAT #: 10418133001 LumiraDx CAT #: L006080101003 Pack size: 3 sets/pack Shelf life: 18 months at 2 - 30°C	the class of the product. (Fee will be accordingly) Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly. Justification required for applying multiple models / products in single application.
95.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan No. 05398418718 Dated:28-04-25	Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & MRN Diagnostics 101 Constitution Blvd, Suite G, Franklin, MA 02038, United States of America FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 MRN ISO Validity: 21-09-2025	LumiraDx SARS-CoV-2 Cluster Class: B Product Name: 1. LumiraDx SARS-CoV-2 Ag Test Strips Roche CAT #: 10418141001 LumiraDx CAT #: L016000101048 Pack size: 48 Test Strips Shelf life: 18 months at 2 - 30°C 2. LumiraDx SARS-CoV-2 Ag Ultra Roche CAT #: 10418184001 LumiraDx CAT #: L016000401048 Pack size: 48 Test Shelf life: 70 weeks at 2 - 30°C 3. LumiraDx SARS-CoV-2 Ag Quality Controls Roche CAT #: 10418206001 LumiraDx CAT #: L016080101002 Pack size: 2 sets/pack Shelf life: 25 months at 2 - 8°C	Deffered for following. Firm shall submit notarized EC Certificate. Clarification required regarding the class of the product. (Fee will be accordingly) Justification required regarding category of device (Set, Family, system, cluster), submission of Fee will be accordingly. Justification required for applying multiple models / products in single application.

			<p>4. LumiraDx SARS-CoV-2 & Flu A/B Roche CAT #: 10418222001 LumiraDx CAT #: L019000101024 Pack size: 24 Tests Shelf life: 77 weeks at 2 - 30°C</p> <p>5. LumiraDx SARS-CoV-2 & Flu A/B Quality Controls Roche CAT #: 10418265001 LumiraDx CAT #: L019080101002 Pack size: 2 sets/pack Shelf life: 24 months at 2 - 8°C</p> <p>6. LumiraDx SARS-CoV-2 & RSV Roche CAT #: 10418303001 LumiraDx CAT #: L021000101024 Pack size: 24 Tests Shelf life: 52 weeks at 2 - 30°C</p> <p>7. LumiraDx SARS-CoV-2 & RSV Quality Controls Roche CAT #: 10418311001 LumiraDx CAT #: L021080101002 Pack size: 2 sets/pack Shelf life: 25 months at 2 - 8°C</p>	
96.	<p>M/s Allied Business System,</p> <p>Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi.</p> <p>ELI-01118</p> <p>Date of R& I 07-05-2025</p>	<p>Legal Manufacturer:</p> <p>M/s Chongqing iSIA BIO-Technology Co., Ltd</p> <p>Address: No. 388, Jingdongfang Avenue Beibei District 400714 Chongqing P.R. China</p> <p>LOA Validity: 04-05-2028</p>	<p>Brand name: Quantum Dot Fluorescent Immuno Analyzer iSIA 01B Model (Reagents) Cluster</p> <p>Generic Name: Quantum Dot Fluorescent Immuno Analyzer iSIA 01B Model (Reagents) Cluster</p>	<p>Deffered for following.</p> <p>Firm shall submit notarized ISO Certificate, LOA, EC Certificate.</p> <p>Legalized / apostiled FSC.</p> <p>Justification required regarding</p>

	Fee: PKR 31,000/- Slip # 8062357810	FSC: China Validity: 14-10-2026 ISO Validity: 04-11-2025 EU QA /CE Certificate Validity: 27-04-2026	Class-B Shelf life: 18-24 months Models/ Specification: iSIA 01B	category of device (Set, Family, system, cluster), submission of Fee will be accordingly. Brief Product description required.																
97.	M/s Glo-Med Technologies, A-21/2 B-1, KDA Scheme 1 (Ext), National Stadium Raod, Karachi (ELI-00712) Date of R& I 16-05-2025 Fee: PKR 50,000/- Slip # 095222322698 & 8667284618	M/s Unimicro Medical Systems (Shenzhen) Co., Ltd., 101, 201, 301, Bldg 38, Xialang Industrial Area, Heshuikou, Matian Street, Guangming District, Shenzhen City, Guangdong Province, 518106, P.R. China LOA Validity: 03-04-2026 FSC: China Validity: 19-10-2025 ISO Validity: 11-11-2026 EU QA /CE Certificate Validity: 24-05-2024	Brand name: Unimicro Disposable Balloon Trocars with Cannula Generic Name: Kaparoscopic access Cannula, Single Use Class-B Shelf life: Models/ Specification: <table><tr><th>Mode I7</th><th>Speci ficati ons</th></tr><tr><td>UNT B- RA05 07</td><td>5mm x 75m m</td></tr><tr><td>UNT B- RA05 10</td><td>5mm x 100m m</td></tr><tr><td>UNT B- RA11 10</td><td>11m m x 100m m</td></tr><tr><td>UNT B- RA12 10</td><td>12m m x 100m m</td></tr><tr><td>UNT B- RB05 07</td><td>5mm x 75m m</td></tr><tr><td>UNT B- RB05 10</td><td>5mm x 100m m</td></tr><tr><td>UNT B- RB11 10</td><td>11m m x 100m m</td></tr></table>	Mode I7	Speci ficati ons	UNT B- RA05 07	5mm x 75m m	UNT B- RA05 10	5mm x 100m m	UNT B- RA11 10	11m m x 100m m	UNT B- RA12 10	12m m x 100m m	UNT B- RB05 07	5mm x 75m m	UNT B- RB05 10	5mm x 100m m	UNT B- RB11 10	11m m x 100m m	Approved subject to submission of following details. shelf life details. Justification required for applying multiple models / products in single application
Mode I7	Speci ficati ons																			
UNT B- RA05 07	5mm x 75m m																			
UNT B- RA05 10	5mm x 100m m																			
UNT B- RA11 10	11m m x 100m m																			
UNT B- RA12 10	12m m x 100m m																			
UNT B- RB05 07	5mm x 75m m																			
UNT B- RB05 10	5mm x 100m m																			
UNT B- RB11 10	11m m x 100m m																			

			<table><tr><td>UNT B- RB12 10</td><td>12m m x 100m m</td></tr><tr><td>UNT B- RC05 07</td><td>5mm x 75m m</td></tr><tr><td>UNT B- RC05 10</td><td>5mm x 100m m</td></tr><tr><td>UNT B- RC11 10</td><td>11m m x 100m m</td></tr><tr><td>UNT B- RC12 10</td><td>12m m x 100m m</td></tr><tr><td>UNT B- RD11 10</td><td>11m m x 100m m</td></tr><tr><td>UNT B- RD12 10</td><td>12m m x 100m m</td></tr></table>	UNT B- RB12 10	12m m x 100m m	UNT B- RC05 07	5mm x 75m m	UNT B- RC05 10	5mm x 100m m	UNT B- RC11 10	11m m x 100m m	UNT B- RC12 10	12m m x 100m m	UNT B- RD11 10	11m m x 100m m	UNT B- RD12 10	12m m x 100m m	
UNT B- RB12 10	12m m x 100m m																	
UNT B- RC05 07	5mm x 75m m																	
UNT B- RC05 10	5mm x 100m m																	
UNT B- RC11 10	11m m x 100m m																	
UNT B- RC12 10	12m m x 100m m																	
UNT B- RD11 10	11m m x 100m m																	
UNT B- RD12 10	12m m x 100m m																	
98.	<p>M/s Pakistan Marketing Services, House No. 40, Near Fauji Foundation University, New Lalazar, Near Rose Lane No. 2, Jehlum Road, Rawalpindi</p> <p>ELI-00198</p> <p>Date of R& I 09-05-2025</p> <p>Fee: PKR 31,000/- Slip # 6885495616</p>	<p>M/s Qingdao Yasee Medical Device Co., Ltd., No. 9, Xiuyuan Rd, High-tech Development Zone, Qingdao City, China</p> <p>LOA Validity: 19-01-2028</p> <p>FSC: UK Validity: 26-05-2025</p> <p>FSC: China Validity: 25-11-2026</p> <p>ISO Validity: 07-04-2027</p> <p>EU QA /CE Certificate Validity: 26-05-2024</p>	<p>Brand name: Yasee Electronic Sphygmomanometer</p> <p>Generic Name: Automated non-invasive Sphygmomanometer</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Models/ Specifications JN-163B</p>	Approved subject to submission of valid EC Certificate.														
99.	<p>M/s Global Biotech Medical Devices Private Limited</p>	<p>Legal Manufacturer & Manufacturing Site: M/s AngioDynamics, 603</p>	<p>Brand name:</p>	Deferred submission of Legalized / apostilled FSC.														

	First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) Date of R& I 12-05-2025 Fee: PKR 31,000/- Slip # 33407296245	Queensbury Avenue, Queensbury, NY 12804, USA Notified Body Name and Address: BSI Group the Netherlands B.V Say Building, John M Keynesplein 91066 EP Amsterdam LOA Validity: 09-04-2027 FSC: USA Validity: 14-01-2027 ISO Validity: 10-05-2027 EU QA /CE Certificate Validity: 01-06-2027	VenaCure EVLT NeverTouch Direct Procedure Kit Generic Name: NeverTouch Direct Procedure Kit Class-B Shelf life: 3 years Models/ Specification: H787114031015 H787165100011	Justify for applying multiple models in single application
100	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) Date of R& I 12-05-2025 Fee: PKR 31,000/- Slip # 62572429897	Legal Manufacturer & Manufacturing Site: M/s AngioDynamics, 603 Queensbury Avenue, Queensbury, NY 12804, USA Notified Body Name and Address: BSI Group the Netherlands B.V Say Building, John M Keynesplein 91066 EP Amsterdam LOA Validity: 09-04-2027 FSC: USA Validity: 14-01-2027 ISO Validity: 10-05-2027 EU QA /CE Certificate Validity: 01-06-2027	Brand name: VenaCure EVLT NeverTouch –FRS Procedure Kit Generic Name: VenaCure EVLT NeverTouch –FRS Procedure Kit Class-B Shelf life: 3 years Models/ Specification: H787114030010 H787114030020 H787114030030 H787114030040 H787114030050 H787114030060 H787114030070 H787114030120 H787114030130 H787114033015 H787114033025	deferred submission of Legalized / apostilled FSC. Justify for applying multiple models in single application
101	M/s Surgical World, Office No. 105, 1st Floor, Rehmani Chambers, Altaf Hussain Road, New	M/s Jiangsu Shuangsheng Medical Appliance Co., Ltd., Dandong Industrial Park, Danyang City (No. 12 Lingkou 122 Highway Industrial Zone)	Brand name: Life Source Generic Name: Oxygen Concentrator	Deffered for following. Firm shal submit valid, Legalized

	Chali, Karachi (ELI-00462) Date of R& I 05-05-2025 Fee: PKR 31,000/- Slip # 043186331269	Danyang P.R. China LOA Validity: 06-05-2026 FSC: China Validity: 26-05-2025 ISO Validity: 27-06-2026 EU QA /CE Certificate Validity:	Class-B Shelf life: 5 years Models/ Specification: SZ-5AW LS-7F-5B LS-7F-10B	FSC. (submit English translation version) Submit EC certificate. Justify for applying multiple models in single application
102	M/s Surgical World, Office No. 105, 1st Floor, Rehmani Chambers, Altaf Hussain Road, New Chali, Karachi (ELI-00462) Date of R& I 05-05-2025 Fee: PKR 31,000/- Slip # 69471510	M/s Jiangsu Shuangsheng Medical Appliance Co., Ltd., Dandong Industrial Park, Danyang City (No. 12 Lingkou 122 Highway Industrial Zone) Danyang P.R. China LOA Validity: 06-05-2026 FSC: China Validity: 26-05-2025 ISO Validity: 27-06-2026 EU QA /CE Certificate Validity:	Brand name: Life Source Generic Name: Portable Phlegm Suction Unit Class-B Shelf life: 5 years Models/ Specification: SS-6A 7AE-A/B/D	Deffered for following. Firm shal submit valid, Legalized FSC. (submit English translation version) Submit EC certificate. Justify for applying multiple models in single application
103	M/s Reliance (Pvt) Ltd, 17/3, Mulana Zafar Ali Khan Road, Lahore-54000, Pakistan. ELI-00158 Date of R& I 06-05-2025 Fee: PKR 31,000/- Slip # 9019658576	M/s SDI Limited, 3-15 Brunsdon Street Bayswater, Victoria 3153, Australia LOA Validity: 08-05-2029 FSC: Australia Issue Date: 30-09-2024 ISO Validity: 26-04-2027 EU QA /CE Certificate Validity: 11-04-2029	Brand name: Riva Star Generic Name: Silver diamine fluoride tooth desensitizing agent Class-B Shelf life: Models/ Specification: SS-6A 7AE-A/B/D	Deferred for evidence of codes/models of the applied product . Submit shelf life details.
104	M/s Global Health Care, Midway Commercial Plaza	M/s Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae- myeon, Chungcheon-si, Gang-	Brand name: Hemochroma Plus	Deferred for submisiion of service life / shelf

	No. 20, Back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi (ELI-00086) Date of R& I 19-05-2025 Fee: PKR 31,000/- Slip # 2565067656	won-do 24398, Korea LOA Validity: 31-12-2025 FSC: Korea Issue date: 14-04-2025 ISO Validity: 31-10-2025 EU QA /CE Certificate Validity: 09-11-2028	Generic Name: Hemochroma Plus Class-B Shelf life: N/a Models/ Specification: FPRR016	life details. Submit details regarding category of device (Set, Family, system, cluster), submission of Submit Fee accordingly.
105	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Date of R& I 20-05-2025 Fee: PKR 31,000/- Slip # 4213117793	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China LOA Validity: 14-04-2027 FSC: China Validity: 05-09-2026 ISO Validity: 31-08-2026 EU QA /CE Certificate Validity: 21-11-2029	Brand name: Mindray Generic Name: Electrocardiograph Class-B Shelf life: 10 Years Models/ Specification: BeneHeart R30	Deferred for following. Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the class). Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.
106	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Date of R& I 20-05-2025 Fee: PKR 31,000/- Slip # 23844255	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China LOA Validity: 14-04-2027 FSC: China Validity: 05-09-2026 ISO Validity: 31-08-2026	Brand name: Mindray Generic Name: Electrocardiograph Class-B Shelf life: 10 Years Models/ Specification: BeneHeart R70	Deferred for following. Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the class). Submit details regarding category of device (Family, system, cluster), submission of Fee

		EU QA /CE Certificate Validity: 21-11-2029		will be accordingly.
107	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Date of R& I 20-05-2025 Fee: PKR 31,000/- Slip # 71504569424	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China LOA Validity: 14-04-2027 FSC: China Validity: 05-09-2026 ISO Validity: 31-08-2026 EU QA /CE Certificate Validity: 21-11-2029	Brand name: Mindray Generic Name: Electrocardiograph Class-B Shelf life: 10 Years Models/ Specification: BeneHeart R700	deferred for following. Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the class). Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.
108	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Date of R& I 20-05-2025 Fee: PKR 31,000/- Slip # 83660961935	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China LOA Validity: 14-04-2027 FSC: China Validity: 05-09-2026 ISO Validity: 31-08-2026 EU QA /CE Certificate Validity: 21-11-2029	Brand name: Mindray Generic Name: Electrocardiograph Class-B Shelf life: 10 Years Models/ Specification: BeneHeart R-900	Deferred for following. Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the class). Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.
109	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China LOA Validity: 14-04-2027	Brand name: Mindray Generic Name: Electrocardiograph Class-B Shelf life: 10 Years	Deffered for following. Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the

	<p>Date of R& I 20-05-2025</p> <p>Fee: PKR 31,000/- Slip # 552846383</p>	<p>FSC: China Validity: 05-09-2026</p> <p>ISO Validity: 31-08-2026</p> <p>EU QA /CE Certificate Validity: 21-11-2029</p>	<p>Models/ Specification: BeneHeart R-90</p>	<p>class).</p> <p>Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.</p>
110	<p>M/s MR Medical Pakistan Pvt Ltd,</p> <p>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</p> <p>ELI-01008</p> <p>Date of R& I 20-05-2025</p> <p>Fee: PKR 31,000/- Slip # 3996222921</p>	<p>M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China</p> <p>LOA Validity: 14-04-2027</p> <p>FSC: China Validity: 05-09-2026</p> <p>ISO Validity: 31-08-2026</p> <p>EU QA /CE Certificate Validity: 21-11-2029</p>	<p>Brand name: Mindray</p> <p>Generic Name: Electrocardiograph</p> <p>Class-B</p> <p>Shelf life: 10 Years</p> <p>Models/ Specification: BeneHeart R-300</p>	<p>Deffered for following.</p> <p>Notarized declaration of conformity letter confirming the class of the product. (Differential Fee will be charged according to the class).</p> <p>Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.</p>
111	<p>M/s Eastern Medical Care Pvt. Ltd., 7-A Block N, Model Town Extension, Lahore</p> <p>Date of R& I 05-05-2025</p> <p>Fee: PKR 31,000/- Slip # 22113086603</p>	<p>M/s Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China</p> <p>LOA Validity: 25-10-2027</p> <p>FSC: China Validity: 24-04-2026</p> <p>FSC: Spain Issue Date: 23-01-2025</p> <p>ISO Validity: 06-08-2027</p> <p>EU QA /CE Certificate Validity: 21-11-2019</p>	<p>Brand name: ABLE</p> <p>Generic Name: Disposable Blood Lines</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: FB-A001V01, FB- A001V02, FB-A001V03, FB-A001V04, FB- A001V05, FB-A002V01, FB-A002V02, FB- A002V03, FB-A002V04, FB-A002V05, FB- A003V01, FB-A003V02, FB-A003V03, FB- A003V04, FB-A003V05, FB-A004V01, FB- A004V02, FB-A004V03,</p>	<p>Deffered for following.</p> <p>Notarized, Valid EC certificate.</p> <p>Submit details regarding category of device (Family, system, cluster), submission of Fee will be accordingly.</p> <p>Justify for applying multiple models / types in single application</p>

			FB-A004V04, FB-A004V05, FB-A005V01, FB-A005V02, FB-A005V03, FB-A005V04, FB-A005V05, FB-A006V01, FB-A006V02, FB-A006V03, FB-A006V04, FB-A006V05, FB-A101V11, FB-A101V12, FB-A102V11, FB-A102V12, FB-A103V11, FB-A103V12, FB-A104V11, FB-A104V12	
112	M/s Eastern Medical Care Pvt. Ltd., 7-A Block N, Model Town Extension, Lahore Date of R& I 05-05-2025 Fee: PKR 31,000/- Slip # 4608391559	M/s Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China LOA Validity: 25-10-2027 FSC: China Validity: 24-04-2026 FSC: Spain Issue Date: 23-01-2025 ISO Validity: 06-08-2027 EU QA /CE Certificate Validity: 21-11-2019	Brand name: ABLE Generic Name: Disposable Fistula Needle Class-B Shelf life: 3 Years Models/ Specification: 14G 15G 16G	Approved subject to submission of Notarized, Valid EC certificate.
113	M/s Apex Medical Private Limited, 81-Saif Town Niaz Baig Road Thokar Lahore Date of R& I 19-05-2025 Fee: PKR 31,000/- Slip # 1560998845	M/s AnHui AnYu Latex Products Co., Ltd., Factory No. 95, YuHe Road, Bengbu of AnHui China LOA: Issuance date and validity period not mentioned on LOA. FSC: China Validity: 19-03-2027 ISO - Validity Date: 07-08-2026 EC Certificate : ISSUANCE Date: 23-03-24	Brand Name Medox Generic Name: Surgical Gloves (Powder free) Applied as: Single Class B Shelf Life: 5 Years Code/sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9	Approved subject to submission of valid and notarized LOA.
114	M/s Apex Medical	M/s AnHui AnYu Latex	Brand Name	Approved subject to

	Private Limited, 81-Saif Town Niaz Baig Road Thokar Lahore Date of R& I 19-05-2025 Fee: PKR 31,000/- Slip #0279636813	Products Co., Ltd., Factory No. 95, YuHe Road, Bengbu of AnHui China LOA: Issuance date and validity period not mentioned on LOA. FSC: China Validity:19-03-2027 ISO - Validity Date: 07-08-2026 EC Certificate : ISSUANCE Date: 23-03-24	Medox Generic Name: Surgical Gloves (Powdered) Applied as: Single Class B Shelf Life: 5 Years Code/sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9	submission of valid and notarized LOA.
115	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 452453893	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: Cooling Gel Patch Class-A Shelf life: 05 years Models/ Specification 4x10cm 5x12cm 5x13cm 10x14cm 10x20cm	Approved Only those sizes mentioned in FSC and specifically applied by applicant.
116	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 32302445604	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: First Aid Bandage (Wound Plaster) Class-A Shelf life: 05 years Models/ Specification Non-woven fabric, Glue 72*19mm 70*18mm 60*15mm 76*38mm 76*25mm 76*45mm	Approved Only those sizes mentioned in FSC and specifically applied by applicant.

			38*38mm 65*19mm 50*45mm 76*22mm 76*50mm 6cm*1m 7cm*1m 8cm*1m 38*22mm 45*10mm 70*12mm Dia22mm Dia25mm	
117	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 52195264200	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: Capsicum Plaster Class-A Shelf life: 05 years Models/ Specification 6.4*4cm 10cm*18cm 12cm*18cm	Approved Only those sizes mentioned in FSC and specifically applied by applicant.
118	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 09096314863	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 20-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: Mosquito Repellant Patch Class-A Shelf life: 05 years Models/ Specification 25mm 30mm 38mm 42mm	Approved Only those sizes mentioned in FSC and specifically applied by applicant.
119	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, Karachi	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South	Brand name: Medicare Generic Name:	Approved Only those sizes mentioned in FSC and specifically applied by applicant.

	<p>SHahrah-e-Liaquat, Karachi</p> <p>(ELI-00098)</p> <p>Date of R&I 14-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 66678946</p>	<p>Road, City West New District, Youngkang City 321300 Zhejiang P.R China.</p> <p>LOA Validity: 24-11-2029</p> <p>FSC: China Validity: 14-07-2026</p> <p>ISO Validity: 25-11-2026</p>	<p>Medicated Plaster</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification 6.4*4cm 10cm*18cm 12cm*18cm</p>	
120	<p>Applicant Name:</p> <p>Mana & Co. Office No. 401, 4th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi</p> <p>(ELI-00098)</p> <p>Date of R&I 14-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 8047302220</p>	<p>Name of Manufacturer:</p> <p>M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China.</p> <p>LOA Validity: 24-11-2029</p> <p>FSC: China Validity: 14-07-2026</p> <p>ISO Validity: 25-11-2026</p>	<p>Brand name:</p> <p>Medicare</p> <p>Generic Name: Medicated Corn Plaster</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification Fabric, Non woven, PE, Cotton & Glue</p> <p>Size: 7x2cm 6x2cm</p>	<p>Deferred for submission of clarification regarding the required sizes / codes as per FSC.</p> <p>Justify for applying multiple model / types in single application and which type for instant application.</p>
121	<p>Applicant Name:</p> <p>Mana & Co. Office No. 401, 4th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi</p> <p>(ELI-00098)</p> <p>Date of R&I 14-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 970934546049</p>	<p>Name of Manufacturer:</p> <p>M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China.</p> <p>LOA Validity: 24-11-2029</p> <p>FSC: China Validity: 14-07-2026</p> <p>ISO Validity: 25-11-2026</p>	<p>Brand name:</p> <p>Medicare</p> <p>Generic Name: Ostomy Bag</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification One piece Ostomy Bag Two Piece ostomy Bag</p>	<p>Deferred for submission of clarification regarding the required sizes / codes as per FSC.</p> <p>Justify for applying multiple model / types in single application and which type for instant application.</p>
122	<p>Applicant Name:</p> <p>Mana & Co. Office No. 401, 4th Floor Masood Chamber, SHahrah-e-Liaquat,</p>	<p>Name of Manufacturer:</p> <p>M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District,</p>	<p>Brand name:</p> <p>Medicare</p> <p>Generic Name:</p>	<p>Approved Only those sizes mentioned in FSC and specifically applied by applicant.</p>

	Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 9959006336	Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Zinc Oxide Adhesive Plaster Class-A Shelf life: 05 years Models/ Specification 2.5cm*3m 5cm*3m 7.5cm*3m 10cm*3m 2.5cm*4m 5cm*4m 7.5cm*4m 10cm*4m 2.5cm*5m 5cm*5m 7.5cm*5m 10cm*5m 2.5cm*9.1m 5cm*9.1m 7.5cm*9.1m 10cm*9.1m 2.5cm*10m 5cm*10m 7.5cm*10m 10cm*10m	
123	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 44744112918	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: IV Dressing Class-A Shelf life: 05 years Models/ Specification Non Woven Fabric, Glue 6.7cm 6x8cm 10x12cm 7*8.5cm	Deffered for following. Submit legalized FSC mentioning the applied product and sizes. Justify for applying multiple model / types in single application.
124	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300	Brand name: Medicare Generic Name: Wound Dressing	Approved Only those sizes mentioned in FSC and specifically applied by applicant.

	(ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 295355954	Zhejiang P.R China. LOA Validity: 20-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Class-A Shelf life: 05 years Models/ Specification Non woven Fabric glue 5cmx7cm 7cmx9cm 9cmx10cm 9cmx15cm 9cmx20cm 9cmx25cm 9cmx30cm 9cmx35cm	
125	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 7179000149	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 20-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: Non-woven Paper Tape Class-A Shelf life: 05 years Models/ Specification 2.5cm*3m 5cm*3m 7.5cm*3m 10cm*3m 2.5cm*4m 5cm*4m 7.5cm*4m 10cm*4m 2.5cm*5m 5cm*5m 7.5cm*5m 10cm*5m 2.5cm*9.1m 5cm*9.1m 7.5cm*9.1m 10cm*9.1m 2.5cm*10m 5cm*10m 7.5cm*10m 10cm*10m	Approved Only those sizes mentioned in FSC and specifically applied by applicant.
126	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China.	Brand name: Medicare Generic Name: Non-woven Fix Roll	Approved Only those sizes mentioned in FSC and specifically applied by applicant.

	Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 53373663895	Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Class-A Shelf life: 05 years Models/ Specification Non Woven Fabric, Glue 10cm*10m 10cmx10yard 15cmx10m 15cmx10yards	
127	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 74959852545	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: Hot and Cold Patch Class-A Shelf life: 05 years Models/ Specification 4x10cm 5x12cm 5x13cm 10*14cm 10*20cm	Approved Only those sizes mentioned in FSC and specifically applied by applicant.
128	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 40225141854	Name of Manufacturer: M/s. Zhejiang Bangli Medical Products Co., Ltd Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Validity: 24-11-2029 FSC: China Validity: 14-07-2026 ISO Validity: 25-11-2026	Brand name: Medicare Generic Name: PE Tape Class-A Shelf life: 05 years Models/ Specification 2.5cm*3m 5cm*3m 7.5cm*3m 10cm*3m 2.5cm*4m 5cm*4m 7.5cm*4m 10cm*4m 2.5cm*5m 5cm*5m	Approved Only those sizes mentioned in FSC and specifically applied by applicant.

			7.5cm*5m 10cm*5m 2.5cm*9.1m 5cm*9.1m 7.5cm*9.1m 10cm*9.1m 2.5cm*10m 5cm*10m 7.5cm*10m 10cm*10m	
129	Applicant Name: Mana & Co. Office No. 401, 4 th Floor Masood Chamber, SHahrah-e-Liaquat, Karachi (ELI-00098) Date of R&I 14-05-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 19349412394	Name of Manufacturer: M/s Wuxi Hongguang Medical Equipment Co., Ltd., No. 21, Xixin Road, Xibei Town 214194 Wuxi City, Peoples Republic of China LOA Validity: 19-11-2029 FSC: China Validity: 12-10-2026 ISO Validity: 01-03-2026 EU Quality Assurance Certificate/CE Certificate Validity: 01-03-2028	Brand name: Medicare Generic Name: Mercury Free Clinical Thermometer Class-B Shelf life: 05 years Models/ Specification CR.W10 CR.W11 CR.W00 CR.W01 CR.W02	Deferred for submission of Justification for applying multiple model in single application and which model for instant application.
130	Applicant Name: Shirazi Trading Comoany Pvt Ktd, 114 -C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi 75500 Godown: 2nd Floor, Nadir House, I.I. Chandrigar Road, Karachi Pakistan (ELI-00263) Date of R&I 15-05-2025	Name of Manufacturer: M/s Getemed Medizin -und Information Stechnik AG, Oderstr. 77 14513 Teltow Deutschland LOA Validity: 30-11-2025 FSC: Germany Issue date: 19-10-2022 ISO Validity: 30-11-2027 EU Quality Assurance Certificate/CE Certificate Validity: 09-10-2025	Brand name: CardioDay Generic Name: Electrocardiographic long-term ambulatory recording analyzer application software Class-B Shelf life: 07 years Models/ Specification : Not applicable	Deffered for following. Firm shall submit Legalized FSC, Notarized LOA, ISO 13485 Certificate and EC Certificate. Justification required for category (Family, single, system), submission of differential fee will be accordingly.

	Fee Details: Paid Fee: 31,000/- Fee Challan No: 3476073063			
131	Applicant Name: Nwill Healthcare, Office No. B-9, Royal Garden Hotel Building, 19- Birdwood Road, Lahore ELI-00164 Date of R&I 16-05-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 8125667137	Name of Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited, Manufacturing Site: 789/139 Moo 1 Nongkham, Sriracha Chonburi 20110, Thailand Head Office: 1 Charoenrat Road,Thungwatdon, Sathon, Bangkok, 10120, Thailand LOA Validity: 18-05-2030 FSC: Thailand Issue date: 16-02-2027 ISO Validity: 11-02-2026 EU Quality Assurance Certificate/CE Certificate Validity: 30-05-2027	Brand name: Niptex Generic Name: Lubricants Water Based- Intended to provide additional vaginal lubrication & Reduce the discomfort caused by vaginal dryness. Class-B Shelf life: 03 years. Models/ Specification	Deffered for following. Firm shall submit details of the lubrication flavours. Justification of the class of the product (Fee will be accordingly). FSC showing multiple models / types, kindly justify for which model this application may further proceed.
132	M/s. Chemical House, 6-C Sikandar Malhi Road,, Canal Park, Gulberg-II, Lahore. (ELI- 00156) R&I detail 02-05-2025 Fee: 6,000/- Slip: 86600669871	Legal Manufacturer: Bio-Rad Laboratories, Inc., 4000 Alfred Nobel Dr. Hercules, CA 94547 USA. Manufacturing Site: Bio-Rad Laboratories (Singapore) Pte Ltd., 1 Kaki Bukit View # 03-01, 05-01 Techview Singapore 415941. • LOA Type: Copy Notarization: Not Notarized Validity: Year-2026 • FSC Type: Copy Issued By: Health Sciences Authority Legalization: Not Legalized Issue Date: 10-04-2025 Validity: Not mentioned	Brand name: CFX OPUS DX Generic Name: PCR Systems. Class: A Codes/Sizes: CFX OPUS 96 DX CFX OPUS 384 DX CFX OPUS DEEPWELL DX CFX MAESTRO DX SE Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC is copy and is not legalized. • Three models of PCR and software has been applied in single application. • LOA is copy and is not notarized. • LOA has been issued by Bio-Rad Europe GmbH, Switzerland while product owner mentioned on FSC is Bio-Rad Laboratories, Inc., 4000 Alfred Nobel

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 20-12-2027 		<p>Dr. Hercules, CA 94547 USA</p> <ul style="list-style-type: none"> • ISO certificate is copy and not notarized. • Information & data regarding shelf life not submitted..
133	<p>M/s. Muller & Phipps Pakistan (Pvt.) Limited, Uzma Court, Mian Clifton Road, Karachi.</p> <p>(ELI- 00030)</p> <p>R&I detail 05-05-2025 Fee: 6,000/- Slip: 336286781212</p>	<p>Name of Manufacturer: M/s. Viking Lab Oy, Vanha Vaasantie 8 C FI-33470 Ylojarvi, Finland.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 25-06-2029 • FSC Type: Copy Issued By: Finnish Medicine Agency Legalization: Not Legalized Issue Date: 19-06-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 18-06-2027 	<p>Brand name: Biofrost Relief</p> <p>Generic Name: Cold therapy gel for muscle & joint pain.</p> <p>Class: A</p> <p>Codes/Sizes: BF-1005-3ml (Sachet) BF-1003-75ml (Roll On) BF-1009-100ml (Tube)</p> <p>Applied as: Single</p> <p>Shelf life: 3 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC is copy and is not legalized. • Three types of packings have been applied in single application.
134	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 34199615</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	<p>Brand name: Bilirubin Test Kit</p> <p>Generic Name: Bilirubin Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS002 (Bilirubin Direct, JENDRASSIK-GROF) CS003 (Bilirubin Total, JENDRASSIK-GROF) CS004 (Bilirubin Total & Direct, JENDRASSIK-GROF) CS024 (Bilirubin Total, DMSO Method) CS025 ((Bilirubin Direct, DMSO Method)</p> <p>Applied as: Kit</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC mentions different articles separately with different codes. • Justification for applying multiple kits in single application. • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.

			Shelf life: 18 Months	
135	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 26645291</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: Calcium Arsenazo III Test Kit</p> <p>Generic Name: Calcium Arsenazo III Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CE007</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
136	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 36338382</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: Urea UV (Urease-GLDH Method) Test Kit</p> <p>Generic Name: Urea UV (Urease-GLDH Method) Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS027</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
137	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 58986401</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p>	<p>Brand name: CK-MB Test Kit</p> <p>Generic Name: CK-MB Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: RT020</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was

		<ul style="list-style-type: none"> • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Applied as: Kit Shelf life: 18 Months	valid at the time of application submission and is not notarized.
138	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 28035328	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: LDL Cholestrol Test Kit Generic Name: LDL Cholestrol Test Kit Class: A Codes/Sizes: CS011 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
139	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 08436258168	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Phosphorus UV Molybdate Generic Name: Phosphorus UV Molybdate Class: A Codes/Sizes: CE003 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.

140	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 1842271266</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: AST/GOT (SL), UV IFCC</p> <p>Generic Name: AST/GOT (SL), UV IFCC</p> <p>Class: A</p> <p>Codes/Sizes: CZ005</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
141	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 86233789045</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: Biotrol (Level I & Level II)</p> <p>Generic Name: Biotrol Normal & Abnormal Control</p> <p>Class: A</p> <p>Codes/Sizes: CC001, CC002</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Articles have been mentioned in FSC separately and are applied in same application. • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
142	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 146317502816</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC</p>	<p>Brand name: Lipase Test Kit</p> <p>Generic Name: Lipase Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CZ011</p> <p>Applied as: Kit</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of

		Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Shelf life: 18 Months	application submission and is not notarized.
143	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 72493029	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Sodium Reagent Test Generic Name: Sodium Reagent Test Class: A Codes/Sizes: CE006 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
144	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 71292525	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Zinc Test Kit Generic Name: Zinc Test Kit Class: A Codes/Sizes: CE004 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
145	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center,	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar	Brand name: CK-NAC Test Kit	The Board deferred the case due to following

	<p>Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 258336330</p>	<p>Street, Northern Marka, Amman, Jordan.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	<p>Generic Name: CK-NAC Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CZ009</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
146	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 4862879997</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	<p>Brand name: Triglycerides (SL), GPO-PAP Test Kit</p> <p>Generic Name: Triglycerides (SL), GPO-PAP Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS016</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
147	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 73142997</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized 	<p>Brand name: Alkaline Phosphatase (SL) DGKC Test Kit</p> <p>Generic Name: Alkaline Phosphatase (SL) DGKC Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CZ001</p> <p>Applied as: Kit</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.

		Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Shelf life: 18 Months	
148	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 243104863	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Creatinine Kinetic, Jafee Reaction Test Kit Generic Name: Creatinine Kinetic, Jafee Reaction Test Kit Class: A Codes/Sizes: CS006 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
149	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 4975580020	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Cholestrol Test Kit Generic Name: Cholestrol Test Kit Class: A Codes/Sizes: CS005 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
150	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487)	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.	Brand name: HDL Cholestrol Precipitation Test Kit Generic Name: HDL Cholestrol	The Board deferred the case due to following deficiencies in the application;

	R&I detail 06-05-2025 Fee: 6,000/- Slip: 03926147	<ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Precipitation Test Kit Class: A Codes/Sizes: CS009 Applied as: Kit Shelf life: 18 Months	<ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
151	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 3493260707	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: HDL-C Direct With Calibrator Test Kit Generic Name: HDL-C Direct With Calibrator Test Kit Class: A Codes/Sizes: CS020 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
152	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 62431582101	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate 	Brand name: LDH (SL), SCE Test Kit Generic Name: LDH (SL), SCE Test Kit Class: A Codes/Sizes: CZ008 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.

		Type: Copy Notarization: Not notarized Validity: 06-07-2025		
153	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 80596930	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Albumin BCG Test Kit Generic Name: Albumin BCG Test Kit Class: A Codes/Sizes: CS001 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
154	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 153709445357	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Alpha Amylase (SL) CNPG3 Test Kit Generic Name: Alpha Amylase (SL) CNPG3 Test Kit Class: A Codes/Sizes: CZ002 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
155	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized	Brand name: Gamma GT (SL), SZASZ Test Kit Generic Name: Gamma GT (SL), SZASZ Test Kit Class: A	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized.

	Fee: 6,000/- Slip: 893505769918	Validity: 02-04-2027 <ul style="list-style-type: none"> • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Codes/Sizes: CZ007 Applied as: Kit Shelf life: 18 Months	<ul style="list-style-type: none"> • ISO certificate has expired but was valid at the time of application submission and is not notarized.
156	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 80698320753	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Potassium Reagent Test Kit Generic Name: Potassium Reagent Test Kit Class: A Codes/Sizes: CE005 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
157	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 4985192382	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Urea Berthelot Test Kit Generic Name: Urea Berthelot Test Kit Class: A Codes/Sizes: CS017 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.

158	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 0778842478</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: Uric Acid (Uricase-PAP) Test Kit</p> <p>Generic Name: Uric Acid (Uricase-PAP) Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS018</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
159	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 859383709555</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025</p>	<p>Brand name: Total Protein, Biouret Test Kit</p> <p>Generic Name: Total Protein, Biouret Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS015</p> <p>Applied as: Kit</p> <p>Shelf life: 18 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
160	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 12729284082</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC</p>	<p>Brand name: Iron Ferrozine Test Kit</p> <p>Generic Name: Iron Ferrozine Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS028</p> <p>Applied as: Kit</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of

		Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Shelf life: 18 Months	application submission and is not notarized.
161	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 8872838295	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Magnesium Xylidyl Blue Kit Generic Name: Magnesium Xylidyl Blue Kit Class: A Codes/Sizes: CE002 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
162	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 1124659042	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: ALT/GPT (SL), UV IFCC Test Kit Generic Name: ALT/GPT (SL), UV IFCC Test Kit Class: A Codes/Sizes: CZ003 Applied as: Kit Shelf life: 18 Months	The Board deferred the case due to following deficiencies in the application; • Copy of FSC is not legalized. • Copy of LOA is not notarized. • ISO certificate has expired but was valid at the time of application submission and is not notarized.
163	M/s. Imco Technologist, Plot No. 155, Sector 31/C1	Name of Manufacturer: M/s. Hangzhou Rollmed Co. Ltd., Room 913, Yuanmao,	Brand name: GD Vacunator Vaccum Blood Collection Tube	The Board deferred the case due to following

	<p>Korangi Industrial Area Karach.</p> <p>(ELI- 00778)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 85390191467</p>	<p>Mansion, No.5, Wen Er, Xihu District 310012, Hangzhou City, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 30-12-2027 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not notarized Validity: 27-01-2026 	<p>Generic Name: Blood Collection Tube</p> <p>Class: A</p> <p>Model/Codes/Sizes: Gel & Clot Activator (0.5ML, 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML)</p> <p>Shelf life: 36 Months</p>	<p>deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is Draft FSC and is unsigned and is not legalized. • Copy of ISO certificate is not notarized. • Stability data has not been submitted. • Applied sizes have not been mentioned in draft FSC. Codes have been mentioned draft FSC.
164	<p>M/s. Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Industrial Area Karach.</p> <p>(ELI- 00778)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 08193163</p>	<p>Name of Manufacturer: M/s. Hangzhou Rollmed Co. Ltd., Room 913, Yuanmao, Mansion, No.5, Wen Er, Xihu District 310012, Hangzhou City, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 30-12-2027 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not notarized Validity: 27-01-2026 	<p>Brand name: GD Vacunator Vacuum Blood Collection Tube</p> <p>Generic Name: Blood Collection Tube</p> <p>Class: A</p> <p>Model/Codes/Sizes: EDTA Tube (0.5ML, 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML)</p> <p>Shelf life: 36 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is Draft FSC and is unsigned and is not legalized. • Copy of ISO certificate is not notarized. • Stability data has not been submitted. • Applied sizes have not been mentioned in draft FSC. Codes have been mentioned draft FSC.
165	<p>M/s. Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Industrial Area Karach.</p> <p>(ELI- 00778)</p> <p>R&I detail</p>	<p>Name of Manufacturer: M/s. Hangzhou Rollmed Co. Ltd., Room 913, Yuanmao, Mansion, No.5, Wen Er, Xihu District 310012, Hangzhou City, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy 	<p>Brand name: GD Vacunator Vacuum Blood Collection Tube</p> <p>Generic Name: Blood Collection Tube</p> <p>Class: A</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is Draft

	06-05-2025 Fee: 6,000/- Slip: 2762003078	Notarization: Not notarized Validity: 30-12-2027 <ul style="list-style-type: none"> • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not notarized Validity: 27-01-2026 	Model/Codes/Sizes: Glucose Tube (0.5ML, 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML) Shelf life: 36 Months	FSC and is unsigned and is not legalized. <ul style="list-style-type: none"> • Copy of ISO certificate is not notarized. • Stability data has not been submitted. • Applied model & sizes have not been mentioned in draft FSC. Codes have been mentioned draft FSC.
166	M/s. Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Industrial Area Karach. (ELI- 00778) R&I detail 06-05-2025 Fee: 6,000/- Slip: 50060068049	Name of Manufacturer: M/s. Hangzhou Rollmed Co. Ltd., Room 913, Yuanmao, Mansion, No.5, Wen Er, Xihu District 310012, Hangzhou City, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 30-12-2027 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not notarized Validity: 27-01-2026 	Brand name: GD Vacunator Vaccum Blood Collection Tube Generic Name: Blood Collection Tube Class: A Model/Codes/Sizes: Coagulation Tube (0.5ML, 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML) Shelf life: 36 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is Draft FSC and is unsigned and is not legalized. • Copy of ISO certificate is not notarized. • Stability data has not been submitted. • Applied model & sizes have not been mentioned in draft FSC. Codes have been mentioned draft FSC.
167	M/s. Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Industrial Area Karach. (ELI- 00778) R&I detail 06-05-2025 Fee: 6,000/- Slip: 6999966858	Name of Manufacturer: M/s. Hangzhou Rollmed Co. Ltd., Room 913, Yuanmao, Mansion, No.5, Wen Er, Xihu District 310012, Hangzhou City, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 30-12-2027 • FSC Not submitted 	Brand name: GD Vacunator Vaccum Blood Collection Tube Generic Name: Blood Collection Tube Class: A Model/Codes/Sizes: ESR Tube (1.28ml, 1.6ml, 2.4ml) Shelf life: 36 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is Draft FSC and is unsigned and is not legalized. • Copy of ISO certificate is not notarized.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 27-01-2026 		<ul style="list-style-type: none"> • Stability data has not been submitted. • Applied model & sizes have not been mentioned in draft FSC. Codes have been mentioned draft FSC.
168	M/s. Qualitron Corporation, E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi. (ELI- 00550) R&I detail 06-05-2025 Fee: 6,000/- Slip: 70424449603	Name of Manufacturer: M/s. Nikon Corporation, 471, Nagaodai-cho, Sakae-ku 244-8533 Yokohama, Kanagawa, Japan. <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026 • FSC (Netherlands-Eur. Union) Type: Copy of apostilled Issued By: Ministry of Health Legalization: Apostilled. Validity: 11-03-2030 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 14-11-2026 	Brand name: Eclipse Ti2-U Microscope Generic Name: Inverted Research Microscope Class: A Model/Codes/Sizes: MEA54200 (as per FSC) Shelf life: Not submitted	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC Netherland has not been submitted. • Original LOA & ISO certificate has not been submitted. • Information & data regarding shelf life has not been submitted.
169	M/s. Qualitron Corporation, E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi. (ELI- 00550) R&I detail 06-05-2025 Fee: 6,000/- Slip: 537378208770	Name of Manufacturer: M/s. Nikon Corporation, 471, Nagaodai-cho, Sakae-ku 244-8533 Yokohama, Kanagawa, Japan. <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026 • FSC (Netherlands-Eur. Union) Type: Copy of apostilled Issued By: Ministry of Health Legalization: Apostilled. Validity: 11-03-2030 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 14-11-2026 	Brand name: Eclipse Ci-L Plus Microscope Generic Name: Upright Microscope Class: A Model/Codes/Sizes: MBA95010 (as per FSC) Shelf life: Not submitted	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC Netherland has not been submitted. • Original LOA & ISO certificate has not been submitted. • Information & data regarding shelf life has not been submitted.
170	M/s. Qualitron	Name of Manufacturer:	Brand name:	The Board deferred

	<p>Corporation, E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi.</p> <p>(ELI- 00550)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 339198172768</p>	<p>M/s. Nikon Corporation, 471, Nagaodai-cho, Sakae-ku 244-8533 Yokohama, Kanagawa, Japan.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026</p> <p>• FSC (Netherlands-Eur. Union) Type: Copy of apostilled Issued By: Ministry of Health Legalization: Apostilled. Validity: 11-03-2030</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 14-11-2026</p>	<p>Eclipse TS2, Eclipse TS2-FL Microscopes Generic Name: Inverted routine Microscope</p> <p>Class: A</p> <p>Model/Codes/Sizes: MFA34100 (Eclipse TS2) MFA34200 (Eclipse TS2-FL) (as per FSC)</p> <p>Shelf life: Not submitted</p>	<p>the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Original FSC Netherland has not been submitted. • Original LOA & ISO certificate has not been submitted. • Information & data regarding shelf life has not been submitted. • Two models have been applied in single application.
171	<p>M/s. Qualitron Corporation, E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi.</p> <p>(ELI- 00550)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 3122334784</p>	<p>Name of Manufacturer: M/s. Nikon Corporation, 471, Nagaodai-cho, Sakae-ku 244-8533 Yokohama, Kanagawa, Japan.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026</p> <p>• FSC (Netherlands-Eur. Union) Type: Copy of apostilled Issued By: Ministry of Health Legalization: Apostilled. Validity: 11-03-2030</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 14-11-2026</p>	<p>Brand name: Eclipse Si RS Microscope Generic Name: Upright Microscope</p> <p>Class: A</p> <p>Model/Codes/Sizes: MCA7720 (as per FSC)</p> <p>Shelf life: Not submitted</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Original FSC Netherland has not been submitted. • Original LOA & ISO certificate has not been submitted. • Information & data regarding shelf life has not been submitted.
172	<p>M/s. Qualitron Corporation, E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi.</p> <p>(ELI- 00550)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 530888620086</p>	<p>Name of Manufacturer: M/s. Nikon Corporation, 471, Nagaodai-cho, Sakae-ku 244-8533 Yokohama, Kanagawa, Japan.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026</p>	<p>Brand name: Eclipse Ei R Microscope Generic Name: Microscope</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The device applied has not been mentioned in FSC. • Original LOA & ISO certificate has

		<ul style="list-style-type: none"> • FSC (Netherlands-Eur. Union) Type: Copy of apostilled Issued By: Ministry of Health Legalization: Apostilled. Validity: 11-03-2030 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 14-11-2026 	Shelf life: Not submitted	not been submitted. <ul style="list-style-type: none"> • Information & data regarding shelf life has not been submitted.
173	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 13972715020	Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted. 	Brand name: Elite H Clean Generic Name: Washing/Cleaning Solution IVD Class: A Code/sizes: HEM00023 (50ml) Applied as: Kit Shelf Life: 24 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • The FSC submitted is copy and not legalized.
174	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 13499254326	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled 	Brand name: Surgical Shadowless Lamp Generic Name: Surgical Shadowless Lamp Class: A Codes/Sizes: SX-11-700L Applied as: Single	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC not submitted. • Copy of LOA is not notarized. • ISO certificate is not notarized and is not readable.

		Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Shelf life: 12 Months	<ul style="list-style-type: none"> • Model Applied is not mentioned in FSC
175	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 13499254326	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Brand name: Electrical Operation Table Generic Name: Electrical Operation Table Class: A Models/Sizes: SXD8801, SXD-8802 Applied as: Single Shelf life: 10 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC not submitted. • Copy of LOA is not notarized. • ISO certificate is not notarized and is not readable. • Two Models have been applied in single application.
176	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 62347435	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Brand name: Electrical Operation Table Generic Name: Electrical Operation Table Class: A Models/Sizes: SXD8804(B) Applied as: Single Shelf life: 10 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC not submitted. • Copy of LOA is not notarized. • ISO certificate is not notarized and is not readable.
177	M/s. Humayun Dental Supplies, 43, Mozang	Legal Manufacturer: M/s Hefei Medicon Plastic	Brand name: Medprotect Dental Bib	The Board deferred the case due to

	<p>Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 05585434747</p>	<p>Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	<p>Generic Name: Dental Bib</p> <p>Class: A</p> <p>Codes/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • FSC does not mention the applied device. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
178	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 99616207415</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original 	<p>Brand name: Medprotect Disposable Air Water Syringe Tips</p> <p>Generic Name: Disposable Air Water Syringe Tips</p> <p>Class: A</p> <p>Codes/Sizes: 88X3.87mm</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as

		<p>Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025</p> <p>• ISO Certificate Not submitted.</p>		<p>manufacturer on Form.</p> <ul style="list-style-type: none"> • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
179	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 29433080937</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manuafacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <p>• LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028</p> <p>• FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025</p> <p>• ISO Certificate Not submitted.</p>	<p>Brand name: Medprotect Suction Saliva Ejector Tube</p> <p>Generic Name: Suction Saliva Ejector</p> <p>Class: A</p> <p>Codes/Sizes: Ø1.5, Ø 3.0, Ø 5.0 (as per FSC)</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted. • Applied Sizes have not been mentioned in form
180	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p>	<p>Brand name: Medprotect Dental Polishing Cup</p> <p>Generic Name: Dental Polishing Cup</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired.

	08-05-2025 Fee: 6,000/- Slip: 9233408079	Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China. <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	Class: A Codes/Sizes: 20X4.5mmX2.35mm (as per FSC) Applied as: Single Shelf life: Not mentioned	<ul style="list-style-type: none"> • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
181	M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore. (ELI- 00063) R&I detail 08-05-2025 Fee: 6,000/- Slip: 3021280756	Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China. Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China. <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	Brand name: Medprotect Dental Polishing Brushes Generic Name: Dental Polishing Brushes Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has expired. • FSC does not mention the applied device. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted

				<p>instead of manufacturing facility.</p> <ul style="list-style-type: none"> Shelf life & stability data has not been submitted.
182	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 793194824</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 ISO Certificate Not submitted. 	<p>Brand name: Medprotect Dental Tray</p> <p>Generic Name: Dental Tray</p> <p>Class: A</p> <p>Model/Sizes: Blue, Green ye-1, ye, 2, ye-3, ye-4, ye-5, ye-6, ye-7, ye-8, ye-9, ye-10 (as per FSC)</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> FSC has expired. Name of legal manufacturer has not been mentioned on FSC. LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. Shelf life & stability data has not been submitted. Applied model not mentioned in form.
183	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 404623698</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p>	<p>Brand name: Medprotect Disposable Irrigation Dental Needle</p> <p>Generic Name: Irrigation Dental Needle</p> <p>Class: A</p> <p>Model/Sizes: 27G, 30G (as per FSC)</p> <p>Applied as: Single</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> FSC has expired. Name of legal manufacturer has not been mentioned on FSC. LOA Submitted is from M/s. Hefei

		<ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	Shelf life: Not mentioned	Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. <ul style="list-style-type: none"> • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted. • Applied model not mentioned in form.
184	M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore. (ELI- 00063) R&I detail 08-05-2025 Fee: 6,000/- Slip: 53659577	Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China. Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China. <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	Brand name: Medprotect Rubber Mixing Cup Generic Name: Rubber Mixing Cup Class: A Model/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has expired. • FSC does not mention the applied device. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has

				not been submitted.
185	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 7664044875</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <p>• LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028</p> <p>• FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025</p> <p>• ISO Certificate Not submitted.</p>	<p>Brand name: Medprotect Sterilization Pouch</p> <p>Generic Name: Sterilization Pouch</p> <p>Class: A</p> <p>Model/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • FSC does not mention the applied device. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
186	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 145054620</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <p>• LOA Type: Original Notarization: By CCPIT</p>	<p>Brand name: Medprotect Surgical Sponge</p> <p>Generic Name: Surgical Sponge</p> <p>Class: A</p> <p>Model/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • FSC does not mention the applied device. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary

		Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted.		Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
187	M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore. (ELI- 00063) R&I detail 08-05-2025 Fee: 6,000/- Slip: 23704058	Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China. Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted.	Brand name: Medprotect Cheek Retractor Generic Name: Cheek Retractor Class: A Model/Sizes: 130x92x21mm Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • FSC has expired. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
188	M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore. (ELI- 00063)	Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.	Brand name: Medprotect Disposable Dental Micro Brush Generic Name:	The Board deferred the case due to following deficiencies in the application;

	<p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 1750506048</p>	<p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	<p>Dental Micro Brush</p> <p>Class: A</p> <p>Model/Sizes: 50mmx112mm (as per FSC)</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<ul style="list-style-type: none"> • FSC has expired. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. • Shelf life & stability data has not been submitted.
189	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 280189165</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 • FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 • ISO Certificate Not submitted. 	<p>Brand name: Medprotect Barrier Adhesive Film</p> <p>Generic Name: Barrier Adhesive Film</p> <p>Class: A</p> <p>Model/Sizes: 10x15cm (1200pieces) (as per FSC)</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has expired. • Name of legal manufacturer has not been mentioned on FSC. • LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. • ISO certificate of legal manufacturer has been submitted instead of

				<p>manufacturing facility.</p> <ul style="list-style-type: none"> Shelf life & stability data has not been submitted.
190	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 6336489866</p>	<p>Legal Manufacturer: M/s Hefei Medicon Plastic Products Co. Ltd., 1, Luyang Industrial Zone, Hefei City, Anhui Province, China.</p> <p>Manufacturing Site: M/s. Hefei Mlush Sanitary Product Co., Ltd., West of Wei A Road, Yaohai Industrial Park, Xinzhan District Hefei City, Anhui Province, China.</p> <ul style="list-style-type: none"> LOA Type: Original Notarization: By CCPIT Validity: 07-05-2028 FSC Type: Original Issued By: Govt Body Legalization: By embassy Validity: 26-04-2025 ISO Certificate Not submitted. 	<p>Brand name: Medprotect Sterilization Roll</p> <p>Generic Name: Sterilization Roll</p> <p>Class: A</p> <p>Model/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> FSC has expired. FSC does not mention the applied device. Name of legal manufacturer has not been mentioned on FSC. LOA Submitted is from M/s. Hefei Mlush Sanitary Product Co., Ltd while M/s Hefei Medicon Plastic Products Co. Ltd., has been mentioned as manufacturer on Form. ISO certificate of legal manufacturer has been submitted instead of manufacturing facility. Shelf life & stability data has not been submitted.
191	<p>M/s. Humayun Dental Supplies, 43, Mozang Road, Lahore.</p> <p>(ELI- 00063)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 54913284174</p>	<p>Name of Manufacturer: M/s Foshan Cingol Medical Instrument Co., Ltd., Building 6-1, Nansha Industrial Village, Jianli North Road, Danzao Town, Nanhai District, Foshan, Guangdong, China.</p> <ul style="list-style-type: none"> LOA Type: Original Notarization: By CCPIT Validity: 09-04-2030 	<p>Brand name: Cingol Dental Chair</p> <p>Generic Name: Dental Chair</p> <p>Class: A</p> <p>Model/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> Model Applied has not been mentioned in form as multiple models have been mentioned in FSC.

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: Govt Body Legalization: Apostilled Validity: 16-12-2026 • ISO Certificate Type: Original Notarization: By CCPIT Validity: 12-03-2027 		<ul style="list-style-type: none"> • Shelf life & data has not been submitted. • Notarized DOC has not been submitted.
192	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 326468414 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	Brand name: Helikang 4-Bar Hip Joint Generic Name: 4-Bar Hip Joint Class: A Codes/Sizes: H1606S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
193	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 47300634 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled 	Brand name: Helikang 3-Prong Rotatable Receiver Adapter Generic Name: 3-Prong Rotatable Receiver Adapter Class: A Codes/Sizes: H1201S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027		
194	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 0196949966 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Manual Lock Knee Joint Generic Name: Manual Lock Knee Joint Class: A Codes/Sizes: H1603S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
195	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 84249405019 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original	Brand name: Helikang 4-Bar Knee Joint Generic Name: 4-Bar Knee Joint Class: A Codes/Sizes: H1601S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		Attested By: CCPIT Validity: 08-04-2027		
196	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 27215903677 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang 4-Bar Disarticulation Knee Joint Generic Name: 4-Bar Disarticulation Knee Joint Class: A Codes/Sizes: H1604S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
197	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 05615697107 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Tube Clamp Adapter Generic Name: Tube Clamp Adapter Class: A Codes/Sizes: H1203A/S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
198	M/s. Pak Mobilizers, Shop # G-34, Jeff	Name of Manufacturer: M/s. Beijing Helikang Prosthetic	Brand name: Helikang Integration	The Board deferred the case due to

	<p>Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 7313836795 Dated: 07-05-2025</p>	<p>Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Tube Adaptor</p> <p>Generic Name: Integration Tube Adaptor</p> <p>Class: A</p> <p>Codes/Sizes: H1206-220A/S/T, H1206-420A/S/T</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
199	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 33380458832 Dated: 07-05-2025</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Brand name: Helikang Sach Foot Adaptor</p> <p>Generic Name: Sach Foot Adaptor</p> <p>Class: A</p> <p>Codes/Sizes: H1301S/T</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
200	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China.</p>	<p>Brand name: Helikang Axis Foot Adapter</p> <p>Generic Name: Axis Foot Adapter</p>	<p>The Board deferred the case due to following deficiencies in the application;</p>

	<p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 7409531384 Dated: 07-05-2025</p>	<p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Class: A</p> <p>Codes/Sizes: H1304S/T</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
201	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 923418944 Dated: 07-05-2025</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Brand name: Helikang Axis Foot</p> <p>Generic Name: Axis Foot</p> <p>Class: A</p> <p>Codes/Sizes: H1701(21-29)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
202	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT</p>	<p>Brand name: Helikang Axis Foot</p> <p>Generic Name: Axis Foot</p> <p>Class: A</p> <p>Codes/Sizes: H1702(15-29)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber

	Fee: 6,000/- Slip: 32504136791 Dated: 07-05-2025	Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Applied as: Single Shelf life: 5 Years	of commerce, not by concerned regulatory body of country of origin.
203	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 93890335442 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang LP Solid Ankle Foot Generic Name: LP Solid Ankle Foot Class: A Codes/Sizes: H1703 Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC does not mention name of device • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
204	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 60096611099 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked	Brand name: Helikang Water Proof Cosmetic Foam Cover Generic Name: Water Proof Cosmetic Foam Cover Class: A Codes/Sizes: H1231A Applied as: Single	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	Shelf life: 5 Years	
205	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 263317506865 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	Brand name: Helikang 4-Prong Pyramid Adapter Generic Name: 4-Prong Pyramid Adapter Class: A Codes/Sizes: H1101A/S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
206	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 907715275 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT 	Brand name: Helikang Height-Adjust Both Sides Adapter Generic Name: Height-Adjust Both Sides Adapter Class: A Codes/Sizes: H1410A/S/T Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027		
207	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 649358174073 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Silicon Lock Generic Name: Silicon Lock Class: A Codes/Sizes: Silicon Lock-A (H1711S-1) Silicon Lock-B (H1711S-2) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • Two types of locks applied in single application. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
208	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 1869582626 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate	Brand name: Helikang Side Bar with Drop Ring Lock Generic Name: Side Bar with Drop Ring Lock Class: A Codes/Sizes: H1118A Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		Type: Original Attested By: CCPIT Validity: 08-04-2027		
209	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 794511378179 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Leather Bar Shape Velcro Generic Name: Leather Bar Shape Velcro Class: A Codes/Sizes: H1711S Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC does not mention name of device. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
210	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 02396759572 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Tamarack Joint Generic Name: Tamarack Joint Class: A Codes/Sizes: H1427A Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
211	M/s. Pak Mobilizers,	Name of Manufacturer:	Brand name:	The Board deferred

	<p>Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 1294970859 Dated: 07-05-2025</p>	<p>M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvjang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Helikang PVA</p> <p>Generic Name: PVA</p> <p>Class: A</p> <p>Codes/Sizes: H2205</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
212	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 35061815053 Dated: 07-05-2025</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvjang Jiayuan, Shunyi District, Beijing, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027</p>	<p>Brand name: Helikang PP Sheet</p> <p>Generic Name: PP Sheet</p> <p>Class: A</p> <p>Codes/Sizes: H1107A</p> <p>Applied as: Single</p> <p>Shelf life: 2 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
213	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvjang Jiayuan, Shunyi District, Beijing,</p>	<p>Brand name: Helikang Plastizottee</p> <p>Generic Name: Plastizottee</p>	<p>The Board deferred the case due to following deficiencies in the application;</p>

	<p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 9772342757 Dated: 07-05-2025</p>	<p>China.</p> <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	<p>Class: A</p> <p>Codes/Sizes: H1417S</p> <p>Applied as: Single</p> <p>Shelf life: 2 Years</p>	<ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
214	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail 08-05-2025 Fee: 6,000/- Slip: 414017548336 Dated: 07-05-2025</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvjang Jiayuan, Shunyi District, Beijing, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	<p>Brand name: Helikang EVA</p> <p>Generic Name: EVA</p> <p>Class: A</p> <p>Codes/Sizes: H1305S</p> <p>Applied as: Single</p> <p>Shelf life: 4 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
215	<p>M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI- 01197)</p> <p>R&I detail</p>	<p>Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1st Floor, Building 9, Zone 1, Lvjang Jiayuan, Shunyi District, Beijing, China.</p> <ul style="list-style-type: none"> • LOA Type: Original 	<p>Brand name: Helikang Surform Blade</p> <p>Generic Name: Surform Blade</p> <p>Class: A</p> <p>Codes/Sizes:</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted.

	08-05-2025 Fee: 6,000/- Slip: 73173165 Dated: 07-05-2025	Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	H1506T Applied as: Single Shelf life: 4 Years	• FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
216	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 076428710 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027	Brand name: Helikang Wrench Generic Name: Wrench Class: A Codes/Sizes: H1506A Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
217	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 53835767 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked	Brand name: Helikang Indelible Pencil Generic Name: Indelible Pencil Class: A Codes/Sizes: H1407S Applied as: Single	The Board deferred the case due to following deficiencies in the application; • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	Shelf life: 5 Years	regulatory body of country of origin.
218	M/s. Pak Mobilizers, Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI- 01197) R&I detail 08-05-2025 Fee: 6,000/- Slip: 25845771 Dated: 07-05-2025	Name of Manufacturer: M/s. Beijing Helikang Prosthetic Co., Ltd., 138-280, 1 st Floor, Building 9, Zone 1, Lvgang Jiayuan, Shunyi District, Beijing, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Issue Date: 21-02-2025 Validity: Untill Revoked • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Appostilled Validity: 14-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 08-04-2027 	Brand name: Helikang Vernier Calliper Generic Name: Vernier Calliper Class: A Codes/Sizes: H1117A Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Stability studies data has not been submitted. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
219	M/s. Biocare Pharma, B-175, Block H, North Nazimabad, Aziz Bhatti Road, Karachi. (ELI- 00634) R&I detail 09-05-2025 Fee: 6,000/- Slip: 20228851163 Dated: 07-05-2025	Name of Manufacturer: M/s. Pergo Medikal ve Ilac Sanayi A.S., Buca Osb Mh 2/20 Sk, No 9 BUCA IZMiR, Turkey. <ul style="list-style-type: none"> • LOA Not Submitted • FSC Type: Copy of apostilled Issued By: M&MD Agency Legalization: Apostilled Validity: 25-01-2026 • ISO Certificate Type: Copy of notarized Notarization: Notarized 	Brand name: Pergo Disposable Suction Liner System Generic Name: Surgical Waste Liner System Class: A Codes/Sizes: Not mentioned in application Applied as: Single	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Notarized LOA has not been submitted. • The applicant has applied multiple disposable items of Disposable Suction Liner System in single application.

		Validity: 23-05-2027	Shelf life: 5 Years	• FSC & ISO certificate are copy.
220	M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan. (ELI- 00833) R&I detail 12-05-2025 Fee: 6,000/- Slip: 6553430881 Dated: 12-05-2025	Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1 st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	Brand name: Medon Vacuum Blood Collection Tube for Single-Use Generic Name: Vacuum Blood Collection Tube Class: A Model: Plain Tube (No Additive) Codes/Sizes: 3ml, 4ml Applied as: Single Shelf life: 24 Months	Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.
221	M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan. (ELI- 00833) R&I detail 12-05-2025 Fee: 6,000/- Slip: 3412686466 Dated: 12-05-2025	Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1 st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	Brand name: Medon Vacuum Blood Collection Tube for Single-Use Generic Name: Vacuum Blood Collection Tube Class: A Model: Clot Activator Tube Codes/Sizes: 3ml, 4ml Applied as: Single Shelf life: 24 Months	Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.
222	M/s. Ali Jan Enterprises, 2601	Name of Manufacturer: M/s. Jiangxi Exquisite	Brand name: Medon Vacuum Blood	Approved subject to NOTRIZED

	<p>Mouj Darya Colony, Kalma Chowk, Multan.</p> <p>(ELI- 00833)</p> <p>R&I detail 12-05-2025 Fee: 6,000/- Slip: 60679756433 Dated: 12-05-2025</p>	<p>Technology Co. Ltd., 1st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027</p>	<p>Collection Tube for Single-Use</p> <p>Generic Name: Vacuum Blood Collection Tube</p> <p>Class: A</p> <p>Model: Gel & Clot Activator Tube</p> <p>Codes/Sizes: 3ml, 4ml</p> <p>Applied as: Single</p> <p>Shelf life: 24 Months</p>	<p>ISO13485 issued by notified body/CAB available in NANDO data base.</p>
223	<p>M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan.</p> <p>(ELI- 00833)</p> <p>R&I detail 12-05-2025 Fee: 6,000/- Slip: 9558882269 Dated: 12-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027</p>	<p>Brand name: Medon Vacuum Blood Collection Tube for Single-Use</p> <p>Generic Name: Vacuum Blood Collection Tube</p> <p>Class: A</p> <p>Model: EDTA.K3</p> <p>Codes/Sizes: 2ml, 3ml</p> <p>Applied as: Single</p> <p>Shelf life: 24 Months</p>	<p>Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.</p>
224	<p>M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan.</p> <p>(ELI- 00833)</p>	<p>Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China.</p> <p>• LOA</p>	<p>Brand name: Medon Vacuum Blood Collection Tube for Single-Use</p> <p>Generic Name: Vacuum Blood Collection Tube</p>	<p>Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.</p>

	R&I detail 12-05-2025 Fee: 6,000/- Slip: 567856400 Dated: 12-05-2025	Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	Class: A Model: Sodium Citrate 3.2% Codes/Sizes: 1.8ml, 2ml Applied as: Single Shelf life: 24 Months	
225	M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan. (ELI- 00833) R&I detail 12-05-2025 Fee: 6,000/- Slip: 690632074 Dated: 12-05-2025	Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1 st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	Brand name: Medon Vacuum Blood Collection Tube for Single-Use Generic Name: Vacuum Blood Collection Tube Class: A Model: Sodium Citrate 3.8% Codes/Sizes: 1.28ml, 1.6ml Applied as: Single Shelf life: 24 Months	Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.
226	M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan. (ELI- 00833) R&I detail 12-05-2025 Fee: 6,000/- Slip: 173359245740 Dated: 12-05-2025	Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1 st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC	Brand name: Medon Vacuum Blood Collection Tube for Single-Use Generic Name: Vacuum Blood Collection Tube Class: A Model: EDTA.Na2 Codes/Sizes:	Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.

		Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	3ml Applied as: Single Shelf life: 24 Months	
227	M/s. Ali Jan Enterprises, 2601 Mouj Darya Colony, Kalma Chowk, Multan. (ELI- 00833) R&I detail 12-05-2025 Fee: 6,000/- Slip: 8058730624 Dated: 12-05-2025	Name of Manufacturer: M/s. Jiangxi Exquisite Technology Co. Ltd., 1 st Road of Yuhu West, Xiaolan Economic Development Zone, Nanchang City, Jiangxi Province, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 31-12-2030 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 09-09-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 25-12-2027	Brand name: Medon Vacuum Blood Collection Tube for Single-Use Generic Name: Vacuum Blood Collection Tube Class: A Model: Lithium Heparin Codes/Sizes: 3ml Applied as: Single Shelf life: 24 Months	Approved subject to NOTRIZED ISO13485 issued by notified body/CAB available in NANDO data base.
228	M/s. Basic Pharmaceuticals (Pvt.) Ltd., 14-A, Babar Block, New Garden Town, Lahore. (ELI- 00408) R&I detail 12-05-2025 Fee: 25,000/- Slip: 14987896 Dated: 12-05-2025	Name of Manufacturer: M/s. RadTag Technologies Inc., 2403-96 Street NW, Edmonnton Alberta Canada, T6N 0A7. • LOA Type: Original Notarization: Notarized Validity: 31-12-2028 • FSC Type: Original Issued By: Health Canada Legalization: Appostilled Issue Date: 11-01-2024 Validity: Not mentioned • ISO Certificate Not submitted	Brand name: RadTag Blood Irradiation Indicator Generic Name: Blood Irradiation Indicator Class: A Model: RT15, RT25 Codes/Sizes: 3ml Applied as: Family Shelf life: 16 Months	The Board deferred the case due to following deficiencies in the application; • Models have not been mentioned in FSC but are mentioned in LOA & DOC. • Notarized ISO 13485 Certificate has not been submitted.
229	M/s. Royal	Name of Manufacturer:	Brand name:	The Board deferred

	Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. (ELI- 00062) R&I detail 12-05-2025 Fee: 6,000/- Slip: 3815990159	M/s. Guangdong Dayang Medical Technology Co., Ltd., Xingxian Development Zone, Changhongling Industrial Park (2 nd Phase), Shishan Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy of attested Notarization: By CCPIT Validity: 16-02-2028 • FSC Type: Copy of apostilled Issued By: CCCIEMHP Legalization: Appostilled Validity: 16-07-2026 • ISO Certificate Type: Copy of attested Notarization: By CCPIT Validity: 24-06-2025	Nebicare Shower Chair Generic Name: Shower Chair Class: A Models/Sizes: DY03790, DY03791, DY03792, DY03791S, DY03794L, DY03793S, DY03797L, DY03798L, DY03799L, DY03798LQ, DY03795L, DY03796L, DY03780L, DY03782L, DY03782L(2), DY03781L, DY03783L, DY03784L, DY03785L Shelf life: Not mentioned	the case due to following deficiencies in the application; • Agency Agreement is copy. • ISO certificate has expired. • Multiple models have been applied in single application. • FSC is copy. • Shelf life & data has not been submitted.
230	M/s. Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. (ELI- 00062) R&I detail 12-05-2025 Fee: 6,000/- Slip: 1336686347	Name of Manufacturer: M/s. Guangdong Dayang Medical Technology Co., Ltd., Xingxian Development Zone, Changhongling Industrial Park (2 nd Phase), Shishan Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy of attested Notarization: By CCPIT Validity: 16-02-2028 • FSC Type: Copy of apostilled Issued By: CCCIEMHP Legalization: Appostilled Validity: 16-07-2026 • ISO Certificate Type: Copy of attested Notarization: By CCPIT Validity: 24-06-2025	Brand name: Nebicare Commode Chair Generic Name: Commode Chair Class: A Models/Sizes: Multiple Models Applied Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • Agency Agreement is copy. • ISO certificate has expired. • Multiple models have been applied in single application. • FSC is copy. • Shelf life & data has not been submitted.
231	M/s. Muller & Phips Pakistan (Pvt.) Limited, Uzma Court, Mian Clifton Road, Karachi.	Name of Manufacturer: M/s. Viking Lab Oy, Vanha Vaasantie 8 C FI-33470 Ylojarvi, Finland.	Brand name: Biofrost Active Generic Name: Cold-Heat Gel for muscle	The Board deferred the case due to following deficiencies in the application;

	<p>(ELI- 00030)</p> <p>R&I detail 13-05-2025 Fee: 6,000/- Slip: 0002498617</p>	<ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 25-06-2029 • FSC Type: Copy Issued By: Finnish Medicine Agency Legalization: Not Legalized Issue Date: 19-06-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 18-06-2027 	<p>& joint pain.</p> <p>Class: A</p> <p>Codes/Sizes: BF-2003-3ml (Sachet) BF-2002-75ml (Roll On) BF-2005-100ml (Tube)</p> <p>Applied as: Single</p> <p>Shelf life: 3 Years</p>	<ul style="list-style-type: none"> • FSC is copy and is not legalized. • Three types of packings have been applied in single application.
232	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>ELI-00416</p> <p>Date of R& I 13-05-2025</p> <p>Fee: PKR 31,000/- Slip # 58825218</p>	<p>Name of Manufacturer: Keeler Ltd., Clewer Hill Road, Windsor, Berkshire, SL4 4 AA, UK.</p> <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: By CCPIT Validity: 20-03-2028 • FSC Type: Copy Issued By: MHRA Legalization: Not legalized Validity: 23-01-2029 • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2026 • EU QMS/CE Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2023 	<p>Brand name: Vantage Plus Digital Binocular Indirect Ophthalmoscope</p> <p>Generic Name: Digital Binocular Indirect Ophthalmoscope</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Models/sizes: 1205-P-2010</p> <p>Shelf Life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has submitted unsigned and unfilled copy of Form 7(A). • LOA is copy not original. • ISO certificate has not been notarized. • Copy of FSC has not been legalized. • Information and data regarding shelf life has not been submitted.
233	<p>M/s Princess Scientific Services, Plot No. 67/62, Adam-Jee Road, 1st Floor, Deen Plaza, Sadar, Rawalpindi.</p> <p>(ELI-00215)</p> <p>Date of R& I 13-05-2025</p>	<p>Manufacturer: Helena Laboratories (UK) Ltd., Queenway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD UK.</p> <ul style="list-style-type: none"> • LOA: Type: Copy of notarized Notarization: Notarized Validity: 10-01-2026 • FSC 	<p>Brand Name: Single Cuvettes (Voucher)</p> <p>Generic Name: Single Cuvettes.</p> <p>Applied as: Kit</p> <p>Class: A</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • LOA is copy of notarized. • FSC is copy and is not legalized. • ISO certificate is copy and is not notarized.

	Fee: PKR 6,000/- Slip # 807591747412	Type: Copy Issued By: MHRA Legalization: Not legalized Validity: 12-04-2026 • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 13-04-2027	Code/sizes: C-101V Shelf Life: Not mentioned	<ul style="list-style-type: none"> Information and data regarding shelf life has not been submitted.
234	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 14-05-2025 Fee: PKR 6,000/- Slip # 03971997	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 03-11-2022 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027	Brand Name: Ventana pan-TRK (EPR17341) Assay Generic Name: Tropomyosin receptor kinase (TRK) proteins assay. Applied as: Single Class: A Code/sizes: 08494665001 Shelf Life: 24 Months (2-8°C)	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> The license to Import issued to the applicant does not mention storage facility at 2-8°C. Original FSC, LOA & ISO Certificate has not been submitted.
235	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 14-05-2025 Fee: PKR 6,000/- Slip # 142758700182	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026	Brand Name: Ventana CLDN18 (43-14A) Assay Generic Name: Claudin 18 (CLDN18) protein assay. Applied as: Single Class: A Code/sizes: 08504148001	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> The license to Import issued to the applicant does not mention storage facility at 2-8°C. Original FSC, LOA & ISO Certificate has not been submitted.

		<ul style="list-style-type: none"> • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 03-11-2022 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027 	Shelf Life: 24 Months (2-8°C)	
236	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 14-05-2025 Fee: PKR 6,000/- Slip # 61589353	Legal Manufacturer: LumiraDx UK Ltd., Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, Scotland, UK. Maufacturing Site: Flextronics International GmbH, Friesacher Strabe 3 9330 Althofen, Austria <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: Not Notarized Issue Date: 17-03-2025 Validity: Not mentioned • FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 17-12-2029 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 15-06-2025 	Brand Name: LumiraDx Instrument Generic Name: LumiraDx Instrument. Applied as: Single Class: A Code/sizes: L001000301001 Shelf Life: Not mentioned.	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • LOA is copy and not notarized. • FSC is copy of apostilled. • Mnaufacturing site has not been mentioned in FSC. • ISO certificate has expired but was valid at the time application submission. • Data & information regarding Shel life has not been submitted.
237	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 14-05-2025 Fee: PKR 6,000/- Slip # 55178674928	Legal Manufacturer: LumiraDx UK Ltd., Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, Scotland, UK. Maufacturing Site: Flextronics International GmbH, Friesacher Strabe 3 9330 Althofen, Austria <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: Not Notarized Issue Date: 17-03-2025 Validity: Not mentioned 	Brand Name: LumiraDx Instrument Serviced Generic Name: LumiraDx Instrument. Applied as: Single Class: A Code/sizes: L001029901001 Shelf Life: Not	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • The device intended for import is serviced. • LOA is copy and not notarized. • FSC is copy of apostilled. • Mnaufacturing site has not been mentioned in FSC.

		<ul style="list-style-type: none"> • FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 17-12-2029 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 15-06-2025 	mentioned.	<ul style="list-style-type: none"> • ISO certificate has expired but was valid at the time application submission. • Data & information regarding Shel life has not been submitted.
238	M/s. Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. (ELI- 00062) R&I detail 14-05-2025 Fee: 6,000/- Slip: 58042971572	Name of Manufacturer: M/s. Zhejiang Hand in Hand Intelligent Health Technology Co., Ltd., Second Floor, No. 12, Xiayantou Nature Country, Jiuzhou Town, East City Street, Yongkang, Jinhua, Zhejiang, China. <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT Validity: 13-04-2035 • FSC Type: Original Legalization: Appostilled Validity: 20-11-2025 • ISO Certificate Type: Original Notarization: By CCPIT Validity: 30-10-2026 	Brand name: Nebicare Plus Electric Wheelchair Generic Name: Electric Wheelchair Class: A Models/Sizes: XSW001-B, XSW002-H, XSW002-C, XSW003-D, XSW003-K, XSW001-B Series, XSW002-H Series, XSW002-C Series, XSW003-D Series, XSW003-K Series Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Multiple models have been applied in single application. • Information and data regarding shelf life has not been submitted.
239	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 065731143238	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original 	Brand name: KMN Gussted Reel Generic Name: Sterillization Gussted Reel Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC. • FSC has not been legalized. • Shelf life & data has not been submitted. • Clarification is required whether the applied product is Heat sealing

		Attested By: CCPIT Validity: 29-06-2026		sterilization gusseted reel as mentioned in FSC. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
240	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 28496777	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026	Brand name: KMN Sterilization Pouches Generic Name: Sterilization Pouches Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC. • FSC has not been legalized. • Shelf life & data has not been submitted. • Clarification is required whether the applied product is Sterilization Pouch or Self- sealing sterilization pouch as two different pouches have been mentioned in FSC. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
241	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 401295349	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. • LOA Type: Original Attested By: CCPIT Validity: March-2030	Brand name: KMN Flat Reel Generic Name: Sterilization Flat Reel Class: A Codes/Sizes: Not mentioned Applied as: Single	The Board deferred the case due to following deficiencies in the application; • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 	Shelf life: Not mentioned	<ul style="list-style-type: none"> • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC. • FSC has not been legalized. • Shelf life & data has not been submitted.
242	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 13361428962	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 	Brand name: KMN Steam Indicator Strips Generic Name: Steam Indicator Strips Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin. • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC. • FSC has not been legalized. • Shelf life & data has not been submitted.
243	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 24181713696	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 	Brand name: KMN Sterilization Crepe Paper Generic Name: Sterilization Crepe Paper Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin. • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC.

		<ul style="list-style-type: none"> • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 		<ul style="list-style-type: none"> • FSC has not been legalized. • Shelf life & data has not been submitted.
244	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 1435001130	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 	Brand name: KMN Tyvek Reel Generic Name: Tyvek Sterilization Reel Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin. • Codes/Sized applied have not been mentioned in application as multiple sizes have been mentioned in FSC. • FSC has not been legalized. • Shelf life & data has not been submitted.
245	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 09549959	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	Brand name: EDTA K3 Blood Collection Tube Glass Generic Name: EDTA K3 Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
246	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street	Brand name: Clot Activator/Separate Gel Blood Collection Tube Glass	The Board deferred the case due to following deficiencies in the

	<p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 8114812075</p>	<p>Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	<p>Generic Name: Gel + Clot Activator Vaccum Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 3ml, 4ml, 5ml, 6ml, 7ml, 8ml</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
247	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 3201664</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	<p>Brand name: Sodium Citrate Collection Tube PET</p> <p>Generic Name: Sodium Citrate Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 1.28ml, 4.5ml, 1.6ml, 2.4ml, 2.7ml, 3.6ml, 1.8ml, 3.2ml</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
248	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 307968530145</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy 	<p>Brand name: Clot Activator/Separate Gel Blood Collection Tube PET</p> <p>Generic Name: Gel + Clot Activator Vaccum Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 3ml, 4ml, 5ml, 6ml, 7ml, 8ml</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding

		Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025	Applied as: Family Shelf life: Not mentioned	shelf life has not been submitted.
249	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 59176081	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025	Brand name: EDTA K2 Blood Collection Tube PET Generic Name: EDTA K2 Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
250	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 6492402841	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025	Brand name: No additive Blood Collection Tube Glass Generic Name: Plain Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
251	M/s. Biocept Intl., Co., Office No. 28-29, /E1,	Name of Manufacturer: M/s. Zhejiang SKG Medical	Brand name: EDTA K2 Blood	The Board deferred the case due to

	<p>Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 473945571799</p>	<p>Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <p>• LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025</p> <p>• ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025</p>	<p>Collection Tube Glass Generic Name: EDTA K2 Vaccum Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
252	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 52154302796</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <p>• LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025</p> <p>• ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025</p>	<p>Brand name: Clot Activator Blood Collection Tube PET Generic Name: Clot Activator Vaccum Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
253	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 33112274401</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <p>• LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027</p>	<p>Brand name: Heparin/Sodium Fluoride Blood Collection Tube PET Generic Name: Heparin/Sodium Fluoride Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml,</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized.

		<ul style="list-style-type: none"> • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	7ml, 8ml, 9ml, 10ml Applied as: Family Shelf life: Not mentioned	<ul style="list-style-type: none"> • Information and data regarding shelf life has not been submitted.
254	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 59504524272	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	Brand name: No additive Blood Collection Tube PET Generic Name: Plain Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
255	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 74943844	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	Brand name: Clot Activator Blood Collection Tube Glass Generic Name: Clot Activator Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml Applied as: Family Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.

256	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 000990568446</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	<p>Brand name: Heparin/Sodium Fluoride Blood Collection Tube Glass</p> <p>Generic Name: Heparin/Sodium Fluoride Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
257	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 015022500</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	<p>Brand name: Sodium Citrate Collection Tube Glass</p> <p>Generic Name: Sodium Citrate Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 1.28ml, 4.5ml, 1.6ml, 2.4ml, 2.7ml, 3.6ml, 1.8ml, 3.2ml</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized. • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
258	<p>M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.</p> <p>(ELI- 01225)</p> <p>R&I detail 15-05-2025</p>	<p>Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized. 	<p>Brand name: EDTA K3 Blood Collection Tube PET</p> <p>Generic Name: EDTA K3 Vaccum Blood Collection Tube</p> <p>Class: A</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC has not been legalized. • Copy of LOA has not been notarized.

	Fee: 25,000/- Slip: 397625294105	Validity: 22-03-2027 <ul style="list-style-type: none"> • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025 	Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	<ul style="list-style-type: none"> • Copy of ISO certificate has not been notarized. • Information and data regarding shelf life has not been submitted.
259	M/s. Al-Huda Enterprises Room No. 5, 2 nd Floor, Patiyala Complex, Patiala Ground, Lahore. (ELI- 01114) R&I detail 15-05-2025 Fee: 6,000/- Slip: 104813683157	Name of Manufacturer: M/s. Firstar Healthcare Company Limited (Guangzhou), Rm.901, Building No.2, Headquarters Center, Tia'an High-Tech Ecological Park, Panyu, 511400 Guangzhou, China. <ul style="list-style-type: none"> • LOA Type: Original Notarization: By CCPIT. Validity: 01-02-2030 • FSC Type: Original Issued By: CCM Legalization: Apostilled Validity: 09-02-2027 • ISO Certificate Type: Original Notarization: By CCPIT Validity: 31-8-2026 	Brand name: Daawee Medical Tape Generic Name: Medical Tape Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has been issued by Chamber of commerce, not by regulatory body. • Models/Codes applied have not been mentioned in application as multiple models have been mentioned in FSC. • Stability data has not been submitted to support the shelf life of 5 years.
260	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 849218693740 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 	Brand name: Plastic Test Tube Generic Name: Plastic Test Tube Class: A Codes/Sizes: 15x75mm, 13x75mm, 13x100mm, 15x100mm, 16x100mm, 16x150mm (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.

		• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025		
261	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 9946173305 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Brand name: Urine Conical Tube Generic Name: Urine Conical Tube Class: A Codes/Sizes: 16x102mm (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
262	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 5358511574 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Brand name: Stool Container Generic Name: Stool Container Class: A Codes/Sizes: 20ml, 30ml, 40ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
263	M/s. Molecular	Name of Manufacturer:	Brand name:	The Board deferred

	<p>Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 9162317354 Dated: 15-05-2025</p>	<p>M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Embedding Cassette</p> <p>Generic Name: Embedding Cassette</p> <p>Class: A</p> <p>Codes/Sizes: Stripe Holes, Square Holes, Round Holes (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted. • Applicant has applied different types of Embedding Cassette in single application.
264	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 6148709263 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Brand name: Cover Glass</p> <p>Generic Name: Cover Glass</p> <p>Class: A</p> <p>Codes/Sizes: 18x18mm, 20x20mm, 22x22mm, 24x24mm, 24x32mm, 24x40mm, 24x50mm, 24x60mm (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
265	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p>	<p>Brand name: Hitachi Cup</p> <p>Generic Name: Hitachi Cup</p> <p>Class: A</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by

	<p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 4643374264 Dated: 15-05-2025</p>	<p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufacturer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Codes/Sizes: 16x38mm (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>regulatory body of country of origin and is not legalized.</p> <ul style="list-style-type: none"> • Stability studies data has not been submitted.
266	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 3505518613 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufacturer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Brand name: Glass Petri Dish</p> <p>Generic Name: Glass Petri Dish</p> <p>Class: A</p> <p>Codes/Sizes: 60MM, 90MM, 100MM, 120MM, 150MM (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
267	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 20240676</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p>	<p>Brand name: Tube Stopper</p> <p>Generic Name: Tube Stopper</p> <p>Class: A</p> <p>Codes/Sizes: 12mm, 13mm, 16mm (as pr FSC)</p> <p>Applied as: Single</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized.

	<p>Dated: 15-05-2025</p>	<ul style="list-style-type: none"> • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025 	<p>Shelf life: 5 Years</p>	<ul style="list-style-type: none"> • Stability studies data has not been submitted.
268	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 819937323 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025 	<p>Brand name: Microscope Slides</p> <p>Generic Name: Microscope Slides</p> <p>Class: A</p> <p>Codes/Sizes: 7101, 7102, 7103, 7104, 7105, 7105-1, 7107, 7109-1, 7109, 7111, 7112, 7113 (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted. • The applicant has applied different types of slides on single application.
269	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 40828468799 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 	<p>Brand name: Plastic Petri Dish</p> <p>Generic Name: Plastic Petri Dish</p> <p>Class: A</p> <p>Codes/Sizes: 60MM, 90MM, 100MM, 120MM, 150MM (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.

		• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025		
270	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 4015199890 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Brand name: Pasteur Pipette Generic Name: Pasteur Pipette Class: A Codes/Sizes: 0.2ml, 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
271	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 3282532551 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. • LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033 • FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Brand name: Urine Container Generic Name: Urine Container Class: A Codes/Sizes: 20ml, 40ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
272	M/s. Molecular	Name of Manufacturer:	Brand name:	The Board deferred

	<p>Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 7016268529 Dated: 15-05-2025</p>	<p>M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Centrifuge Tube</p> <p>Generic Name: Centrifuge Tube</p> <p>Class: A</p> <p>Codes/Sizes: 0.2ml, 0.5ml, 1.5ml, 2.0ml, 5ml, 10ml, 15ml, 50ml (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
273	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 54079494191 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Brand name: Inoculation Loop</p> <p>Generic Name: Inoculation Loop</p> <p>Class: A</p> <p>Codes/Sizes: 1ul, 10ul (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by regulatory body of country of origin and is not legalized. • Stability studies data has not been submitted.
274	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p>	<p>Brand name: Pipette Tips Graduated</p> <p>Generic Name: Pipette Tips Graduated</p> <p>Class: A</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC has not been issued by

	<p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 708303531 Dated: 15-05-2025</p>	<p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Codes/Sizes: 10ul, 20ul, 50ul, 100ul, 200ul, 300ul, 1000ul, 1250ul (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>regulatory body of country of origin and is not legalized.</p> <p>• Stability studies data has not been submitted.</p>
275	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 5455255812 Dated: 15-05-2025</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p> <p>• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025</p>	<p>Brand name: Glass Test Tube</p> <p>Generic Name: Glass Test Tube</p> <p>Class: A</p> <p>Codes/Sizes: 10x75mm, 12x75mm, 12x100mm, 13x100mm, 15x150mm, 16x160mm, 18x180mm, 20x150mm, 20x200mm, 25x150mm, 25x200mm, 30x150mm, 30x200mm, 35x200mm, 6x30mm, 7x30mm (as pr FSC)</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <p>• FSC has not been issued by regulatory body of country of origin and is not legalized.</p> <p>• Stability studies data has not been submitted.</p>
276	<p>M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore.</p> <p>(ELI- 01219)</p> <p>R&I detail 16-05-2025 Fee: 6,000/- Slip: 91109819</p>	<p>Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China.</p> <p>• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033</p>	<p>Brand name: Swab</p> <p>Generic Name: Swab</p> <p>Class: A</p> <p>Codes/Sizes: 12x150mm with tube, 150mm without tube (as pr FSC)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <p>• FSC has not been issued by regulatory body of country of origin and is not legalized.</p>

	Dated: 15-05-2025	<ul style="list-style-type: none">• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Applied as: Single Shelf life: 5 Years	<ul style="list-style-type: none">• Stability studies data has not been submitted.• Applicant has applied two types of swabs in single application.
277	M/s. Molecular Concern, 208 Block-P, Gulberg-3, Near Gulab Devi Hospital, Ferozpur Road, Lahore. (ELI- 01219) R&I detail 16-05-2025 Fee: 6,000/- Slip: 66669355308 Dated: 15-05-2025	Name of Manufacturer: M/s. Jiangsu Benoy Lab Instrument Co. Ltd., No.16, Wei'er Road, Shanggang Industrial Zone, Jianhu District, Yancheng, Jiangsu, China. <ul style="list-style-type: none">• LOA Type: Original Attested By: CCPIT Legalization: Appostilled Validity: 15-04-2033• FSC Type: Original Issued By: Manufactuer Attested By: CCPIT Legalization: Not Legalized Validity: 16-04-2027• ISO Certificate Type: Original Attested By: CCPIT Validity: 18-11-2025	Brand name: Glass Beaker Generic Name: Glass Beaker Class: A Codes/Sizes: 5ml, 10ml, 25ml, 50ml, 100ml, 150ml, 200ml, 250ml, 300ml, 400ml, 500ml, 600ml, 1000ml, 2000ml, 3000ml, 5000ml, 10000ml (as pr FSC) Applied as: Single Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none">• FSC has not been issued by regulatory body of country of origin and is not legalized.• Stability studies data has not been submitted.
278	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11 th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 8291315693 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12 th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China, China. <ul style="list-style-type: none">• LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N60 (As per FSC) Shelf life: 10 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none">• Copy of LOA & ISO certificate has been attached instead of original and differential fee for system

		• ISO Certificate Type: Copy of attested Attested By: CCPIT Validity: 31-08-2026		
279	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11 th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 55281339 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12 th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China. • LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026 • ISO Certificate Type: Copy of attested Attested By: CCPIT Validity: 31-08-2026	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N120 (As per FSC) Applied as: Kit Shelf life: 10 Years	The Board deferred the case due to following deficiencies in the application; • Copy of LOA & ISO certificate has been attached instead of original and differential fee for system.
280	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11 th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 572173279554 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12 th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China. • LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026 • ISO Certificate Type: Copy of Attested Attested By: CCPIT Validity: 31-08-2026	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N240 (As per FSC) Applied as: Kit Shelf life: 10 Years	The Board deferred the case due to following deficiencies in the application; • Copy of LOA & ISO certificate has been attached. • Differential fee for system
281	M/s. MR Medical	Name of Manufacturer:	Brand name:	Approved subject to

	<p>Pakistan Pvt Ltd., Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad.</p> <p>(ELI- 01008)</p> <p>R&I detail 20-05-2025 Fee: 6,000/- Slip: 899824415805 Dated: 16-05-2025</p>	<p>M/s. Hunan Mindray Medical Technology Co. Ltd., 3/F, West, Building C, Luvalley Science & Technology Innovation and Entrepreneurship Park, No. 1698, Yuelu West Avenue, High-Tech Development Zone, Changsha, 410221, P.R. China.</p> <p>• LOA Type: Original Attested By: CCPIT Validity: 09-12-2029</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 03-07-2025</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 02-11-2027</p>	<p>Hunan Mindray Anaerobic Culture Bottles</p> <p>Generic Name: Anaerobic Culture Bottles</p> <p>Class: A</p> <p>Model: TDR Resin Anaerobic</p> <p>Codes/Sizes: 35ml Bottle (20 Bottles/Kit, 25 Bottles/Kit, 100 Bottles/Kit (As per FSC)</p> <p>Applied as: Kit</p> <p>Shelf life: 12 Months</p>	<p>submission of original valid FSC by the applicant before issuance of the enlistment letter.</p>
282	<p>M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad.</p> <p>(ELI- 01008)</p> <p>R&I detail 20-05-2025 Fee: 6,000/- Slip: 31545706313 Dated: 16-05-2025</p>	<p>Name of Manufacturer: M/s. Hunan Mindray Medical Technology Co. Ltd., 3/F, West, Building C, Luvalley Science & Technology Innovation and Entrepreneurship Park, No. 1698, Yuelu West Avenue, High-Tech Development Zone, Changsha, 410221, P.R. China.</p> <p>• LOA Type: Original Attested By: CCPIT Validity: 09-12-2029</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 03-07-2025</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 02-11-2027</p>	<p>Brand name: Hunan Mindray Aerobic Culture Bottles</p> <p>Generic Name: Anaerobic Culture Bottles</p> <p>Class: A</p> <p>Model: TDR Resin Aerobic</p> <p>Codes/Sizes: 35ml Bottle (20 Bottles/Kit, 25 Bottles/Kit, 100 Bottles/Kit (As per FSC)</p> <p>Applied as: Kit</p> <p>Shelf life: 12 Months</p>	<p>Approved subject to submission of original valid FSC by the applicant before issuance of the enlistment letter.</p>
283	<p>M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11th</p>	<p>Name of Manufacturer: M/s. Hunan Mindray Medical Technology Co. Ltd., 3/F, West,</p>	<p>Brand name: Hunan Mindray Aerobic Culture Bottles</p>	<p>Approved subject to submission of original valid FSC</p>

	<p>Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad.</p> <p>(ELI- 01008)</p> <p>R&I detail 20-05-2025 Fee: 6,000/- Slip: 57805091344 Dated: 16-05-2025</p>	<p>Building C, Luvalley Science & Technology Innovation and Entrepreneurship Park, No. 1698, Yuelu West Avenue, High-Tech Development Zone, Changsha, 410221, P.R. China.</p> <p>• LOA Type: Original Attested By: CCPIT Validity: 09-12-2029</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 03-07-2025</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 02-11-2027</p>	<p>Generic Name: Anaerobic Culture Bottles</p> <p>Class: A</p> <p>Model: TDR Resin Peds</p> <p>Codes/Sizes: 25ml Bottle (20 Bottles/Kit, 25 Bottles/Kit, 100 Bottles/Kit (As per FSC)</p> <p>Applied as: Kit</p> <p>Shelf life: 12 Months</p>	<p>by the applicant before issuance of the enlistment letter.</p>
284	<p>M/s Altimi Biosciences (Pvt. Ltd., Office No. 201, Plot No. 43-C, Second Floor, Lane-10, Bukhari Commercial, Phase VI, DHA, Karachi.</p> <p>(ELI-00575)</p> <p>Date of R&I 20-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Slip: 792818489660</p>	<p>Name of Manufacturer: M/s. Anji Hongde Medical Products Co., Ltd., Building No. 1, 3, 4, 5, Bamboo Industrial Zone, Xiaofeng Town, Anji County, Zhejiang, China.</p> <p>• LOA Type: Original Notarization: By CCPIT Validity: 24-11-2034</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 07-02-2026</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 31-10-2027</p>	<p>Brand name: Ultimate Dignity Underpad</p> <p>Generic Name: Underpad/Dignity Sheets</p> <p>Class: A</p> <p>Codes/Sizes: 60x40cm, 60x90cm</p> <p>Applied as: Single</p> <p>Shelf life: 3 Years</p>	<p>The Board approved the device for enlistment.</p>
285	<p>M/s Altimi Biosciences (Pvt. Ltd., Office No. 201, Plot No. 43-C, Second Floor, Lane-10, Bukhari Commercial, Phase VI, DHA, Karachi.</p>	<p>Name of Manufacturer: M/s. Anji Hongde Medical Products Co., Ltd., Building No. 1, 3, 4, 5, Bamboo Industrial Zone, Xiaofeng Town, Anji County, Zhejiang, China.</p> <p>• LOA</p>	<p>Brand name: Ultimate Prep Pads</p> <p>Generic Name: Alcohol Pads</p> <p>Class: A</p>	<p>The Board approved the device for enlistment.</p>

	<p>(ELI-00575)</p> <p>Date of R&I 20-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Slip: 1642048404</p>	<p>Type: Original Notarization: By CCPIT Validity: 24-11-2034</p> <p>• FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 07-02-2026</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 31-10-2027</p>	<p>Codes/Sizes: 6x3cm</p> <p>Applied as: Single</p> <p>Shelf life: 3 Years</p>	
286	<p>M/s SZ Surgical Supplier, Office No. S-12, 2nd Floor, Ghulam Said Medicine Market, Namak Mandi, Peshawar.</p> <p>(ELI-00662)</p> <p>Date of R&I 20-05-2025</p> <p>Fee Details: Paid Fee: 6,000/- Slip: 305574915006</p>	<p>Name of Manufacturer: M/s. Taian Dalu Medical Instrument Co., Ltd., West Part of Yitianmen Street, Hi-Tech Zone, Taian, Shandong, China.</p> <p>• LOA Type: Copy of attested Notarization: By CCPIT Validity: 23-04-2030</p> <p>• FSC Type: Copy of apostilled Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 14-01-2026</p> <p>• ISO Certificate Type: Copy of attested Attested By: CCPIT Validity: 21-10-2027</p>	<p>Brand name: Dry Powder Inhaler</p> <p>Generic Name: Dry Powder Inhaler</p> <p>Class: A</p> <p>Codes/Sizes: Not mentioned in application</p> <p>Applied as: Single</p> <p>Shelf life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Model(s) applied have not been mentioned in form since FSC mentions multiple models. • LOA, FSC & ISO Certificate are copies, not original. • Aging/Stability studies not submitted.
287	<p>M/s. Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi.</p> <p>(ELI- 00062)</p> <p>R&I detail 20-05-2025 Fee: 6,000/- Slip: 82299427</p>	<p>Name of Manufacturer: M/s. Foshan Hongfeng Co. Ltd., No.4-2, Leqiang Road, Leping, Sanshui, Foshan District, Guangdong Province, China.</p> <p>• LOA Type: Original Notarization: By CCPIT Validity: 31-05-2035</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Appostilled Validity: 08-07-2026</p>	<p>Brand name: Nebicare+ Medical Air Mattress</p> <p>Generic Name: Medical Air Mattress</p> <p>Class: A</p> <p>Models/Sizes: HF6001, HF6002, HF6002U, HF6005, HF6008, HF601, HF608, HF609, HF6P01, HF-A, HF62012</p> <p>Applied as: Family</p>	<p>Approved subject to differential fee of family nad service life</p>

		• ISO Certificate Type: Original Notarization: By CCPIT Validity: 13-06-2027	Shelf life: Not mentioned	
288	M/s. Total Care Pvt. Ltd., Lahore. (ELI- 01240) R&I detail 20-05-2025 Fee: 6,000/- Slip: 60946401920	Name of Manufacturer: M/s. ALPS South LLC, 2895 42 nd Ave. North Saint Peteburg, FL USA. • LOA Not Submitted • FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 08-07-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 13-10-2026	Brand name: Gel Liner for Prosthetic Use Generic Name: Gel Liner for Prosthetic Use Class: A Models/Sizes: Multiple Applied as: Kit Shelf life: Not mentioned	The Board deferred the case due to following deficiencies in the application; • Applicant has not submitted application of Form-6(A). Complete application is required to be submitted as per form. • Notarized LOA has not been submitted. • Multiple models/coded have been mentioned in FSC. The codes mentioned by applicant in covering letter, does not exist in FSC. • FSC is copy and is not legalized. • FSc has expired but was valid at the time of submission. • ISO certificate is copy and is not notarized.
289	M/s. Safe Health Pakistan Bizcon, Office No. 25, 2 nd Floor Dilkushan Chamber Marston Road, Karachi. (ELI- 01275) R&I detail 20-05-2025 Fee: 6,000/- Slip: 72708195933	Name of Manufacturer: M/s. Taizhou Kangjian Medical Equipments Co., Ltd., The machine Electricity Zone (Hang Ni Kan) of Yuhuan City, Zhejiang Province 317600, China. • LOA Type: Original Notarization: By CCPIT Validity: 31-12-2029 • FSC	Brand name: Sterile Vaginal Speculum for Single Use Generic Name: Vaginal Speculum Class: A Models/Sizes: Multiple Applied as: Single	approved

		Type: Original Issued By: Govt. Body Legalization: Apostilled. Validity: 02-11-2026 • ISO Certificate Type: Original Notarization: Notarized Validity: 27-09-2027	Shelf life: 5 Years	
290	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 07-11-2019 Fee: 25,000/- Slip: 24268467489-20,000/- 1997576 (Manual)-5,000/-	Name of Manufacturer: M/s. Baisheng Medical Co., Ltd., No. 11, Fusheng Rd, Xinhui District, Jiangmen, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 10-01-2027 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 25-12-2025 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 07-11-2025 • EC Certificate Type: Copy Notarization: Not Notarized Validity: 26-05-2024	Brand name: OBS Diathermy Pencil Generic Name: Electrosurgical Pencil Class: B Models/Codes/Sizes: BS-D series (OBS-Db, OBS-Dr, OBS-Df, OBS-Dt, OBS-Dl, OBS-Dd, OBS-Ds, OBS-De, OBS-Dc, OBS-Di, OBS-Dm, OBSDa) Shelf life: 3 Years	Approved subject submission of valid FSC and CE certificate
291	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 598578790106	Name of Manufacturer: M/s. Primed Halberstadt Medizintechnik, GmbH, Domplatz 34 D-38820 Halberstadt. Germany. • LOA Type: Copy Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: 02-05-2017 Validity: Not mentioned	Brand name: Pleural Puncture Set Generic Name: Pleural Puncture Set Class: B Applied as: Family Models/Codes/Sizes: 21104, 21105 , 27040 , 21106 , 27041 Shelf life: 5 Years	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 04-11-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 04-11-2026 		
292	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 2739013219	Name of Manufacturer: M/s. Primed Halberstadt Medizintechnik, GmbH, Domplatz 34 D-38820 Halberstadt. Germany. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: 02-05-2017 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not notarized Validity: 04-11-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 04-11-2026 	Brand name: Thoracic & Trocar Catheter Generic Name: Thoracic & Trocar Catheter Class: B Applied as: Family Models/Codes/Sizes: 21041 , 21042 , 21043 , 21047 , 21048, 21050 , 24150 , 24152 , 24154 , 24156 , 24158, 21044 , 21045, 21046, 21049 , 21055, 21076, 24151, 24153, 24155, 24157, 24159 Trocar Catheter: 21057 , 21058 , 21059 , 21053 , 21051 , 21052, 21054 Shelf life: 5 Years	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models
293	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 4638934510	Name of Manufacturer: M/s. Primed Halberstadt Medizintechnik, GmbH, Domplatz 34 D-38820 Halberstadt. Germany. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: 02-05-2017 	Brand name: OPTILINE Cardio Thoracic Drainage System Generic Name: Cardio Thoracic Drainage System Class: B Applied as: Family Models/Codes/Sizes: 27100, 27101, 27103, 27104, 27105, 27106,	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models

		Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not notarized Validity: 04-11-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 04-11-2026	27107, 27108, 27109, 27116, 27118, 27119, 27120, 27121, 27122, 27125, 27126, 27127, 27129, 27131, 27134, 27135, 27136, 27112, 27113, 27115, 27102 Shelf life: 5 Years	
294	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 7423252837	Name of Manufacturer: M/s. Primed Halberstadt Medizintechnik, GmbH, Domplatz 34 D-38820 Halberstadt. Germany. • LOA Type: Copy Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: 02-05-2017 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not notarized Validity: 04-11-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 04-11-2026	Brand name: Low Vacuum System Generic Name: Low Vacuum System Class: B Applied as: Family Models/Codes/Sizes: 21581, 21586, 21587, 21593, 21598, 21599, 21601, 21602, 21605, 21606, 21607, 21621, 21622, 21631, 21632, 22072, 22073, 22086, 22087, 22088, To 22480 Shelf life: 5 Years	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models
295	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 33289393451	Name of Manufacturer: M/s. Baisheng Medical Co., Ltd., No. 11, Fusheng Rd, Xinhui District, Jiangmen, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 10-01-2027 • FSC Type: Copy Issued By: Govt. Body	Brand name: OBS E.C.G Electrode Generic Name: E.C.G Electrode Class: B Applied as: Family Models/Codes/Sizes: 301 A , 301 B , 301 I 302 B , 302 E , 302 P	Approved subject submission of valid FSC mentioning applied product, CE certificate

		<p>Legalization: Not legalized Validity: 25-12-2025</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 07-11-2025</p> <p>• EC Certificate Type: Copy Notarization: Not Notarized Validity: 26-05-2024</p>	<p>Shelf life: 2 Years</p>	
296	<p>M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi.</p> <p>(ELI- 00072)</p> <p>R&I detail 02-01-2023 Fee: 25,000/- Slip: 34464690</p>	<p>Name of Manufacturer: M/s. Baisheng Medical Co., Ltd., No. 11, Fusheng Rd, Xinhui District, Jiangmen, Guangdong, China.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 10-01-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 25-12-2025</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 07-11-2025</p> <p>• EC Certificate Type: Copy Notarization: Not Notarized Validity: 26-05-2024</p>	<p>Brand name: OBS Electrosurgical Diathermy Pad</p> <p>Generic Name: Electrosurgical Diathermy Pad</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Models/Codes/Sizes: GBS-Dm, GBS-Db, GBS-Rm, GBS-Rb REF # 1030ac , 1031ac , 1030a , 1031a , 1030b , 1031b , 1030n , 1031n , 1041a , 1040a , 1040ac , 1041ac , 2030, 2130 , 2031, 2131, 4030, 4030c, 4040, 4040c</p> <p>Shelf life: 2 Years</p>	<p>Approved subject submission of valid FSC mentioning applied product, CE certificate</p>
297	<p>M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi.</p> <p>(ELI- 00072)</p> <p>R&I detail 02-01-2023 Fee: 25,000/- Slip: 5533928696</p>	<p>Name of Manufacturer: M/s. Baisheng Medical Co., Ltd., No. 11, Fusheng Rd, Xinhui District, Jiangmen, Guangdong, China.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 10-01-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body</p>	<p>Brand name: OBS Skin Stapler & Remover</p> <p>Generic Name: Skin Stapler & Remover</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Models/Codes/Sizes: OBS-MW , OBS-MR ,</p>	<p>Approved subject submission of valid FSC mentioning applied product, CE certificate</p>

		<p>Legalization: Not legalized Validity: 25-12-2025</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 07-11-2025</p> <p>• EC Certificate Type: Copy Notarization: Not Notarized Validity: 26-05-2024</p>	<p>OBS-MH , B1</p> <p>Shelf life: 3 Years</p>	
298	<p>M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi.</p> <p>(ELI- 00072)</p> <p>R&I detail 02-01-2023 Fee: 25,000/- Slip: 5669915615</p>	<p>Name of Manufacturer: M/s. Ningbo Shengyurui Medical Appliances Co., Ltd. No.138 Binhaisi Rd., Hangzhou Bay New Zone, Ningbo, Zhejiang Province, China.</p> <p>• LOA Type: Copy Notarization: By CCPIT Issue Date: 08-03-2021 Validity: Not mentioned</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 12-05-2026</p> <p>• ISO Certificate Type: Copy Notarization: Not notarized Validity: 08-03-2025</p> <p>• EC Certificate Type: Copy Notarization: By CCPIT Validity: 08-03-2024</p>	<p>Brand name: Soundway Aerosol Therapy Nebulizer</p> <p>Generic Name: Nebulizer</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Models/Codes/Sizes: A0201, A1215, A0202, A1216, A0203, A0204, A7224, A8638, A0956, A8297, A0295 A0919, A1201, A0920, A1202, A1203, A7296, A0288, A0208, A0218, A1204, A0931, A1295, A1919, A0297, A0298, A8221, A1288, A0209, A0219, A0279, A1920, A0280, A1931, A1277, A1278, A8222, A0241, A1208, A1218, A1279, A0635, A1280, A0636, A0205, A0206, A8223, A0242, A1209, A1219 ,A1205, A1635, A1206, A1636, A0922, A0924, A8224, A0243, A0210, A0220, A0923, A0245, A1922, A0246, A1924, A1923, A8296, A0244, A1210, A1220 A0637, A1245, A0638 A1246 A1637, A1638 A7291, A1241, A0228, A0238 A0207, A0631, A0221 A0632, A0222, A0223 A7292,</p>	<p>Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models</p>

			A1242, A0229 A0239 , A0224, A1631, A0296, A1632, A1221, A1222 ,A7293, A1243, A1228, A1238, A1223, A0247 ,A1224, A0281, A1296, A0291, A7294, A1244 ,A1229, A1239 A0292, A1281, A1293, A0282 ,A1294, A0225, A8291, A0105, A0230, A0240, A0226, A0283 A1225, A1282 ,A1226 ,A0917 ,A8292 A0106 A1230, A1240 ,A0918 ,A1283 ,A0925 A0952 A1917, A1918 ,A8293 ,A3211 ,A7295 A0248 A1925, A1952 ,A0641 ,A0633 ,A0642 A1641 A8294, A3212 ,A7298 ,A1248 ,A1642, A0634 ,A0227 ,A1633 ,A0211, A0212 ,A7637, A0915 ,A8295 ,A0288 ,A0213, A1634 ,A0214 ,A7221 ,A1211 A1212 A7638, A0916 ,A8298 ,A1288 ,A1213, A7222, A1214 ,A7223 A0215 ,A0216 A8637, A0921, A7297 Shelf life: 5 Years	
299	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 9499755321	Name of Manufacturer: M/s. Ningbo Shengyurui Medical Appliances Co., Ltd. No.138 Binhaisi Rd., Hangzhou Bay New Zone, Ningbo, Zhejiang Province, China. • LOA Type: Copy Notarization: By CCPIT Issue Date: 08-03-2021 Validity: Not mentioned • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 12-05-2026 • ISO Certificate Type: Copy Notarization: Not notarized	Brand name: Soundway Breathing and Anaesthesia System Generic Name: Breathing and Anaesthesia System Class: B Applied as: Family Models/Codes/Sizes: A1701, A1702 ,A1703 ,A1704 ,A1705 A1706 A1707 ,A1721 ,A1722 ,A1723 A1724 A1725 ,A1726 ,A1727 ,A1711 ,A1712 A1713 A1714 A1715 ,A1716 ,A1717 ,A1731 A1732 A1733	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models

		Validity: 08-03-2025 • EC Certificate Type: Copy Notarization: By CCPIT Validity: 08-03-2024	A1734 ,A1735 ,A1736 ,A1737 A3011 A3012 A3013 ,A3014 ,A3015 ,A3016 A3017 A3051 ,A3052 ,A3053 ,A3054 ,A3055 A3056 A3057 B0201 ,B0223 ,B0251 ,B0202 B0224 B0252 ,B0203 ,B0226 ,B0254 ,B0204 B0227 B0253 B0205 ,B0228 ,B0255 ,B0206 B0229 B0256 ,B0207 ,B0238 ,B0254 ,B0101 B0131 B0151 B0102 ,B0132 ,B0153 ,B0105 B0135 B0155 B0103 ,B0133 ,B0156 ,B0104 B0134 B0157 B0106 ,B0136 ,B0158 ,B0117 B0147 B0159 B0501 ,B0502 ,B0507 ,B0503 B0505 B0510 B0521 ,B0401 ,B0402 ,B0403 B0404 B0405 B0406 ,B0407 ,B0408 ,B0409 B0410 B0411 B0412 ,B0421 ,B0422 ,B2402 B2403 B2404 B2422 ,B2413 ,B2407 ,B2408 B2409 B2427 B2428 ,B2405 ,B0701 ,B0731 B0751 B0702 B0732 ,B0752 ,B0704 ,B0734 B0754 B0703 B0733 ,B0753 ,B0705 ,B0735 B0755 B0706 B0736 ,B0756 ,B0707 ,B0737 B0757 B0708 B0738 ,B0758 ,B0709 ,B0739 B0759 B0711 B0741 ,B0761 ,B0712 ,B0742 B0762 B0713 B0743 ,B0763 ,B0714 ,B0744 B0764 B1721 B1731 ,B1741 ,B1722 ,B1732 B1742 B1724 B1734 ,B1744 ,B0901 B0931 B0951 B0902 B0932 ,B0952 ,B0903 B0933 B0953 B0904 B0934 ,B0954 ,B0907 B0947 B0967 B0909 B0939 ,B0959 ,B0910 B0940 B0940 B0911 B0941 ,B0961 ,B0912	
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			B0942 B0962 B0913 B0943 ,B0963 ,B0914 B0944 B0964 B0915 B0945 ,B0965 ,B0937 B0921 B0938 B0950 B0922 ,B0956 ,B0917 B0923 B0935 B0916 B0926 ,B0936 ,B1001 B1002 B1101 B0714 B0715, B0765 ,B0765 Shelf life: 3 Years	
300	M/s. Medco Health Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 348574270	Name of Manufacturer: M/s. Ningbo Shengyurui Medical Appliances Co., Ltd. No.138 Binhaisi Rd., Hangzhou Bay New Zone, Ningbo, Zhejiang Province, China. • LOA Type: Copy Notarization: By CCPIT Issue Date: 08-03-2021 Validity: Not mentioned • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 12-05-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 08-03-2025 • EC Certificate Type: Copy Notarization: By CCPIT Validity: 08-03-2024	Brand name: Soundway Nasal Canula Generic Name: Nasal Canula Class: B Applied as: Family Models/Codes/Sizes: C0307 C0313 C0319 C0357 C0358 C0359 C0306 C0312 C0318 C1307 C1313 C1319 C1723 C1357 C1358 C1359 C1306 C1312 C1318 C0330 C0331 C0332 C1330 C1331 C1332 C1724 C0320 C0321 C0322 C0341 C0342 C0343 C0381 C0382 C0383 C0324 C0325 C0327 C1725 C0326 C0344 C0345 C0347 C0346 C0323 C0205 C0206 C0207 C0208 C0209 C2205 C3721 C2206 C1207 C1208 C1209 C3205 C3206 C3207 C3208 C3209 C0420 C0421 C0422 C3722 C0423 C0424 A0421 A0422 A0423 A0424 A0425 A1421 A1422 A1423 A1424 A1425 C3723 C0215 C0216 C0217 C0218 C0219 C2215 C2216 C2217 C2218 C2219 C1215 C1216 C3724 C1217 C1218 C1219 C3215 C3216 C3217 C3218 C3219	Approved subject submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models

			C0225 C0226 C0227 C0228 C3725 C0229 C2225 C2226 C2227 C2228 C2229 C1225 C1226 C1227 C1228 C1229 C3225 A0405 C3226 C3227 C3228 C3229 C0235 C0236 C0237 C0238 C0239 C1235 C1236 C1237 A0406 C1238 C1239 C0741 C0742 C0743 C0744 C0745 C1741 C1742 C1743 C1744 C1745 A0407 C0751 C0752 C0753 C0754 C0755 C1751 C1752 C1753 C1754 C1755 C0201 C0202 A0408 C0203 C0248 C0249 C1201 C1202 C1203 C0258 C0259 C0211 C0212 C0213 C0268 H0401 C0269 C1211 C1212 C1213 C0278 C0279 C0221 C0222 C0223 C0288 C0289 C1221 H0402 C1222 C1223 C0298 C0299 C0210 C0220 C0230 C1210 C1220 C1230 C0204 C0214 H0403 C0224 C1204 C1214 C1224 C0701 C0702 C0703 C0704 C0705 C2701 C2702 C2703 C2704 C2705 C1701 C1702 C1703 C1704 C1705 C3701 C3702 C3703 C3704 C3705 C0706 C0707 C1706 C1707 C0711 C0712 C0713 C0714 C0715 C2711 C2712 C2713 C2714 C2715 C1711 C1712 C1713 C1714 C1715 C3711 C3712 C3713 C3714 C3715 C0721 C0722 C0723 C0724 C0725 C2721 C2722 C2723 C2724 C2725 C1721 C1722 Shelf life: 5 Years	
301	M/s. Medco Health	Name of Manufacturer:	Brand name:	Approved subject

Care, 155, C.P. Barar Society. Alamgir Road, Karachi. (ELI- 00072) R&I detail 02-01-2023 Fee: 25,000/- Slip: 01189634040	M/s. Ningbo Shengyurui Medical Appliances Co., Ltd. No.138 Binhaisi Rd., Hangzhou Bay New Zone, Ningbo, Zhejiang Province, China. • LOA Type: Copy Notarization: By CCPIT Issue Date: 08-03-2021 Validity: Not mentioned • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 12-05-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 08-03-2025 • EC Certificate Type: Copy Notarization: By CCPIT Validity: 08-03-2024	Soundway Oxygen Mask Generic Name: Oxygen Mask Class: B Applied as: Family Models/Codes/Sizes: A0101 A1118 A2010 A0114 A0102 A0901 A2011 A0121 A0103 A0903 A2013 A0122 A0104 A0941 A2014 A0123 A0148 A0902 A3002 A0124 A3101 A0904 A3003 A0125 A3102 A0942 A3004 A0126 A3103 A1902 A3005 A1101 A3104 A1904 A3008 A1102 A1107 A1942 A3009 A1103 A0115 A2002 A3010 A0132 A2003 A3011 A0117 A2004 A3013 A0118 A2005 A3014 A3115 A2008 A0109 A1132 A2009 A0110 A1117 A2010 A0111 A0111 A0112 A0113 A0301 A0302 A0303 A0304 A0335 A1301 A1302 A1303 A1304 A1335 A0909 A1909 A0305 A0306 A0307 A0308 A0336 A1305 A1306 A1307 A1308 A1336 A0912 A1912 A0309 A0310 A0311 A0312 A0401 A0402 A0403 A0404 A1401 A1402 A1403 A1404 A0939 A0938 A0945 A1939 A1938 A1945 A0509 A0510 A0511 A0512 A1509 A1510 A0944 A1913 A1914 A1944 A0151 A0152 A0153 A0505 A0506 A0507 A0508 A1505 A0948 A0946 A1947 A1946 A1948 A1101 A1102 A1103 A1111 A1112 A1113	submission of valid legalized FSC mentioning applied product, CE certificate and evidence of models
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			A1114 A1115 A1116 A1104 A1124 A0601 A0602 A0107 A0108 Shelf life: 5 Years	
302	M/s. Al-Umar Dental Supply, Opp. Nishtar Institute of Dentistry, Distt. Jail Road, Multan. (ELI- 00853) R&I detail 06-05-2025 Fee: 50,000/- Slip: 729317446656	Name of Manufacturer: M/s. Bloomden Bioceramics (HuNan) Co., Ltd., No. 301, 5 th Building, Hi-Tech Int'l Enterprise, Port, LianDong U Valley, Linyu Road, Dongfanghong Street, Hi-tech Development Zone, Changsha, Hunan Province, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 21-04-2030 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 06-11-2025 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 09-12-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 10-01-2030 	Brand name: Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank Generic Name: Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank Class: B Models/Codes/Sizes: HT-Plus, ST-C, ST-ML, SHT, SHT-C, SHT-ML, UT, UT-C, UT-ML Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of FSC submitted is not legalized. • Applicant has applied different models as family as fee of Rs. 50000 has been deposited. • Copy ISO certificate has not been notarized. • Copy of EU QMS certificate has not been notarized.
303	M/s. Amanco, 402 Marin Point Block 9 Clifton Karachi. (ELI- 00853) R&I detail 06-05-2025 Fee: 31,000/- Slip: 0489456597	Name of Manufacturer: M/s. Longfian Scitech Co., Ltd., Building B5, Kechuang Branch, National University Science Park, No. 666 Lixing Street, Baoding 071051 Hebei, China. <ul style="list-style-type: none"> • LOA Type: Copy of attested Notarization: By CCPIT Issue Date: 08-04-2025 Validity: Not mentioned. • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 04-07-2026 	Brand name: Longfian Oxygen Concentrator Generic Name: Oxygen Concentrator Class: B Models/Codes/Sizes: Not mentioned Shelf life: not mentioned	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • Original FSC, LOA & ISO Certificate have not been submitted. • Copy of CE certificate has been submitted and is expired. • Model(s) applied have not been mentioned as multiple models

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy of attested Notarization: By CCPIT Validity: 19-03-2025 • EC Certificate Type: Copy of attested Notarization: By CCPIT Validity: 18-03-2024 		<p>have been mentioned in FSC.</p> <ul style="list-style-type: none"> • Information and data regarding shelf life has not been submitted. • Notarized DOC has not been submitted.
304	<p>M/s. Fresenius Medical Care Pakistan Pvt. Ltd., Lahore.</p> <p>(ELI- 00315)</p> <p>R&I detail 07-05-2025 Fee: 31,000/- Slip: 26908349</p>	<p>Legal Manufacturer: M/s. Fresenius Medical Care AG, 61346 Bad Homburg, Germany</p> <p>Manufacturing Site: Nova Med GmbH Antalya Serbest Bolgesi Merkez Subesi, Liman Serbest Bolgesi Mahallesi No. 16 07130 Antalya, Turkey</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 17-12-2025 • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 02-10-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 04-04-2028 • EU QMS Certificate Type: Original Notarization: Notarized Validity: 18-06-2025 	<p>Brand name: Adapter Calcium SecuNect/LL</p> <p>Generic Name: Accessories for HD sterilized by ETO</p> <p>Class: B</p> <p>Models/Codes/Sizes: F00008114</p> <p>Shelf life: 3 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Original LOA has not been submitted. • Address of legal manufacturer mentioned on FSC is different from address mentioned on ISO Certificate & EU QMS Certificate.
305	<p>M/s. Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi.</p> <p>(ELI- 00049)</p> <p>R&I detail 07-05-2025 Fee: 31,000/- Slip: 09779761034 Dated: 24-04-2025</p>	<p>Name of Manufacturer: M/s. Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, 528225 Guangdong Province, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2028 • FSC 	<p>Brand name: Ultimed Haemodialysis Catheter</p> <p>Generic Name: Haemodialysis Catheter</p> <p>Class: B</p> <p>Codes/Sizes: Not mentioned in application</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of LOA is not notarized. • Copy of EC certificate is not notarized. • Copy of FSC submitted is not legalized. A page

		Type: Copy Issued By: Govt. Body Attested By: CCPIT Legalization: Not legalized Validity: 10-02-2027 • ISO Certificate Type: Copy of attested Notarization: By CCPIT Validity: 12-03-2026 • EC Certificate Type: Copy Notarization: Not Notarized Validity: 27-05-2024	Shelf life: 5 Years	of FSC also missing. • Codes/Sizes applied have not been mentioned in application. • Stability studies conclusion mentions 42 months validity while the applicant has applied for 5 years shelf life. • Three types (single, double triple) of catheters have been applied in single application.
306	M/s. Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi. (ELI- 00049) R&I detail 07-05-2025 Fee: 31,000/- Slip: 759653253 Dated: 24-04-2025	Name of Manufacturer: M/s. Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, 528225 Guangdong Province, China. • LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2028 • FSC Type: Copy Issued By: Govt. Body Attested By: CCPIT Legalization: Not legalized Validity: 10-02-2027 • ISO Certificate Type: Copy of attested Notarization: By CCPIT Validity: 12-03-2026 • EC Certificate Type: Copy Notarization: Not Notarized Validity: 27-05-2024	Brand name: Ultimed Central Venous Catheter Generic Name: Central Venous Catheter Class: B Codes/Sizes: Not mentioned in application Shelf life: 5 Years	The Board deferred the case due to following deficiencies in the application; • Copy of LOA is not notarized. • Copy of EC certificate is not notarized. • Copy of FSC submitted is not legalized. • Codes/Sizes applied have not been mentioned in application. • Stability studies conclusion mentions 42 months validity while the applicant has applied for 5 years shelf life. • Three types (single, double triple) of catheters have been applied in single application.
307	M/s. Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi.	Name of Manufacturer: M/s. Weifang KAWA Medical Products Co., Ltd., No.2 Xingan Road, Shouguang Beiluo Industrial Park 262700 Weifang,	Brand name: IV Catheter with Injection Port (IVC-02) Generic Name:	The Board deferred the case due to following deficiencies in the application;

	<p>(ELI- 00049)</p> <p>R&I detail 07-05-2025 Fee: 31,000/- Slip: 94149369187 Dated: 29-04-2025</p>	<p>Shandong, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy of attested Notarization: by CCPIT Validity: 19-10-2026 • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 27-02-2033 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 30-11-2026 • EC Certificate Type: Copy Notarization: Not Notarized Validity: 04-11-2029 	<p>IV Catheter with Injection Port Class: B</p> <p>Codes/Sizes: IVC-02</p> <p>Shelf life: 5 Years</p>	<ul style="list-style-type: none"> • ISO certificate is not notarized. • CE certificate mentions only Class-A Devices and is not notarized. • Copy of FSC is not legalized. • Original LOA has not been submitted.
308	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 31,000/- Slip # 034454047</p>	<p>Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <ul style="list-style-type: none"> • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted. 	<p>Brand name: Erba H3 CON</p> <p>Generic Name: Erba H3 CON L (1X3ML) Erba H3 CON N (1X3ml) Erba H3 CON H (1X3ML)</p> <p>Class: B</p> <p>Code/sizes: Erba H3 CON L (HEM00033) Erba H3 CON N (HEM00034) Erba H3 CON H (HEM00035) Erba H3 CON (HEM00072) (as per Free sale certificate):</p> <p>Applied as: Kit</p> <p>Shelf Life: 120 Days (2-8°C)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The FSC submitted is copy and not legalized. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted. • Original LOA has not been submitted.
309	<p>M/s Martin Dow</p>	<p>Legal Manufacturer:</p>	<p>Brand name:</p>	<p>The Board deferred</p>

	<p>Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 31,000/- Slip # 3177965287</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 01-12-2027</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Elite H Cal</p> <p>Generic Name: Haematology Calibrator</p> <p>Class: B</p> <p>Code/sizes: Not mentioned:</p> <p>Applied as: Kit</p> <p>Shelf Life: 60 Days (2-8°C)</p>	<p>the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The FSC submitted is copy and not legalized. • The device mentioned on orm-6(A) is Elite H Cal while documents and fee of DDimer R 60 has been attached in file. Documents of Erba Elite H Cal are required to be submitted. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted. • Original LOA has not been submitted.
310	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 31,000/- Slip # 50869489</p>	<p>Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026</p>	<p>Brand name: Erba Thrombin Time</p> <p>Generic Name: Thrombine Time Kit</p> <p>Class: B</p> <p>Code/sizes: EHL00007 (10x2ml) (as per Free sale certificate):</p> <p>Applied as: Kit</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The FSC submitted is copy and not legalized. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted.

		<ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted. 		<ul style="list-style-type: none"> • Original LOA has not been submitted
311	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 31,000/- Slip # 32520675</p>	<p>Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <ul style="list-style-type: none"> • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted. 	<p>Brand name: Erba Thrombin Reagent</p> <p>Generic Name: Thrombin Reagent</p> <p>Class: B</p> <p>Code/sizes: Erba Thrombin Reagent 10 (EHL00005) Erba Thrombin Reagent 20 (EHL00006) (as per Free sale certificate):</p> <p>Applied as: Kit</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The FSC submitted is copy and not legalized. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted. • Original LOA has not been submitted.
312	<p>M/s United Healthcare, Plot No. 330/B, 2nd Floor DMCH, Bahadurabad, Karachi.</p> <p>ELI-00293</p> <p>Date of R& I 09-05-2025</p> <p>Fee: PKR 31,000/- Slip # 078962532</p>	<p>Name Manufacturer: Tiachang City Anrui Medical Equipments Co., Ltd., Watang Team Renhe Industrial District Tanchang City Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA: Type: Copy of attested Notarization: CCPIT Validity: 21-04-2030 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 15-01-2026 	<p>Brand name: Safety Feel Sterile Surgical Gloves for Single Use Powder Free</p> <p>Generic Name: Surgical Gloves</p> <p>Class: B</p> <p>Models/Sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9</p> <p>Shelf Life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • LOA is copy not original. • Copy of ISO certificate is not notarized. • FSC of Reference country is Copy not original.

		<ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 19-07-2027 • EU QMS/CE Certificate: Not Submitted. • FSC of Reference Country (Spain): Type: Copy Legalization: Legalized Issue Date: 24-09-221 Validity: Not mentioned 		
313	<p>M/s United Healthcare, Plot No. 330/B, 2nd Floor DMCH, Bahadurabad, Karachi.</p> <p>ELI-00293</p> <p>Date of R& I 09-05-2025</p> <p>Fee: PKR 31,000/- Slip # 81075811</p>	<p>Name Manufacturer: Tiachang City Anrui Medical Equipments Co., Ltd., Watang Team Renhe Industrial District Tanchang City Anhui Province, China.</p> <ul style="list-style-type: none"> • LOA: Type: Copy of attested Notarization: CCPIT Validity: 21-04-2030 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 15-01-2026 • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 19-07-2027 • EU QMS/CE Certificate: Not Submitted. • FSC of Reference Country (Spain): Type: Copy Legalization: Legalized Issue Date: 24-09-221 Validity: Not mentioned 	<p>Brand name: Safety Feel Sterile Surgical Gloves for Single Use Powdered</p> <p>Generic Name: Surgical Gloves</p> <p>Class: B</p> <p>Models/Sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9</p> <p>Shelf Life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Copy of FSC is not legalized. • LOA is copy not original. • Copy of ISO certificate is not notarized. • FSC of Reference country is Copy not original.
314	<p>M/s Maher Apparels, Lahore.</p> <p>ELI-01330</p> <p>Date of R& I 09-05-2025</p>	<p>Name Manufacturer: Changzhou Major Medical Products Co., Ltd., No. 1, Beiyang Road, Hexi Village, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu, China 213144.</p>	<p>Brand name: Medelast Hydrocolloid Wound Dressing Ultra Thin</p> <p>Generic Name: Hydrocolloid Wound Dressing</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Notarized LOA has not been submitted.

	<p>Fee: PKR 31,000/- Slip # 5955313212</p>	<p>LOA: Not Submitted.</p> <p>• FSC Type: Copy of apostilled Issued By: CCCIEMHP Legalization: Apostilled Validity: 02-01-2027</p> <p>• ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 19-09-2026</p> <p>• EU QMS Certificate: Type: Copy Notarization: By CCPIT Validity: 14-07-2029</p>	<p>Class: B</p> <p>Models/Sizes: 5x5cm, 10x10cm, 15x15cm, 20x20cm</p> <p>Shelf Life: 3 Years</p>	<ul style="list-style-type: none"> • FSC is copy and has not been issued by regulatory body of country of origin. • ISO certificate is copy. • EU QMS certificate is copy.
315	<p>M/s Advance Medical System, Office No.8, Rehman Plaza 90/A-1, Depot Line Coast Guard Avenue, Karachi.</p> <p>ELI-00699</p> <p>Date of R& I 12-05-2025</p> <p>Fee: PKR 31,000/- Slip # 9979272185</p>	<p>Name of Manufacturer: Ningbo David Medical Device Co., Ltd., No2, Keyuan Road, Shipu Science and Technology Park, Xiangshan 315731 Ningbo, Zhejiang Province, China.</p> <p>• LOA: Type: Original Notarization: By CCPIT Validity: 12-03-2026</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Not legalized Validity: 22-11-2025</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 31-05-2025</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Brand name: Neonate Bilirubin Therapy Equipment</p> <p>Generic Name: Bilirubin Therapy Equipment</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/sizes: XHZ-200 (as per Free sale certificate & LOA)</p> <p>Shelf Life: 8 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC Submitted is not legalized. • ISO certificate has expired but was valid at the time of application submission. • EU QMS/CE Certificate has not been submitted.
316	<p>M/s Advance Medical System, Office No.8, Rehman Plaza 90/A-1, Depot Line Coast Guard Avenue, Karachi.</p> <p>ELI-00699</p>	<p>Name of Manufacturer: Ningbo David Medical Device Co., Ltd., No2, Keyuan Road, Shipu Science and Technology Park, Xiangshan 315731 Ningbo, Zhejiang Province, China.</p>	<p>Brand name: Infant Radiant Warmer</p> <p>Generic Name: Infant Radiant Warmer</p> <p>Applied as: Single</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC Submitted is not legalized.

	<p>Date of R& I 12-05-2025</p> <p>Fee: PKR 31,000/- Slip # 343414656600</p>	<p>• LOA: Type: Original Notarization: By CCPIT Validity: 12-03-2026</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Not legalized Validity: 22-11-2025</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 31-05-2025</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Class: B</p> <p>Models/sizes: HKN-9010 (as per Free sale certificate & LOA)</p> <p>Shelf Life: 8 Years</p>	<ul style="list-style-type: none"> • ISO certificate has expired but was valid at the time of application submission. • EU QMS/CE Certificate has not been submitted.
317	<p>M/s Advance Medical System, Office No.8, Rehman Plaza 90/A-1, Depot Line Coast Guard Avenue, Karachi.</p> <p>ELI-00699</p> <p>Date of R& I 12-05-2025</p> <p>Fee: PKR 31,000/- Slip # 7561663896</p>	<p>Name of Manufacturer: Ningbo David Medical Device Co., Ltd., No2, Keyuan Road, Shipu Science and Technology Park, Xiangshan 315731 Ningbo, Zhejiang Province, China.</p> <p>• LOA: Type: Original Notarization: By CCPIT Validity: 12-03-2026</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Not legalized Validity: 22-11-2025</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 31-05-2025</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Brand name: Transcutaneous Jaundice Detector</p> <p>Generic Name: Transcutaneous Jaundice Detector</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/sizes: BM-100A (as per Free sale certificate & LOA)</p> <p>Shelf Life: 8 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • FSC Submitted is not legalized. • ISO certificate has expired but was valid at the time of application submission. • EU QMS/CE Certificate has not been submitted.
318	<p>M/s Ghazali Brothers, Ground Floor & Second Floor, Karmjee Building North Napier Road, Karachi.</p> <p>ELI-00240</p>	<p>Name of Manufacturer: Guangzhou AXD Electronic Co., Ltd., Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Toen, Baiyun District, Guangzhoy City, Guangdong Province, China.</p>	<p>Brand name: Care Compressor Nebulizer Machine</p> <p>Generic Name: Compressor Nebulizer Machine</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Evidence of Payment of fee has not been attached.

	<p>Date of R& I 12-05-2025</p> <p>Fee: Not deposited</p>	<p>• LOA: Type: Original Notarization: By CCPIT Validity: 17-04-2035</p> <p>• FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 29-05-2022 Validity: 22-11-2025</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 25-03-2028</p>	<p>Applied as: Single</p> <p>Class: B</p> <p>Models/sizes: Not mentioned</p> <p>Shelf Life: Not mentioned.</p>	<ul style="list-style-type: none"> • Model applied has not been mentioned in application as multiple models have been mentioned in FSC. • Information and data regarding shelf life has not been submitted.
319	<p>M/s Ghazali Brothers, Ground Floor & Second Floor, Karmjee Building North Napier Road, Karachi.</p> <p>ELI-00240</p> <p>Date of R& I 12-05-2025</p> <p>Fee: Not deposited</p>	<p>Name of Manufacturer: Guangzhou AXD Electronic Co., Ltd., Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Toen, Baiyun District, Guangzhoy City, Guangdong Province, China.</p> <p>• LOA: Type: Original Notarization: By CCPIT Validity: 17-04-2035</p> <p>• FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 29-05-2022 Validity: 22-11-2025</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 25-03-2028</p>	<p>Brand name: Accumax Minor Compressor Nebulizer Machine</p> <p>Generic Name: Compressor Nebulizer Machine</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/sizes: Not mentioned</p> <p>Shelf Life: Not mentioned.</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • Evidence of Payment of fee has not been attached. • Model applied has not been mentioned in application as multiple models have been mentioned in FSC. • Information and data regarding shelf life has not been submitted.
320	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>ELI-00416</p> <p>Date of R& I 13-05-2025</p>	<p>Name of Manufacturer: Keeler Ltd., Clewer Hill Road, Windsor, Berkshire, SL4 4 AA, UK.</p> <p>• LOA: Type: Copy of attested Notarization: By CCPIT Validity: 20-03-2028</p> <p>• FSC Type: Copy</p>	<p>Brand name: Keeler TonoCare Tonometer</p> <p>Generic Name: Tonometer</p> <p>Applied as: Single</p> <p>Class: B</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has submitted unsigned and unfilled copy of Form 7(A). • LOA is copy not original.

	<p>Fee: PKR 31,000/- Slip # 72384127</p>	<p>Issued By: MHRA Legalization: Not legalized Validity: 23-01-2029</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2026</p> <p>• EU QMS/CE Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2023</p>	<p>Models/sizes: 2418-P-2000 (as per Free sale certificate & LOA)</p> <p>Shelf Life: Not mentioned</p>	<ul style="list-style-type: none"> • Copy of FSC has not been legalized. • ISO certificate has not been notarized. • Copy of CE Certificate submitted is not notarized and has expired. • Information and data regarding shelf life has not been submitted.
321	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>ELI-00416</p> <p>Date of R& I 13-05-2025</p> <p>Fee: PKR 31,000/- Slip # 24520106215</p>	<p>Name of Manufacturer: Keeler Ltd., Clewer Hill Road, Windsor, Berkshire, SL4 4 AA, UK.</p> <p>• LOA: Type: Cop Notarization: By CCPIT Validity: 20-03-2028</p> <p>• FSC Type: Copy Issued By: MHRA Legalization: Not legalized Validity: 23-01-2029</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2026</p> <p>• EU QMS/CE Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2023</p>	<p>Brand name: Pulsair Intellipuff Tonometer</p> <p>Generic Name: Tonometer</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/sizes: 2418-P-2001 (as per Free sale certificate & LOA)</p> <p>Shelf Life: Not mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has submitted unsigned and unfilled copy of Form 7(A). • LOA is copy not original. • Copy of FSC has not been legalized. • ISO certificate has not been notarized. • Copy of CE Certificate submitted is not notarized and has expired. • Information and data regarding shelf life has not been submitted.
322	<p>M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.</p> <p>ELI-00009</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 9596259802</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026</p> <p>• FSC</p>	<p>Brand Name: Elecsys Anti-Tg</p> <p>Generic Name: Anti-Tg</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes: 09005021214</p> <p>Shelf Life: 15 Months (2-8°C)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • EU QMS Certificate of manufacturing site has not been submitted.

		<p>Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 17-03-2025 Validity: Not mentioned</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-10-2025</p> <p>• EU QMS Certificate: Not Submitted</p>		
323	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 66380455847</p>	<p>Name of Manufacturer (As per FSC): GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Original Issued By: Danish Medicine Agency Legalization: Legalized Validity: 30-09-2026</p> <p>• ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2026</p> <p>• EU QMS/EC Certificate: Not Submitted</p>	<p>Brand Name: Interton Family Name: Move Hearing Aid Type: BTE</p> <p>Generic Name: Hearing Aid</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Sizes: MV665-DW, MV465-DW, MV365-DW, MV265-DW, MV670-DW, MV470-DW, MV370-DW, MV270DW, MV170-MV680-DWH, MV480-DWH, MV380DWH, MV280-DWH, MV180-DWH, MV690-DW, MV490-DW, MV390-DW, MV290-DW</p> <p>Shelf Life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has applied multiple models of single family (as FSC) in single application. • The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S. • The name of manufacturer mentioned on FSC is Interton A/S while manufacturer mentioned on Form are GN ReSound (Malaysia) & GN Resound China Ltd. • CE Certificate of Interton A/S has been submitted instead of GN Hearing A/S.
324	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p>	<p>Legal Manufacturer (as per FSC): GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <p>Manufacturing Site1 (as per</p>	<p>Brand Name: Interton Family Name: Move Hearing Aid Type: ITC</p> <p>Generic Name:</p>	<p>The Board deferred the case due to following deficiencies in the application;</p>

	<p>ELI-01011</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 30684205</p>	<p>FSC): GN ReSound (Malaysia) Sdn Bhd , No. 5, Jalan i-Park 1/1, Kawasan Perindustrian i-Park, 81000 Bandar Indahpura, Kulai, Johor, Malaysia.</p> <p>Manufacturing Site2 (as per FSC): GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area 361006 Xiamen, China.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Original Issued By: Danish Medicine Agency Legalization: Legalized Validity: 19-09-2026</p> <p>• ISO – Certificate: Not submitted.</p> <p>• EU QMS/EC Certificate: Not Submitted</p>	<p>Hearing Aid</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Sizes: MV6CIC-MP, MV6CIC-LP, MV6CIC-HP, MV4CIC-MP, MV4CIC-LP, MV4CIC-HP, MV3CIC-MP, MV3CIC-LP, MV3CIC-HP</p> <p>Shelf Life: 5 Years</p>	<ul style="list-style-type: none"> • The applicant has applied multiple models of single family (as FSC) in single application. • The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S. • ISO Certificate of manufacturing sites has not been submitted. • CE Certificate of Interton A/S has been submitted instead of manufacturing sites.
325	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 624458423523</p>	<p>Name of Manufacturer (As per FSC): GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Original Issued By: Danish Medicine Agency Legalization: Legalized Validity: 30-09-2026</p> <p>• ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2026</p>	<p>Brand Name: Interton</p> <p>Family Name: Move</p> <p>Hearing Aid Type: BTE</p> <p>Generic Name: Hearing Aid</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Sizes: MV661-DRW, MV461-DRW, MV361-DRW, MV261-DRW, MV662-DRW, MV462-DRW, MV362-DRW, MV262-DRW, MV661-DRWC, MV461-DRWC, MV361-DRWC</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has applied multiple models of single family (as FSC) in single application. • The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S. • The name of manufacturer mentioned on FSC is Interton A/S while

		<ul style="list-style-type: none"> • EU QMS/EC Certificate: Not Submitted 	Shelf Life: 5 Years	<p>manufacturer mentioned on Form are GN ReSound (Malaysia) & GN Resound China Ltd.</p> <ul style="list-style-type: none"> • CE Certificate of Interton A/S has been submitted instead of GN Hearing A/S.
326	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 599641119</p>	<p>Name of Manufacturer (As per FSC): GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <ul style="list-style-type: none"> • LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 • FSC Type: Original Issued By: Danish Medicine Agency Legalization: Legalized Validity: 30-09-2026 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2026 • EU QMS/EC Certificate: Not Submitted 	<p>Brand Name: Interton Family Name: Move Hearing Aid Type: ITE</p> <p>Generic Name: Hearing Aid</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Sizes: MV6ITC-DW-UP, MV6ITC-DW-MP, MV6ITC-DW-HP, MV4ITC-DW-UP, MV4ITC-DW-MP, MV4ITC-DW-HP, MV3ITC-DW-UP, MV3ITC-DW-MP, MV3ITC-DW-HP, MV6CIC-W-MP, MV6CIC-W-HP, MV6CIC-W-LP, MV4CIC-W-MP, MV4CIC-W-LP, MV4CIC-W-HP, MV3CIC-W-MP, MV3CIC-W-LP, MV3CIC-W-HP</p> <p>Shelf Life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has applied multiple models of single family (as FSC) in single application. • The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S. • The name of manufacturer mentioned on FSC is Interton A/S while manufacturer mentioned on Form are GN ReSound (Malaysia) & GN Resound China Ltd. • CE Certificate of Interton A/S has been submitted instead of GN Hearing A/S.
327	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R& I</p>	<p>Name of Manufacturer (As per FSC): GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <ul style="list-style-type: none"> • LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 	<p>Brand Name: Interton Family Name: Move Hearing Aid Type: ITE</p> <p>Generic Name: Hearing Aid</p> <p>Applied as: Single</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has applied multiple models of single

	<p>14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 94218291673</p>	<ul style="list-style-type: none"> • FSC Type: Original Issued By: Danish Medicine Agency Legalization: Legalized Validity: 30-09-2026 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2026 • EU QMS/EC Certificate: Not Submitted 	<p>Class: B</p> <p>Models/Sizes: MV6ITE-DW-UP, MV6ITE-DW-MP, MV6ITE-DW-HP, MV4ITE-DW-UP, MV4ITE-DW-MP, MV4ITE-DW-HP, MV3ITE-DW-UP, MV3ITE-DW-MP, MV3ITE-DW-HP</p> <p>Shelf Life: 5 Years</p>	<p>family (as FSC) in single application.</p> <ul style="list-style-type: none"> • The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S. • The name of manufacturer mentioned on FSC is Interton A/S while manufacturer mentioned on Form are GN ReSound (Malaysia) & GN Resound China Ltd. • CE Certificate of Interton A/S has been submitted instead of GN Hearing A/S.
328	<p>M/s Rosaceae Pharma (Pvt.) Ltd., Altimi House, Suite No. 301-A, 21-C, Khalid Commercial Street No. 4, Phase 7 Ext. DHA, Karachi.</p> <p>(ELI-01280)</p> <p>Date of R&I 19-05-2025</p> <p>Fee Details: Paid Fee: 31,000/- Slip: 6974922871</p>	<p>Name of Manufacturer: M/s Eschweiler GmbH & Co. KG, Holzkoppelweg 35 D-24118 Kiel, Germany</p> <p>LOA: Type: Original Notarization: Notarized Validity: 18-03-2030</p> <p>FSC: Type: Original Issued By: Govt. Body Legalization: Not Legalized Issue Date: 25-03-2025 Validity: Not mentioned</p> <p>ISO Certificate: Type: Original Notarization: Notarized. Validity: 02-06-2025</p> <p>EU QA Certificate Not Submitted</p>	<p>Brand name: ESCHWEILER Modular Pro BGA Analyser</p> <p>Generic Name: Modular Pro BGA Analyser</p> <p>Class: B</p> <p>Article No: MP 123-Hb</p> <p>Shelf life: 10 Years</p>	<p>The Board approved the case subject to submission of valid legalized FSC by the applicant before issuance of the registration letter.</p>
329	<p>M/s Rosaceae Pharma (Pvt.) Ltd., Altimi House, Suite No. 301-A, 21-C, Khalid</p>	<p>Name of Manufacturer: M/s Eschweiler GmbH & Co. KG, Holzkoppelweg 35 D-24118 Kiel, Germany</p>	<p>Brand name: ESCHWEILER Modular Pro BGA + ISE Analyser</p> <p>Generic Name:</p>	<p>The Board approved the case subject to submission of valid legalized FSC by the</p>

	<p>Commercial Street No. 4, Phase 7 Ext. DHA, Karachi.</p> <p>(ELI-01280)</p> <p>Date of R&I 19-05-2025</p> <p>Fee Details: Paid Fee: 31,000/- Slip: 5592187642</p>	<p>LOA: Type: Original Notarization: Notarized Validity: 18-03-2030</p> <p>FSC: Type: Original Issued By: Govt. Body Legalization: Not Legalized Issue Date: 25-03-2025 Validity: Not mentioned</p> <p>ISO Certificate: Type: Original Notarization: Notarized. Validity: 02-06-2025</p> <p>EU QA Certificate Not Submitted</p>	<p>Modular Pro BGA + ISE Analyser</p> <p>Class: B</p> <p>Article No: MP 12345678-Hb</p> <p>Shelf life: 10 Years</p>	<p>applicant before issuance of the registration letter.</p>
330	<p>M/s Rosaceae Pharma (Pvt.) Ltd., Altimi House, Suite No. 301-A, 21-C, Khalid Commercial Street No. 4, Phase 7 Ext. DHA, Karachi.</p> <p>(ELI-01280)</p> <p>Date of R&I 19-05-2025</p> <p>Fee Details: Paid Fee: 31,000/- Slip: 51344923653</p>	<p>Name of Manufacturer: M/s Eschweiler GmbH & Co. KG, Holzkoppelweg 35 D-24118 Kiel, Germany</p> <p>LOA: Type: Original Notarization: Notarized Validity: 18-03-2030</p> <p>FSC: Type: Original Issued By: Govt. Body Legalization: Not Legalized Issue Date: 25-03-2025 Validity: Not mentioned</p> <p>ISO Certificate: Type: Original Notarization: Notarized. Validity: 02-06-2025</p> <p>EU QA Certificate Not Submitted</p>	<p>Brand name: ESCHWEILER Modular Pro BGA + ISE + META Analyser Generic Name: Modular Pro BGA + ISE + META Analyser</p> <p>Class: B</p> <p>Article No: MP 12345678-12-Hb</p> <p>Shelf life: 10 Years</p>	<p>The Board approved the case subject to submission of valid legalized FSC by the applicant before issuance of the registration letter.</p>
331	<p>M/s Rosaceae Pharma (Pvt.) Ltd., Altimi House, Suite No. 301-A, 21-C, Khalid Commercial Street No. 4, Phase 7 Ext. DHA, Karachi.</p> <p>(ELI-01280)</p>	<p>Name of Manufacturer: M/s Eschweiler GmbH & Co. KG, Holzkoppelweg 35 D-24118 Kiel, Germany</p> <p>LOA: Type: Original Notarization: Notarized</p>	<p>Brand name: Consumables for ESCHWEILER Analysers Generic Name: Consumables for ESCHWEILER Analysers</p>	<p>The Board approved the case subject to submission of legalized FSC and shelf life information of consumables by the applicant before issuance of the registration letter.</p>

	<p>Date of R&I 19-05-2025</p> <p>Fee Details: Paid Fee: 125,000/- Slip: 6710649261</p>	<p>Validity: 18-03-2030</p> <p>FSC: Type: Original Issued By: Govt. Body Legalization: Not Legalized Issue Date: 25-03-2025 Validity: Not mentioned</p> <p>ISO Certificate: Type: Original Notarization: Notarized. Validity: 02-06-2025</p> <p>EU QA Certificate Not Submitted</p>	<p>Class: B</p> <p>Applied as: Cluster</p> <p>Article No: 1. 50 1 20 35-PO2-fill solution 2. 50 1 30 35-PCO2-fill solution 3. 50 3 10 35-pH-fill solution 4. 50 3 20 35-K+-fill solution 5. 50 3 30 35-Na+-fill solution 6. 50 3 40 35-Ca++-fill solution 7. 50 3 50 35-Cl--fill solution 8. 50 3 60 35-Li+-fill solution 9. 50 5 10 35 - Reference-fill solution 10. 50 6 10 80 - Protein remover 11. 50 6 10 84 - Electrode cleaner 12. 50 6 10 88 - Activating solution 13. 40 6 10 00-WASH 1 (rinsing solution for BGA) 14. 40 6 10 15-WASH 2 (rinsing solution for ISE) 15. 40 6 10 10-WASH 2 (rinsing solution for BGA+ISE) 16. 40 6 10 11-WASH 2+M (rinsing solution for BGA+ISE+META) 17. 40 6 10 20-BGA 1 (calibration solution for BGA - low) 18. 40 6 10 30-BGA 2 (calibration solution for BGA+ISE - low) 19. 40 6 10 40 - BGA 3 (calibration solution for BGA+ISE - low) 20. 40 6 10 50-BGA 4 (calibration solution for BGA+ISE - high) 21. 40 6 10 60-CAL 3 (calibration solution for</p>	
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			<p>ISE-low) 22. 40 6 10 65-CAL 4 (calibration solution f. ISE - high) 23. 40 6 10 45-CAL 3 (calibration solution f. BGA+ISE-low) 24. 40 6 10 55-CAL 4 (calibration solution for BGA+ISE-high) 25. 40 6 10 56-CAL4+M (calibration solution for BGA+ISE + META - high) 26. 50 6 20 31-QC Level 1/2/3 ESCHWEILER Control Solutions CombiPack 27. 50 6 20 41-QC Level 1 ESCHWEILER Control Solution 28. 50 6 20 51-QC Level 2 ESCHWEILER Control Solution 29. 50 6 20 61-QC Level 3 ESCHWEILER Control Solution 30. 70 6 10 00-Rinsing solution modular pro BGA 31. 70 6 10 10-Rinsing solution modular pro BGA/ISE 32. 70 6 10 20-Rinsing solution modular pro BGA META 33. 70 6 10 40- CALPACK modular pro BGA 34. 70 6 10 50- CALPACK modular pro BGA/ISE 35. 70 6 10 60 - CALPACK modular pro BGA/ISE/META</p> <p>Shelf life: 1. 50 1 20 35-PO2-fill solution (Not mentioned) 2. 50 1 30 35-PCO2-fill Solution (Not mentioned)</p>	
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			<p>3. 50 3 10 35-pH-fill Solution (Not mentioned)</p> <p>4. 50 3 20 35-K+-fill Solution (Not mentioned)</p> <p>5. 50 3 30 35-Na+-fill solution (Not mentioned)</p> <p>6. 50 3 40 35-Ca++-fill Solution (Not mentioned)</p> <p>7. 50 3 50 35-Cl-fill solution (Not mentioned)</p> <p>8. 50 3 60 35-Li+-fill solution (Not mentioned)</p> <p>9. 50 5 10 35 - Reference-fill solution (Not mentioned)</p> <p>10. 50 6 10 80 - Protein remover (Not mentioned)</p> <p>11. 50 6 10 84 - Electrode cleaner (Not mentioned)</p> <p>12. 50 6 10 88 - Activating Solution (Not mentioned)</p> <p>13. 40 6 10 00-WASH 1 (rinsing solution for BGA) (20 months)</p> <p>14. 40 6 10 15-WASH 2 (rinsing solution for ISE) (20 months)</p> <p>15. 40 6 10 10-WASH 2 (rinsing solution for BGA+ISE) (20 months)</p> <p>16. 40 6 10 11-WASH 2+M (rinsing solution for BGA+ISE+META) (20 months)</p> <p>17. 40 6 10 20-BGA 1 (calibration solution for BGA - low) (15 months)</p> <p>18. 40 6 10 30-BGA 2 (calibration solution f.BGA-High) (15 months)</p> <p>19. 40 6 10 40 - BGA 3 (calibration solution for BGA+ISE - low) (15 months)</p> <p>20. 40 6 10 50-BGA 4 (calibration solution for BGA+ISE - high) (15 months)</p> <p>21. 40 6 10 60-CAL 3 (calibration solution for ISE-low) (15 months)</p> <p>22. 40 6 10 65-CAL 4 (calibration solution for</p>	
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			<p>ISE - high) (15 months)</p> <p>23. 40 6 10 45-CAL 3 (calibration solution for BGA+ISE-low) (15 months)</p> <p>24. 40 6 10 55-CAL 4 (calibration solution for BGA+ISE-high) (15 months)</p> <p>25. 40 6 10 56-CAL4+M (calibration solution for BGA+ISE + META - high) (15 months)</p> <p>26. 50 6 20 31-QC Level 1/2/3 ESCHWEILER Control Solutions CombiPack (Not mentioned)</p> <p>27. 50 6 20 41-QC Level 1 ESCHWEILER Control Solution(Not mentioned)</p> <p>28. 50 6 20 51-QC Level 2 ESCHWEILER Control Solution(Not mentioned)</p> <p>29. 50 6 20 61-QC Level 3 ESCHWEILER Control Solution(Not mentioned)</p> <p>30. 70 6 10 00-Rinsing solution modular pro BGA (20 months)</p> <p>31. 70 6 10 10-Rinsing solution modular pro BGA/ISE(20 months)</p> <p>32. 70 6 10 20-Rinsing solution modular pro BGA META(20 months)</p> <p>33. 70 6 10 40- CALPACK modular pro BGA (Not mentioned)</p> <p>34. 70 6 10 50- CALPACK modular pro BGA/ISE (15 months)</p> <p>35. 70 6 10 60 - CALPACK</p> <p>modular pro BGA/ISE/META (15 months)</p>	
332	M/s Mediland Pakistan	Manufacturer:	Brand Name:	The Board deferred

	(Pvt.) Ltd., Office No. B-09, 2nd Floor, Masood Arcade IJP Road Near Saidpur Road Rawalpindi. ELI-00202 Date of R& I 12-05.2025 Fee: Rs. 100,000/- Slip No. 0399297473	KLS Martin Se & Co. KG Address: KLS Martin Platz 1 78532 Tuttlingen Germany. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 30-06-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Issue Date: 17-03-2025 Validity: Not mentioned • ISO – Certificate: Type: Original Notarization: Notarized Validity: 28-08-2025 • EU QMS Certificate: Type: Original Notarization: Notarized Validity: 24-05-2027	KLS Martin OMF Implants Generic Name: Oral & Maxillo-facial implants system Applied as: System Class: C Code/sizes: Not provided Shelf Life: Not mentioned	the case due to following deficiencies in the application; • Application has been submitted as system, however, the articles applied does not fall under the definition of system. Moreover, the FSC mentions different articles separately, not as a system. • LOA is copy and does not mention authorization of applied device. • Copy of FSC submitted has not been legalized. • Shelf life alongwith stability studies have not been submitted.
333	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 07-05-2025 Fee: PKR 62,000/- Slip # 022173549 Dated: 28-04-2025	Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026 • ISO – Certificate: Type: Copy of notarized	Brand name: Erba PT-INR Multical Generic Name: PT % / INR Calibrator (4 x 1ml, 4 levels) Applied as: Kit Class: C Code/sizes: EHL00013 (as per Free sale certificate): Shelf Life: 36 Months (2-8°C)	The Board deferred the case due to following deficiencies in the application; • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The FSC submitted is copy and not legalized. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted. • Original LOA & ISO certificate has not been submitted.

		Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted.		
334	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 07-05-2025 Fee: PKR 62,000/- Slip # 0880396551 Dated: 28-04-2025	Legal Manufacturer: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Manufacturing Site: Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: Govt. Body Legalization: Not Legalized Validity: 18-01-2026 • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-12-2027 • EU QMS/CE Certificate: Not Submitted.	Brand Name: Erba DDimer R 60 Generic Name: R1: 1 x 7 ml DDimer Buffer R2: 1 x 4 ml DDimer Latex R3: 2 x 7 ml DDimer Diluent R4: 1 x 1 ml DDimer Calibrator Applied as: Kit Class: C Code/sizes: Not Provided Shelf Life: 18 Months (2-8°C)	The Board deferred the case due to following deficiencies in the application; • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • The device mentioned on orm-7(A) is Erba DDimer R 60 while documents and fee of Elite H Cal has been attached in file. Documents of Erba DDimer R 60 are required to be submitted. • The FSC submitted is copy and not legalized. • Notarized EU QMS/CE Certificate of the manufacturer, has not been submitted.
335	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. ELI-00009 Date of R& I 14-05-2025 Fee: PKR 62,000/- Slip # 71996124 Dated: 10-04-2025	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 • FSC	Brand Name: Elecsys Calcitonin Generic Name: Elecsys Calcitonin Applied as: Kit Class: C Code/sizes: 09005676214 Shelf Life: 18 Months (2-8°C)	The Board deferred the case due to following deficiencies in the application; • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • EU QMS Certificate of manufacturing site has not been submitted.

		<p>Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 17-03-2025 Validity: Not mentioned</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-10-2025</p> <p>• EU QMS Certificate: Not Submitted</p>		<p>• Original FSC, LOA & ISO certificate are required.</p>
336	<p>M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.</p> <p>ELI-00009</p> <p>Date of R& I 14-05-2025</p> <p>Fee: PKR 62,000/- Slip # 68954734715 Dated: 15-04-2025</p>	<p>Manufacturer: Vetana Medical Systems Inc., 1910 E. Innovation Park Dr. Tucson, AZ 85711, USA.</p> <p>• LOA: Not Provided.</p> <p>• FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 20-08-2026</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027</p> <p>• EU QMS Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-11-2026</p>	<p>Brand Name: Ventana PTEN (SP218) Rabbit Monoclonal Primary Antibody</p> <p>Generic Name: Ventana PTEN (SP218) Rabbit Monoclonal Primary Antibody</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Code/sizes: 07970200001</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • LOA from Legal manufacturer/distributor mentioned on FSC, has not been submitted. • Original FSC and ISO certificate has not been submitted.
337	<p>M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, Lahore.</p> <p>ELI-00771</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 62,000/- Slip # 768631745461 Dated: 02-05-2025</p>	<p>Manufacturer: Heal Force Huayao Biological Technology (Shanghai) Co. Ltd., 2/F, Building 3, 6788 Songze Avenue, Qingpu District, Shanghai, China.</p> <p>• LOA: Type: Copy Notarization: Not notarized Validity: 31-12-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body</p>	<p>Brand Name: Infant Radiant Warmer</p> <p>Generic Name: Infant Radiant Warmer</p> <p>Applied as: Family</p> <p>Class: C</p> <p>Codes: Not mentioned on FSC Models: FXQ3, FXQ4, FXQ4A, FXQ4B, FXQ4H</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • LOA has not been notarized. • FSC submitted has not been legalized and is expired. • Separate application is required for each model.

		<p>Legalization: Not legalized Validity: 08-09-2024</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized. Validity: 11-09-2026</p> <p>• CE Certificate: Type: Copy Notarization: Not Notarized Validity: 05-04-2027</p>	<p>Shelf Life: 36 Months</p>	<ul style="list-style-type: none"> • ISO Certificate of the manufacturer, is not notarized. • CE certificate of the manufacturer, is not notarized. • Shelf-life stability data has not been submitted.
338	<p>M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, Lahore.</p> <p>ELI-00771</p> <p>Date of R& I 07-05-2025</p> <p>Fee: PKR 62,000/- Slip # 1285408030 Dated: 02-05-2025</p>	<p>Manufacturer: Heal Force Huayao Biological Technology (Shanghai) Co. Ltd., 2/F, Building 3, 6788 Songze Avenue, Qingpu District, Shanghai, China.</p> <p>• LOA: Type: Copy Notarization: Not notarized Validity: 31-12-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 23-03-2025</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized. Validity: 11-09-2026</p> <p>• CE Certificate: Not submitted.</p>	<p>Brand Name: Infant Incubator</p> <p>Generic Name: Infant Incubator</p> <p>Applied as: Family</p> <p>Class: C</p> <p>Codes: Not mentioned on FSC</p> <p>Models: YXK-5G, YXK-5GB, YXK-6G, YXK-2000G, YXK-2000GA</p> <p>Shelf Life: 36 Months</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • LOA has not been notarized. • FSC submitted has not been legalized and is expired. • Separate application is required for each model. • ISO Certificate of the manufacturer, is not notarized. • CE certificate of the manufacturer, has not been submitted. • Shelf-life stability data has not been submitted.
339	<p>M/s Life-Tec, Unit B, 1st Floor, Block 20D, G-8 Markaz, Islamabad.</p> <p>ELI-00155</p> <p>Date of R& I 08-05-2025</p> <p>Fee: PKR 62,000/- Slip # 48400453 Dated: 16-04-2025</p>	<p>Manufacturer: Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy</p> <p>• Distribution Contract: Type: Copy Notarization: Not notarized Validity: 31-12-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body</p>	<p>Brand Name: Plasmart Plasmafilters</p> <p>Generic Name: Plasma Filters</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Codes: M03863, M03864,</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The brand name mentioned from applied codes on FSC is Plasmart 50-EO Sterile. Moreover, the applicant has applied plasma filters with

		<p>Legalization: Not legalized Issue Date: Not mentioned Validity: Not Mentioned</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized. Validity: 23-03-2027</p> <p>• EU QMS Certificate: Type: Copy Notarization: Not Notarized. Validity: 31-05-2028</p>	<p>M03865</p> <p>Shelf Life: Not Mentioned</p>	<p>different sizes/dimensions as Single which should be applied as family with additional fee.</p> <ul style="list-style-type: none"> • Copy of Distribution contract submitted has not been notarized. Moreover, annexure with list of products has been attached. • Copy of FSC submitted has not been legalized. • ISO Certificate of the manufacturer, is not notarized. • EU QMS certificate of the manufacturer, is not notarized. • Shelf-life stability data has not been submitted.
340	<p>M/s Life-Tec, Unit B, 1st Floor, Block 20D, G-8 Markaz, Islamabad.</p> <p>ELI-00155</p> <p>Date of R& I 05-05-2025</p> <p>Fee: PKR 62,000/- Slip # 341293648211 Dated: 16-04-2025</p>	<p>Manufacturer: Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy</p> <p>• Distribution Contract: Type: Copy Notarization: Not notarized Validity: 31-12-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: Not mentioned Validity: Not Mentioned</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized. Validity: 23-03-2027</p> <p>• EU QMS Certificate: Type: Copy</p>	<p>Brand Name: AFERsmart Plus 110-230V</p> <p>Generic Name: Therapeutic Apheresis System</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Codes: M90414</p> <p>Shelf Life: Not Mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applicant has applied system as single. Additional fee is required. • Copy of Distribution contract submitted has not been notarized. Moreover, annexure with list of products has been attached. • Copy of FSC submitted has not been legalized. • ISO Certificate of the manufacturer, is not notarized. • EU QMS certificate of the

		Notarization: Not Notarized. Validity: 31-05-2028		<p>manufacturer, is not notarized.</p> <ul style="list-style-type: none"> Shelf-life stability data has not been submitted.
341	<p>M/s Life-Tec, Unit B, 1st Floor, Block 20D, G-8 Markaz, Islamabad.</p> <p>ELI-00155</p> <p>Date of R& I 05-05-2025</p> <p>Fee: PKR 62,000/- Slip # 693338700 Dated: 16-04-2025</p>	<p>Manufacturer: Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy</p> <p>• Distribution Contract: Type: Copy Notarization: Not notarized Validity: 31-12-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: Not mentioned Validity: Not Mentioned</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized. Validity: 23-03-2027</p> <p>• EU QMS Certificate: Type: Copy Notarization: Not Notarized. Validity: 31-05-2028</p>	<p>Brand Name: FRACTIOsmart</p> <p>Generic Name: Plasma Fractionator</p> <p>Applied as: Not selected</p> <p>Class: C</p> <p>Codes: M90099 (Small 2.0), M90100 (Medium 2.0), M90101 (Large 2.0), M90149 (Small 1.0), M90150 (Medium 1.0) M90151 (Large 1.0)</p> <p>Shelf Life: Not Mentioned</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> The applicant has applied plasma fractionator with different sizes/dimensions as Single which should be applied as family with additional fee. Copy of Distribution contract submitted has not been notarized. Moreover, annexure with list of products has been attached. Copy of FSC submitted has not been legalized. ISO Certificate of the manufacturer, is not notarized. EU QMS certificate of the manufacturer, is not notarized. Shelf-life stability data has not been submitted.
342	<p>M/s Eastern Medical Care (Pvt.) Ltd., 7A, Block N, Model Town Extension Lahore</p> <p>ELI-00130</p> <p>Date of R& I 05-04-2025</p> <p>Fee: PKR 62,000/- Slip # 9148161257 Dated: 17-04-2025</p>	<p>Manufacturer: Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, China.</p> <p>• Sole Distribution Agreement: Type: Original Notarization: By CCPIT Validity: 25-10-2027</p>	<p>Brand Name: Able-Disposable Silicon Foley Catheter</p> <p>Generic Name: Disposable Silicon Foley Catheter</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Sizes:</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> The applicant has applied three types of Foley Catheters in single application. FSC has been issued by Chamber of commerce, not

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 24-04-2026 • ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 06-08-2027 • FSC (Spain): Type: Original Issued By: Govt. Body Legalization: Apostilled Date of Issue: 23-01-2025 Validity: Not mentioned 	1-Way (6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR) 2-Way (6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR) 3-Way (6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR, 26FR) Shelf Life: 36 Months	by concerned regulatory body of country of origin.
343	M/s Eastern Medical Care (Pvt.) Ltd., 7A, Block N, Model Town Extension Lahore ELI-00130 Date of R& I 05-04-2025 Fee: PKR 62,000/- Slip # 287678899 Dated: 17-04-2025	Manufacturer: Foshan Biosun Medical Technology Co., Ltd., 1-5F Building 4, No.89 Taoyuan East Road, Shishan, Nanhai, 528115, Foshan Guangdong, China <ul style="list-style-type: none"> • LOA: Not submitted. • FSC Type: Original (in other file) Issued By: Govt. Body Legalization: Apostilled Validity: 05-11-2026 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 17-06-2027 • EU QMS Certificate: Type: Copy Notarization: By CCPIT Validity: 05-08-2029 	Brand Name: Biosky Disposable Bilirubin Adsorption Column Generic Name: Disposable Bilirubin Adsorption Column Applied as: Single Class: C Codes/Models/Sizes: DX100, DX150, DX250, DX350, DX400 Shelf Life: 24 Months	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • The applicant has applied three types of Foley Catheters in single application. • FSC has been issued by Chamber of commerce, not by concerned regulatory body of country of origin.
344	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I	Manufacturer: Bonree Medical Co., Ltd., 1 st Floor, Building No.2, Building No.4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China.	Brand Name: Bonree Silicon Foley Catheter Generic Name: Silicon Foley Catheter Applied as: Single	The Board deferred the case due to following deficiencies in the application; <ul style="list-style-type: none"> • The applicant has applied three types of Foley Catheters

	<p>14-05-2025</p> <p>Fee: PKR 62,000/- Slip # 2612889208 Dated: 21-04-2025</p>	<p>• LOA: Type: Copy of attested Notarization: By CCPIT Validity: 30-12-2028</p> <p>• FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 24-10-2025</p> <p>• ISO – Certificate: Type: Copy of attested Notarization: By CCPIT Validity: 31-07-2025</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Class: C</p> <p>Sizes: 2-Way Pediatric (6FR, 8FR, 10FR) 2-Way Standard (12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR, 26FR) 3-Way Standard (16FR, 18FR, 20FR, 22FR, 24FR, 26FR)</p> <p>Shelf Life: 5 Years</p>	<p>in single application.</p> <ul style="list-style-type: none"> • Copy of FSC submitted does not mention name of device applied. • FQA CE/EU QMS certificate has not been submitted. • Stability data has not been submitted. • Copies of LOA, FSC, ISO certificate have been submitted instead of originals.
345	<p>M/s Reckitt Benckiser Pakistan Limited, Plot No. 73, B, C & D, K-28, Phase-II, Lyari Quarter, Hawks Bay Road, Karachi.</p> <p>ELI-01031</p> <p>Date of R&I 02-05-2025</p> <p>Fee: PKR 62,000/- Slip # 5540819905 Dated: 02-05-2025</p>	<p>Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, GNR, HULL, North Humberside, HU8 7DS, UK. Manufacturing Site: SSL Manufacturing (Thailand) Ltd., Wellgrow Industrial Estate 96 & 100, Moo 5, Bangna-Trad Rd, K.M.36, Bangsamak, Bangpakong, Chachoengsao, 24180, Thailand.</p> <p>• LOA: Type: Copy Notarization: Notarized Dated: 15-11-2023 Validity: Not mentioned.</p> <p>• FSC Type: Copy Issued By: MHRA Legalization: Apostilled Validity: 05-05-2025</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 30-10-2025</p> <p>• EU QMS/CE Certificate: Not Submitted.</p>	<p>Brand Name: Durex Mutual Pleasure</p> <p>Generic Name: Lubricated Condom</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Codes/Sizes: Not mentioned</p> <p>Shelf Life: 5 Years</p>	<p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The applied product has not been mentioned in FSC. • FQA CE certificate of manufacturing site has not been attached.

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.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5912-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 DEC certificates validity 27-05-2024 with extension notification.	INN61V INNEA AQUA Pre-filled syringe of 2ml, with 2.5% Sodium Hyaluronate (50mg/2ml) Class-D Shelf Life: 36 Months Code/size as per FSC	Approved
2.	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 DEC 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	Approved
3.	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 DEC 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	Approved
4.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5915-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 DEC certificates validity 27-05-2024 with extension notification.	PROMVIA HYDRO BALANCE 100mg 2,5% of Sodium Hyaluronate salt and trehalose) Class-D Shelf Life: 36 Months Code/size as per FSC	Approved

5.	Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi ELI-00240	<u>Legal Manufacturer:</u> Hangzhou Alltest Biotech Co.,Ltd 550, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China FSC – China Issued on 22-08-2023 Validity – 2 years Original submitted in Caretest Pregnancy (hCG) Rapid Test Dipstick Dossier FSC Germany issuance 04-11-2024	Caretest HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) Class-C Shelf life: 2 years Code/sizes: IHBSG-402	Approved
6.	Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi ELI-00240	<u>Legal Manufacturer:</u> Hangzhou Alltest Biotech Co.,Ltd 550, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China FSC – China Issued on 22-08-2023 Validity – 2 years Original submitted in Caretest Pregnancy (hCG) Rapid Test Dipstick Dossier FSC Germany issuance 04-11-2024	Caretest HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) Class-C Shelf life: 2 years Codes/sizes: IHC-402	approved
7.	Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi ELI-00240	<u>Legal Manufacturer:</u> Hangzhou Alltest Biotech Co.,Ltd 550, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China FSC – China Issued on 22-08-2023 Validity – 2 years Original submitted in Caretest Pregnancy (hCG) Rapid Test Dipstick Dossier FSC Germany issuance 04-11-2024	Caretest Malaria P.f/Pv Rapid Test Cassette (Whole Blood) Class-C Shelf life: 2 years Codes/sizes: IMPV-402	approved
8.	Ghazali Brothers, 1 st	<u>Legal Manufacturer:</u>	Caretest Typhoid Rapid Test	approved

	Floor, Azainab Court, Campbell Street, Karachi ELI-00240	Hangzhou Alltest Biotech Co.,Ltd 550, Yin Hai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China FSC – China Issued on 22-08-2023 Validity – 2 years Original submitted in Caretest Pregnancy (hCG) Rapid Test Dipstick Dossier FSC Germany issuance 04-11-2024	Cassette (Serum/Plasma) Class-C Shelf life: 2 years Codes/sizes: ITY-302	
9.	Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi ELI-00240	<u>Legal Manufacturer:</u> Hangzhou Alltest Biotech Co.,Ltd 550, Yin Hai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, China FSC – China Issued on 22-08-2023 Validity – 2 years Original submitted in Caretest Pregnancy (hCG) Rapid Test Dipstick Dossier FSC Germany issuance 04-11-2024	Caretest Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) Class-C Shelf life: 2 years Codes/sizes: IDES-402	approved
10.	M/S Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1523-P Evaluator: AD-III	<u>Legal Manufacturer:</u> FFOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO Plain Gut Sutures (Sterile Absorbable surgical suture) Class-D Shelf Life: 5 years Code & Sizes: List provided	The board discussed that applied medical device was previously registered as drug since 2011 and was being imported by the firm since years before applying under Medical Devices rules, 2017, therefore, the board decided to take expert opinion regarding safety and performance of applied product from three surgeons from different hospitals for consideration of the Board.

11.	M/S Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1522-P Evaluator: AD-III	<u>Legal Manufacturer:</u> FFOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO CHAROMIC CATGUT Sterile Absorbable Surgical Suture) Class-D Shelf Life: 5 years Codes: Not provided	The board discussed that applied medical device was previously registered as drug since 2011 and was being imported by the firm since years before applying under Medical Devices rules, 2017, therefore, the board decided to take expert opinion regarding safety and performance of applied product from three surgeons from different hospitals for consideration of the Board.
12.	M/s. Ali Gohar & Company (Pvt) Ltd. ELI-00004	<u>Legal Manufacturer:</u> Smiths Medical ASD Inc., 1500 EurEka park lower premberton Ashford Kent, TN25, 4BF, UK FSC: United Kingdom Validity: 18/03/2024 LOA Validity: 14/12/2027 OR EC Certificate: Validity: 18/03/2023	Brand Name: Portex® (Choice Blue Vibratory PEP Device) Loss of Resistance Device Class B Claimed Shelf Life:05-Years Codes / Sizes (if any) 27-8000 27-8001 27-8050	Deferred for clarification of Legal manufacturer and Manufacturing site as per FSC and submission of notarized EC, ISO certificate of manufacturing site and LoA.
13.	M/s. Ali Gohar & Company (Pvt) Ltd. ELI-00004	<u>Legal Manufacturer:</u> Smiths Medical ASD Inc., 1500 EurEka park lower premberton Ashford Kent, TN25, 4BF, UK FSC: United Kingdom Validity: 18/03/2024 LOA Validity: 14/12/2027 FSC: FSC of Reference Country Validity: 00-00-20— OR EC Certificate: Validity: 26/05/2024	Brand Name: Acapella® Green (Vibratory PEP Therapy System) Class B Claimed Shelf Life:05-Years Codes / Sizes (if any) 21-1530 Model/Version Acapella DH Green Mouthpiece NS: 21-1530	Deferred for clarification of Legal manufacturer and Manufacturing site as per FSC and submission of notarized EC, ISO certificate of manufacturing site and LoA.

14.	<p>Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi</p> <p>(ELI-00015)</p>	<p>Legal Manufacture</p> <p>QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany</p> <p>Copy of FSC: Germany Issuance DATE: 16- 3 - 2022</p> <p>ISO 13485 Issuance Date: 19 Aug 2021 Expiry Date: 14 June 2024</p> <p>FQA Issuance Date: 6 May 2021 Expiry Date: 26 May 2024 (Original submitted with HBV RG PCR Kit)</p> <p>LOA Issuance date: 11 October 2018 Validity: 5 Years (Original submitted with HBV RG PCR Kit)</p>	<p>QIAstat-Dx Respiratory SARS-CoV-2 Panel</p> <p>Class C</p> <p>Shelf Life: 9 months</p> <p>Codes: 691214</p> <p>Date of submission: 13 Dec 2022</p> <p>Fee submitted: PKR 50,000/-</p>	<p>Deferred for submission of notrized and valid LoA, ISO 13485 & FQA or clarification that QIAstat-Dx Respiratory SARS- CoV-2 panel (class C) does not require FQA.</p>
15.	<p>Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi</p> <p>(ELI-00015)</p> <p>Evaluator</p>	<p>Legal Manufacture</p> <p>QIAGEN GmbH, Qiagen Strasse 1, 0724 Hilden, Germany FSC: Germany Issuance DATE: 16- 3 - 2022</p> <p>ISO Issuance Date: 3 May 2022 Expiry Date: 14 June 2024</p> <p>FQA Issuance Date: 6 May 2021 Expiry Date: 26 May 2024 (Original submitted with HBV RG PCR Kit)</p>	<p>QIAstat-Dx® Meningitis/Encephalitis</p> <p>Class C</p> <p>Shelf Life: 9 months</p> <p>Codes: 69161 1</p> <p>Date of submission: 15 Dec 2022</p> <p>Fee submitted: PKR 50,000/-</p>	<p>Deferred for submission of notrized and valid LoA, ISO 13485 & FQA or clarification that QIAstat-Dx Meningitis/Encephalitis panel (class C) does not require FQA.</p>

		LOA Issuance date: 11 October 2018 Validity : 5 Years (Original submitted with HBV RG PCR Kit)		
16.	Briogene Pvt Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI- 00015) -4658-	Manufacture By ISLAB Biyoteknoloji Tibbi Malzeme Saglik Hiz. San. ve Tic. A.S. Kaynarca Mah. Kadirli Sok. D. B1 ok Apt No. 10B Pendik/Istanbul Turkey FSC: Turkey (Istanbul) Issuance date of FSC: 04-01-2021. valid for 36 Months.	ODAK Blood Grouping OBG-liss diluent OBGLISS-500 • Codes as per FSC: • Class-B Claimed Shelf life: 13 Months	Deferred for Clarification of CE certificate of applied product and clarification of class
17.	M/s Medtronic Pakistan Private Limited	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000 Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II, Bayan Lepas, Pulau Pinang, Malaysia 11900. MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD. 149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus	Patient Connector 24967 Shelf life: 5 years Class: A COPY of USFDA FSC valid till June 2022	Deferred for submission of 1. Fee voucher submitted for Patient Connector. 2. Notified and valid ISO certificate for all manufacturers. 3. Stability studies.

		ManufacturingSdinBhd Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900		
18.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [714-7L] Feb-2025	BM Disposable Enteral Feeding Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 65267853330	Disposable Enteral Feeding: Enteral Feeding Set, a vital tool designed to deliver nourishment and medication directly into the patient's gastrointestinal tract. This set is meticulously crafted to ensure safety, precision, and comfort, making it indispensable for hospitals, clinics, and home healthcare environments. The Enteral Feeding Set is a crucial component in modern healthcare, offering reliability, precision, and patient comfort in enteral feeding procedures. Whether used in hospitals, clinics, or home settings, this set provides healthcare providers with the tools they need to deliver optimal nutrition and medication directly to the gastrointestinal tract, promoting faster recovery and improved patient outcomes.	Already decided in 93 rd meeting.
19.	Medzntech Pvt.Ltd., D-21 Sector 16-A Govt. Teachers CO- operative Housing Society, KDA Scheme 33, Karachi (ELI-00657) R&I date: 06-03-2025 Fee Rs 31000/- vide Challan no. 1601051333	M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX, USA 76134 LOA/sole agency :11-11- 2029(Notarized copy of LOA) FSC USFDA Valid till: 10-10-2025 EC Certificate 24-04- 2025 (copy) ISO-13485 Validity: 20-02-2027(Copy) Alcon Research, LLC, 15800 Alton Parkway, IRVINE CA, USA	NGenuity 3D Visualization System 1.5 (Model: 8065000399) Generic Name : NGenuity 3D Visualization System Applied as : Not Mentioned Class: B Shelf life: N/a Codes/Sizes	Approved. Registrartion letter will be issued with codes/models and manudfacturer /sites as per FSC.

		92618. EMBEDTEK, LLC, N7W23700 Bluemound Rd Ste 100, Waukesha, WI, USA 53188		
20.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI- 01234)	Assure Tech (Hangzhou) Co., Ltd. Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China	Cure Sure Blood Glucose Monitoring System (Meter + Strips) Class B	Approved in Class C. Firm shall submit differential fee of class C for system and provide service life
21.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI- 01234)	Assure Tech (Hangzhou) Co., Ltd. Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China	Cure Sure Pregnancy Test Strip Class B	Approved in Class C. Firm shall submit differential fee of class C and provide shelf life
22.	Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI- 01234)	Assure Tech (Hangzhou) Co., Ltd. Building No. 4, 1418-50, Moganshan Road, Gongshu District, hangzhou, 310011 Zhejiang PR China	Xaet Pregnancy Test Strip Class B	Approved in Class C. Firm shall submit differential fee of class C and provide shelf life
23.	M/s Nasir Brother 22B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. ELI-00036 R&I details 01/09/23	Legal Manufacture M/s Wuxi Exanovo Medical Instruments Co., Ltd Address: C2-LianDong U Gu, Xebai Town, Xishan District, Wuxi2149, Jiangsu Province P.R China. FSC Validity: 16/10/2025 LOA Validity: 06/03/2028	Brand Name Vcare, V.well Aneroid Sphygmomanometer Class: A Claimed Shelf Life 5 Years Code/sizes Not Applicable	Approved (V. well) Aneroid Sphygmomanometer Fee shall be as per updated DRAP fee SRO.
24.	M/s Nasir Brother	Legal Manufacture M/s Wuxi Exanovo Medical	Brand Name Vcare, V.well, OTAM	Approved 'V. well' Stethoscope

	22B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. ELI-00036 R&I details 01/09/23	Instruments Co., Ltd Address: C2-LianDong U Gu, Xebai Town, Xishan District, Wuxi2149, Jiangsu Province P.R China. FSC Validity: Different Product LOA Validity: 06/03/2028	Stethoscope Class: A Shelf Life: 5 Years Code/sizes Not Applicable	Fee shall be as per updated DRAP fee SRO.
25.	Oasis Medical Systems, Bangalow No. A-86, block C, Gulshan-e- Jamal, Karachi, 75360, Pakistan. (ELI-00495) Dossier#1448-C Date:04-04-23	Legal Manufacturer: UTAS technologies S.R.O., 1, Stavitselska st., Bratislava,83104, Slovakia FSC: Slovakia Issued: 26-04-2021	UTAS (Patient Monitor UM-300S) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deffered for following. Provide justification of the product category (family, system, cluster) fee will be accordingly. Justify for applying multiple model / types in single application.
26.	M/s. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	<u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid jan 2025 LOA Validity: 31/12/2028	Brand Name; KAYO Red Cap (Clot Activator) Vacuum Blood Collection Tubes Generic Name; Blood collecting vacuum Tube(vecutanier) Class A Shelf Life: 2 Years Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	Approved.
27.	M/s. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	<u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid 19 sep 2026 FSC: Guatemala	Brand Name; KAYO Purple Cap (ETDA K3) Vacuum Blood Collection Tubes Generic Name; Blood collecting vacuum Tube(vecutanier) Class A Shelf Life: 2	Approved.

		Valid up 23Jan 2026 LOA Validity: 31/12/2028	Years Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	
28.	M/s. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	<u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid Jan 2025 FSC: Guatemala Valid up 23Jan 2026 LOA Validity: 31/12/2028	Brand Name; KAYO Black Cap (ESR) 109m/129m Sodium Citrate Vacuum Blood Generic Name; Blood collecting vacuum Tube(vecutanier) Class A Shelf Life: 2 Years Sizes 1.6ml & 1.8ml	Approved.
29.	M/s. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	<u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid jan 2025 LOA Validity: 31/12/2028	Brand Name; KAYO Red Cap (No Additive) Plan Vacuum Blood Collection Tubes Generic Name; venous blood specimen collection vacuum Tube(vecutanier) Class A Shelf Life: 2 Years Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	Approved
30.	M/s. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028 Fee 6000	<u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid jan 2025 LOA Validity: 31/12/2028	Brand Name; KAYO Blue Cap (Sodium Citrate 3.2%) Coagulation Vacuum Blood Collection Generic Name; Blood collecting vacuum Tube(vecutanier) Class A Shelf Life: 2 Years Sizes 1.8ml & 2.7ml	Approved.

31.	<p>M/s. <u>East Health Care</u></p> <p>A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.</p> <p>ELI-01115 Mfg 09/08/2023 Exp 8/08/2028</p>	<p><u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.</p> <p>FSC: China Validity: Valid jan 2025</p> <p>LOA Validity: 31/12/2028</p>	<p>Brand Name; KAYO Purple Cap (ETDA K2) Vacuum Blood Collection Tubes</p> <p>Generic Name; venous blood specimen collection vacuum Tube(vecutanier)</p> <p>Class A</p> <p>Shelf Life: 2 Years</p> <p>Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml</p>	Approved.
32.	<p>M/s. <u>East Health Care</u></p> <p>A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.</p> <p>ELI-01115 Mfg 09/08/2023 Exp 8/08/2028</p>	<p><u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.</p> <p>FSC: China Validity: Valid jan 2025</p> <p>LOA Validity: 31/12/2028</p>	<p>Brand Name; KAYO Yellow Cap (SST Clot Activator) Vacuum Blood Collection Tubes</p> <p>Generic Name; venous blood specimen collection vacuum Tube(vecutanier)</p> <p>Class A</p> <p>Shelf Life: 2 Years</p> <p>Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml</p>	Approved.
33.	<p>M/s. <u>East Health Care</u></p> <p>A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.</p> <p>ELI-01115 Mfg 09/08/2023 Exp 8/08/2028</p>	<p><u>Legal Manufacturer:</u> M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.</p> <p>FSC: China Validity: Valid jan 2025</p> <p>LOA Validity: 31/12/2028</p>	<p>Brand Name; KAYO Green Cap (Heparin) Vacuum Blood Collection Tubes</p> <p>Generic Name; venous blood specimen collection vacuum Tube(vecutanier)</p> <p>Class A</p> <p>Shelf Life: 2 Years</p> <p>Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml</p>	Approved.

Name Address of Importer	Name M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi
Detail of ELM/ELI	ELI- 00273
Name Address of Manufacturer	Legal Manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: i. Changzhou Kanghui Medical innovations Co Ltd, No.11 North Changjiang road Xinbei Zone, Changzhou, Jiangsu, China.
Brand Name Generic name	Bone Plates -
Country of origin FSC	Fsc: Original Legalized FSC Submitted. Validity Till:29-08-23 expired at submission
Date of application received along with Fee	23-11-2023, Fees 50,000
Class of medical device	C
Stability data/ service life	Shelf Life: NA
Documents submitted Marketing Authorization Letter: Production Quality Management System Certificate (Iso 13485) Full Quality Assurance Certificate or Equivalent: Design Examination Declaration of Conformity (Doc) provided/not provided	Marketing Authorization Letter: LOA issuance date 16-10-2023 Production Quality Management System Certificate (Iso 13485) Original Notarized Iso 13485 Certificate Valid till 30-06-2026 issuance date 01-07-2023 Full Quality Assurance Certificate / CE: Original Notarized Full Quality Assurance Certificate Valid till 26-05-2024 issuance date 26-02-2021. Design Examination NA Declaration of Conformity (Doc): Original Doc submitted.
Codes/ sizes	Thickness hole length and width variables SDDW53, SDDW50, SDDW52, SDDW55, SDDW51, SDDw62, SDDW59, SDDW53S, SDDW52S, SDDG55S, SDDW50S, SDDW51S, SDDW62S, SDDW59S, SDXZ40, SDXZ75, SDXZ73, SDXZ74, SDXZ06, SDXZ45, SDXZ68, SDXZ72, SDXG78, SDXG46, SDXG47, SDXZ70, SDXZ76, SDXZ77, SDXZ57, SDXZ58, SDXG33, SDXG43, SDXG52, SDXG51, SDXG35, SDXG34, SDXG59, SDXG54, SDXG53, SDXZ07, SDXG07, SDXZ08, SDXG08, SDXG30, SDXG29, SDXZ10, SDXG10, SDXZ09, SDXG09, SDDG19, SDDG20, SDXG37, SDDZ40, SDDG40, SDDG41, SDXG36, SDXG32, SDXG42, SDXG41, SDXG25, SDXG27, SDXZ11, SDXZ66, SDXZ67, SDXG22, SDXG23, SDXZ28, SDXZ27, SDDZ36, SDXZ71, SDDG44, SDDG45, SDDG59, SDDG50, SDDG51, SDDZ37, SDDZ38, SDDG38, SDDG39, SDDG47, SDDG46, DDG52, SDDG53, SDDG49, SDDG48, SDDZ22,

	SDDG22, SDDZ21, SDDG21, SDDG13, SDDG14
Decision	Deferred for submission of 1. Shelf life and metallurgy data 2. Clarification of serial number on FSC for applied bone plate and highlighting the applied codes on FSC. 3. Submission of separate application against each serial number (product) of bone plate on FSC. 4. Clarification of applied product as system or otherwise and accordingly submit complete catalogue.

Case No.2

Name Address of Importer	Name M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi
Detail of ELM/ELI	ELI- 00273
Name Address of Manufacturer	Legal Manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: i. Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.
Brand Name Generic name	Bone Screws -
Country of origin FSC	Fsc: Original Legalized FSC Submitted. Validity Till: 18-11-2024
Date of application received along with Fee	23-11-2023
Class of medical device	C
Stability data/ service life	Shelf Life: NA
Documents submitted Marketing Authorization Letter: Production Quality Management System Certificate (Iso 13485) Full Quality Assurance Certificate or Equivalent: Design Examination Declaration of Conformity (Doc) provided/not provided	Marketing Authorization Letter: LOA issuance date 16-10-2023 Production Quality Management System Certificate (Iso 13485) Copy of Original Notarized Iso 13485 Certificate Valid till 30-06-2026 issuance date 01-07-2023 Production Quality Assurance Certificate or Equivalent: Copy of Original Notarized Full Quality Assurance Certificate Valid till 26-05-2024 issuance date 26-02-2021. Design Examination NA Declaration of Conformity (Doc): Original Doc submitted.
Codes/ sizes	SDLD01, DJY-III, SDLD03S, DJY-11-02, DJY-II, HBQ03, HAQ03, HAQ06, DJY-II-01, DJY-V, DJY-IV, SDLD03 Sterile/ non sterile

Remarks	Sterile and non-sterile codes applied in single application, shelf life data is not provided
Decision	Deferred for submission of 1. Shelf life and metallurgy data. 2. Clarification of serial number on FSC for applied bone screw and highlighting the applied codes on FSC. 3. Submission of separate application against each serial number (product) of bone screw on FSC. 4. Clarification of applied product as system or otherwise and accordingly submit complete catalogue.

Case No.3

Name Address of Importer	Name M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi
Detail of ELM/ELI	ELI- 00273
Name Address of Manufacturer	Legal Manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.
Brand Name Generic name	General Spine System -
Country of origin FSC	Fsc (China): Copy of Original Legalized FSC Submitted. Validity Till: 18-11-2024 (Original Free Sale Certificate Attached with Registration Application of Bone Screws dated 7 th November 2023)
Date of application received along with Fee	23-11-2023
Class of medical device	C
Stability data/ service life	Shelf Life: NA
Documents submitted Marketing Authorization Letter: Production Quality Management System Certificate (Iso 13485) Full Quality Assurance Certificate or Equivalent: Design Examination	Marketing Authorization Letter: LOA issuance date 16-10-2023 Production Quality Management System Certificate (Iso 13485) Copy of Original Notarized Iso 13485 Certificate Valid till 30-06-2026 issuance date 01-07-2023 (Original Notarized ISO Attached with Registration Application of Bone Plates dated 7 th November 2023) Production Quality Assurance Certificate or Equivalent: Copy of Original Notarized Full Quality Assurance Certificate Valid till 26-05-2024 issuance date 26-02-2021. (Original Notarized FQA Attached with Registration Application of Bone Plates dated 7 th November 2023) Design Examination NA

Declaration of Conformity (Doc) provided/not provided	Declaration of Conformity (Doc): Original Doc submitted.
Codes/ sizes	RF-S01, LD01
Decision	Deferred for submission of 1. Shelf life data. 2. Clarification of serial number on FSC for applied General Spine System and highlighting the applied codes on FSC. 3. Submission of separate application against each serial number (product) of General Spine System on FSC. 4. Clarification of applied product as system or otherwise and accordingly submit complete catalogue.

Case No.4

Name Address of Importer	Name M/s Medtronic Pakistan Private Limited Address of Importer Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi
Detail of ELM/ELI	ELI- 00273
Name Address of Manufacturer	Legal Manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minneapolis MN 55432 USA. Manufacturing Site: Changzhou Kanghui Medical innovations Co Ltd, No.11 North Chengjiang road Xinbei Zone, Changzhou, Jiangsu, China.
Brand Name Generic name	Lockable Intermedullary Nails -
Country of origin FSC	Fsc: Copy of Original Legalized FSC Submitted. Validity Till: 18-11-2024 (Original Free Sale Certificate Attached with Registration Application of Bone Screws dated 7 th November 2023)
Date of application received along with Fee	23-11-2023
Class of medical device	C
Stability data/ service life	Shelf Life: NA
Documents submitted Marketing Authorization Letter: Production Quality Management System Certificate (Iso 13485) Full Quality Assurance Certificate or Equivalent:	Marketing Authorization Letter: LOA issuance date 16-10-2023 Production Quality Management System Certificate (Iso 13485) Copy of Original Notarized Iso 13485 Certificate Valid till 30-06-2026 issuance date 01-07-2023 (Original Notarized ISO Attached with Registration Application of Bone Plates dated 7 th November 2023) Production Quality Assurance Certificate or Equivalent: Copy of Original Notarized Full Quality Assurance Certificate Valid till 26-05-2024 issuance date 26-02-2021. (Original Notarized FQA Attached with Registration Application of Bone Plates dated

Design Examination	7 th November 2023)
Declaration of Conformity (Doc) provided/not provided	Design Examination NA Declaration of Conformity (Doc): Original Doc submitted.
Codes/ sizes	KGD I, KSDXIIS, KSD XIII, KSDXIIS, KSDXII, KSDXIS, KSDXI, KSDVIS, KSDVI, KSDIV S, KSDIV, KSD IIS, KSDIII, KSD IIS, KSD II, KSD I S, KSD I, KGM IIS, KGM II, KGM I S, KGM I, KGDIIIS, KGDIII, KGDII S, KGD II, KGD I S, JSDVIII, JGM IIS, JSDVII, JJD III, JGM V, JGM III, JGM II, JGD VI, JGD III, JGD VII, JJD V, JGM IIS, JGD IIS, JGD VIIS, JJD VS, JGD IIS, JSDX, JSDIX, JSD IVS, JSD IV, JSDIXS, JSDVIIS, JSDVIIS, JJD IIS, JGM VS
Decision	Deferred for submission of shelf life data and clarification whether application is for Lockable Intramedullary Nail present at serial 17 or 21 of FSC. Clarification of applied product as system or otherwise and accordingly submit complete catalogue.

Case No. 01. REQUEST OF OZARK BIOPHARM (PVT) LTD. C-22 EXCESS, MAIN CHAMBER ROAD, RAWAT, ISLAMABAD.

The application of the firm M/s BioPharm International, Rawat, Islamabad, for the grant of Establishment License to import medical devices, approved in 91st MDB meeting held on 17.06.2025, as per following details.

Sr.No.	Name of Establishment	Name of Inspector (s)	Cold Chain (Yes/No)	Recommendations by the panel.	Decision in 91 st MDB meeting held on 17.06.2025
01	M/s Ozark BioPharm International, C-22 Excess, Main Chamber Road, Rawat, Islamabad	Mr. Waqar Ahmed, Deputy Director, DRAP, Islamabad	No	Recommended for storage of room temperature medical devices.	Approved for storage of room temperature medical devices.

Issuance of Establishment License to import medical devices (ELI) is pending and has not been issued so far. In the meanwhile, the firm submitted an application reference number MD/725 dated 10.07.2025 for change of the name/title of the company and requested for issuance/grant of Establishment License to import medical devices (ELI) with revised name/title, as per following details.

Name of Establishment as approved in 91 st MDB meeting held on 17.06.2025	Proposed Name of Establishment	Remarks	Decision
M/s Ozark BioPharm International, C-22 Excess, Main Chamber Road, Rawat, Islamabad	M/s Ozark Biopharm (Pvt) Ltd. C-22 Excess, Main Chamber Road, Rawat, Islamabad.	<ul style="list-style-type: none"> Revised Form 2 with fee Rs: 25000/- (81073741652) provided. SECP Certificate of incorporation with company title/name as <i>Ozark Biopharm (Private) Limited</i> 	The Board acceded to the request of the firm for issuance of Establishment License to Import Medical Devices (ELI) with the title M/s Ozark Biopharm (Pvt) Ltd. C-22

		<ul style="list-style-type: none"> •Taxpayer Registration Certificate •Form-1 (application for company incorporation) •Memorandum of association 	Excess, Main Chamber Road, Rawat, Islamabad
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Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

DECISIONS OF 94TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 05-08-2025

MINUTES OF CASES APPLIED ON MDMC LICENSING & PRODUCT REGISTRATION PORTAL
(AGENDA PART-II)

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

CLASS A MEDICAL DEVICES

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	Chohan & Company 21 BAHADURABAD BLOCK 2 Karachi Fee: Rs 6000 /- Challan No.: 301190489140 Date of submission: 21 July 2025 MDMR-20250721-00005	Manufacturer Dalian Rongbang Medical Healthy Devices Co.,Ltd Address: Maoyingzi Hamlet, Dalianwan Town, Ganjingzi District, Dalian, China. P.C.116113 ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: NYCOTECH (ALCOHOL PAD (Isopropyl Alcohol 70%) External Use Only) Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 65x30mm 65x100mm PACK SIZE: 100 PCS per Box 200 PCS per Box Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved

Evaluator Name: Waqar Ahmed (Evaluator-II)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	MMS Enterprises 323-Rewaz Garden, Lahore Pakistan Fee: Rs 6000 /- Challan No.: 1138706981 Date of submission: 24 July 2025 MDMR-20250724-00003	Legal Manufacturer (as per FSC) Jiangsu Kangjie Medical Devices Co., Ltd. Address: No.6, Zhanbei Road, Jiangyan District, Taizhou City, Jiangsu Province China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: KJ (Vacuum Blood Collection Tube For Single -Use) SODIUM FLOURIDE/POTASSIUM OXALATE (GLUCOSE TUBE) Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 1ml 1.28ml 1.6ml 1.8ml 2ml 2.4ml 2.5ml 2.7ml 3ml 3.2ml 3.5ml 3.6ml 4ml 4.5ml 5ml 5.5ml 6ml 6.5ml 7ml 7.5ml 8ml 8.5ml 9ml 10ml Specify grouping: Single	Approved

			Storage condition: 5 °C~25°C	
2	MMS Enterprises 323-Rewaz Garden, Lahore Pakistan Fee: Rs 6000 /- Challan No.: 1652864478 Date of submission: 23 July 2025 MDMR-20250723-00013	Legal Manufacturer (as per FSC) Jiangsu Kangjie Medical Devices Co., Ltd. Address: No.6, Zhanbei Road, Jiangyan District, Taizhou City, Jiangsu Province China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: KJ (Vacuum Blood Collection Tube For Single -Use) SODIUM CITRATE 3.2% Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 1ml 1.28ml 1.6ml 1.8ml 2ml 2.4ml 2.5ml 2.7ml 3ml 3.2ml 3.5ml 3.6ml 4ml 4.5ml 5ml 5.5ml 6ml 6.5ml 7ml 7.5ml 8ml 8.5ml 9ml 10ml Specify grouping: Single Storage condition: 5 °C~25°C	Approved
3	MMS Enterprises 323-Rewaz Garden, Lahore Pakistan Fee: Rs 6000 /- Challan No.: 1424200139 Date of submission: 24 July 2025 MDMR-20250724-00012	Legal Manufacturer (as per FSC) Jiangsu Kangjie Medical Devices Co., Ltd. Address: No.6, Zhanbei Road, Jiangyan District, Taizhou City, Jiangsu Province China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: KJ (Vacuum Blood Collection Tube For Single -Use) Lithium Heparin Tube Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 1ml 1.28ml 1.6ml 1.8ml 2ml 2.4ml 2.5ml 2.7ml 3ml 3.2ml 3.5ml 3.6ml 4ml 4.5ml 5ml 5.5ml 6ml 6.5ml 7ml 7.5ml 8ml 8.5ml 9ml 10ml Specify grouping: Single Storage condition: 5 °C~25°C	Approved
4	MMS Enterprises 323-Rewaz Garden, Lahore Pakistan Fee: Rs 6000 /- Challan No.: 9871482250 Date of submission: 24 July 2025 MDMR-20250724-00022	Legal Manufacturer (as per FSC) Jiangsu Kangjie Medical Devices Co., Ltd. Address: No.6, Zhanbei Road, Jiangyan District, Taizhou City, Jiangsu Province China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: KJ (Vacuum Blood Collection Tube For Single -Use) Sodium Heparin Tube Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 1ml 1.28ml 1.6ml 1.8ml 2ml 2.4ml 2.5ml 2.7ml 3ml 3.2ml 3.5ml 3.6ml 4ml 4.5ml 5ml 5.5ml 6ml 6.5ml 7ml 7.5ml 8ml 8.5ml 9ml 10ml Specify grouping: Single Storage condition: 5 °C~25°C	Approved

			°C~25°C	
5	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 70324071 Date of submission: 24 July 2025 MDMR-20250724- 00024	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (EDTA K2 / SODIUM FLUORIDE) (BLOOD COLLECTION TUBE (EDTA K2 / SODIUM FLUORIDE)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 2ML, 3ML, 4ML, 5ML Specify grouping: Single Storage condition: Room temperature	Approved
6	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 6709650635 Date of submission: 24 July 2025 MDMR-20250724- 00027	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE EDTA K3 (BLOOD COLLECTION TUBE EDTA K3) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML Specify grouping: Single Storage condition: Room temperature	Approved
7	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 76565120987 Date of submission: 24 July 2025 MDMR-20250724- 00029	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (ESR TUBE SODIUM CITRATE 4NC) (BLOOD COLLECTION TUBE (ESR TUBE SODIUM CITRATE 4NC)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 1.6ML, 1.8ML, 2ML,2.5ML, 3ML, 4ML Specify grouping: Single Storage condition: Room temperature	Approved
8	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (HEPARIN LITHIUM) (BLOOD	Approved

	karachi Fee: Rs 6000 /- Challan No.: 26608404 Date of submission: 24 July 2025 MDMR-20250724-00031	LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	COLLECTION TUBE (HEPARIN LITHIUM)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML Specify grouping: Single Storage condition: Room temperature	
9	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 26367143594 Date of submission: 24 July 2025 MDMR-20250724-00034	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (PT TUBE SODIUM CITRAT 9NC) (BLOOD COLLECTION TUBE (PT TUBE SODIUM CITRAT 9NC)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 2ML, 3ML, 4ML, 4.5ML, 5ML Specify grouping: Single Storage condition: Room temperature	Approved
10	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 45102622729 Date of submission: 24 July 2025 MDMR-20250724-00036	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (SODIUM FLUORIDE/POTASSIUM OXALATE) (BLOOD COLLECTION TUBE (SODIUM FLUORIDE/POTASSIUM OXALATE)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 2ML, 3ML, 4ML, 5ML Specify grouping: Single Storage condition: Room temperature	Approved
11	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.:	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building,	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (SODIUM FLUORIDE/HEPARIN LITHIUM) (BLOOD COLLECTION TUBE (SODIUM	Approved

	15293451148 Date of submission: 24 July 2025 MDMR-20250724-00037	Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	FLUORIDE/HEPARIN LITHIUM)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 2ML, 3ML, 4ML, 5ML Specify grouping: Single Storage condition: Room temperature	
12	LIOCON BIOMEDICAL SERVICES Office no 20, 2nd floor, Habib Plaza Satellite Town, 4th road, Rawalpindi. Fee: Rs 6000 /- Challan No.: 317379094 Date of submission: 24 July 2025 MDMR-20250724-00039	Legal Manufacturer (as per FSC) Dewei Medical Equipment co., ltd Address: 5th Floor, No 4, Building shiyou industrial Park, Jun'an, Shundae, Foshan, China, 528329 ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: Dewei Diluent DW-3680 (20L) (Hematology Reagent Diluent) Class A Shelf life/ service life: 24 months Codes/Sizes (if any): DW-3680 (20L) Specify grouping: Single Storage condition: 2-35 celcius	Approved
13	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 89110112257 Date of submission: 23 July 2025 MDMR-20250723-00020	Manufacturer Changzhou Major Medical Products Co., Ltd. Address: No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS NON WOVEN SURGICAL TAPES (SURGICAL TAPES) Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 1cm×4.57m, 1.25cm×4.57m, 1.5cm×4.57m, 2.5cm×4.57m, 3.8cm×4.57m, 5cm×4.57m, 7.5cm×4.57m, 10cm×4.57m, 30cm×4.57m, 1cm×5m, 1.25cm×5m, 1.5×5m, 2.5cm×5m, 3.8cm×5m, 5cm×5m, 7.5cm×5m, 10cm×5m, 30cm×5m, 1cm×9.14m, 1.25cm×9.14m, 1.5cm×9.14m, 2.5cm×9.14m,	Approved

			3.8×9.14m, 5cm×9.14m, 7.5cm×9.14m, 10cm×9.14m, 30cm×9.14m, 1cm×10m, 1.25cm×10m, 1.5cm×10m, 2.5cm×10m, 3.8×10m, 5cm×10m, 7.5cm×10m, 10cm×10m, 30cm×10m, 1cm×13.71m, 1.25cm×13.71m, 1.5cm×13.71m, 2.5cm×13.71m, 3.8cm×13.71, 5cm×13.71m, 7.5cm×13.71m, 10cm×13.71m, 30cm×13.71m, (0.5- 4.0)"x(2.0-10.0)m Specify grouping: Single Storage condition: Room temperature	
14	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 215287590 Date of submission: 24 July 2025 MDMR-20250724- 00033	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (HEPARIN SODIUM) (BLOOD COLLECTION TUBE (HEPARIN SODIUM)) Class A Shelf life/ service life: 36 months Codes/Sizes (if any): 1ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML Specify grouping: Single Storage condition: Room temperature	Approved
15	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 491555788868 Date of submission: 24 July 2025 MDMR-20250724- 00038	Manufacturer Hubei Joy Bone Medical Products Co., Ltd. Address: Wulou Village, Chengbei, Yingcheng City, Hubei Province, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: A1 SURGICS PLASTER OF PARIS (PLASTER OF PARIS BANDAGE) Class A Shelf life/ service life: 60 months Codes/Sizes (if any): 5x200cm, 7.5x200cm, 10x200cm, 12.5x200cm, 15x200cm, 20x200cm, 5x270cm, 7.5x270cm, 10x270cm,	Approved

			12.5x270cm, 15x270cm, 20x270cm, 5x300cm, 7.5x300cm, 10x300cm, 12.5x300cm, 15x300cm, 20x300cm, 5x360cm, 7.5x360cm, 10x360cm, 12.5x360cm, 15x360cm, 20x360cm, 5x380cm, 7.5x380cm, 10x380cm, 12.5x380cm, 15x380cm, 20x380cm, 5x400cm, 7.5x400cm, 10x400cm, 12.5x400cm, 15x400cm, 20x400cm, 5x450cm, 7.5x450cm, 10x450cm, 12.5x450cm, 15x450cm, 20x450cm, 5x460cm, 7.5x460cm, 10x460cm, 12.5x460cm, 15x460cm, 20x460cm, 5x500cm, 7.5x500cm, 10x500cm, 12.5x500cm, 15x500cm, 20x500cm, Specify grouping: Single Storage condition: Room temperature	
16	A.Feroz & Co Medicine Street No.1, Marriot Road, Karachi Fee: Rs 6000 /- Challan No.: 45345450656 Date of submission: 25 July 2025 MDMR-20250725- 00010	Manufacturer JIANGSU KANGHUA MEDICAL EQUIPMENT CO., LTD. Address: SANHEKOU, CHANGZHOU, JIANGSU, 213115, CHINA ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Brand Name: STAR STERILE VAGINA DILATOR FOR SINGLE USE (DISPOSABLE STERILE VAGINAL SPECULUM) (STERILE VAGINA DILATOR FOR SINGLE USE) Class A Shelf life/ service life: 60 months Codes/Sizes (if any): L, M, S Specify grouping: Single Storage condition: Store in cool, clean, dry, and insect- free location. Protect from direct sunlight and damp conditions.	Deferred for provision of Free sale certificate from concerned regulatory authority.
17	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs 6000 /- Challan No.: 887900604384	Manufacturer HEBEI FREE TRADE ZONE SHENGHONG MEDICAL DEVICE CO LTD Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive	Brand Name: A1 SURGICS BLOOD COLLECTION TUBE (GEL + CLOT ACTIVATOR) (BLOOD COLLECTION TUBE (GEL+ CLOT ACTIVATOR)) Class A	Approved

	Date of submission: 24 July 2025 MDMR-20250724-00030	Bonded Zone, Zhengding District, China ISO 13485: Submitted EC Certificate: N/A FSC: Submitted LOA: Submitted	Shelf life/ service life: 36 months Codes/Sizes (if any): 3ML, 3.5ML, 4ML, 5ML, 6ML, 7ML, 8ML, 8.5ML Specify grouping: Single Storage condition: Room temperature	
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CLASS B, C & D MEDICAL DEVICES

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	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	Clifton Enterprises Ground Floor, 166 Shadman 1, Tehsil and District Lahore Fee: Rs. 31000 /- Challan No.: 1652856414 Date of submission: 27 July 2025 MDMR-20250727-00013	Manufacturer Tianchang City Anrui Medical Equipments Co., Ltd. Address: Renhe Industrial District 239331 Tianchang City, Anhui Province, China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: Medi-Pro Plus (Sterile Surgical Gloves for Single Use Powdered Free) Class B Shelf life/ service life: 60 months Codes/Sizes (if any): 6, 6.5, 7, 7.5, 8, 8.5, 9 Specify grouping: Single Storage condition: Room Temperature Device	Approved
2	Amtronech 560 A-Block, Faisal Town Fee: Rs. 31000 /- Challan No.: 493349126 Date of submission: 23 July 2025 MDMR-20250723-00024	Legal Manufacturer (as per FSC) Changsha Magill Medical Technology, Co., Ltd Address: M/s Changsha Magill Medical Technology, Co., Ltd. Room 101-201, 1st Bldg # 41, Yannong Road, Hi-Tech Development Zone, Changsha, 410205, Hunan, China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: Safe LM Video laryngeal Mask (Disposable Video Laryngeal Mask) Class B Shelf life/ service life: 60 Months Codes/Sizes (if any): Flexiview No. 2, 2.5, 3, 4, 5 Specify grouping: single Storage condition: • Temperature: -20°C to +55°C •Humidity: 0% to 93% (No condensation) • Atmospheric Pressure: 50kPa to 106kPa	Approved
3	Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e-Faisal	Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang,	Brand Name: DISPOSABLE GRASPING FORCEPS (DISPOSABLE GRASPING FORCEPS) Class B Item Name: DISPOSABLE GRASPING FORCEPS	Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly,

	<p>Fee: Rs. 31000 /- Challan No.: 0673990990 Date of submission: 24 July 2025 MDMR-20250724-00043</p>	<p>PEOPLE'S REPUBLIC OF CHINA</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2307/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2312/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2316/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2318/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2320/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5031-2323/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1807/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1812/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1816/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1818/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1820/</p>	<p>add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>
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			<p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1823/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5032-1827/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2307/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2312/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2316/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2318/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2320/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2323/</p> <p>Item Name: DISPOSABLE GRASPING FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5033-2327/</p> <p>Specify grouping: Family Storage condition: Temperature of -10C° ≈40C°</p>	
4	Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p>	<p>Brand Name: HYSTO-ONE (REUSABLE CORE BIOPSY INSTRUMENT) Class B Shelf life/ service life: 60 months Codes/Sizes (if any): 10002</p>	Approved

	<p>Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 9907940533 Date of submission: 24 July 2025 MDMR- 20250724-00026</p>	<p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Specify grouping: Single Storage condition: Normal Room Temperature</p>	
5	<p>Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e- Faisal Fee: Rs. 31000 /- Challan No.: 222398523582 Date of submission: 25 July 2025 MDMR- 20250725-00006</p>	<p>Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: STONE RETRIEVAL BALLOON (STONE RETRIEVAL BALLOON) Class B Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-85 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-12 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-15 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-18 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-85-12-15 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2317-13-15-18 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5051- 2085 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>Codes/Sizes (if any): AG-5051-2012 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5051-2015 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5051-2018 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5051-20-85-12-15 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5051-20-13-15-18 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-85 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-12 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-15 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-18 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-85-12-15 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5053-2317-13-15-18 /</p> <p>Item Name: STONE</p> <p>RETRIEVAL BALLOON</p>	
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			Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5053-20-85-12-15 / Item Name: STONE RETRIEVAL BALLOON Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5053-20-13-15-18 / Specify grouping: Family Storage condition: Temperature of -10C° ≈40C°	
6	Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e- Faisal Fee: Rs. 31000 /- Challan No.: 252854353227 Date of submission: 24 July 2025 MDMR- 20250724-00046	Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: DISPOSABLE GUIDE WIRE (DISPOSABLE GUIDE WIRE) Class B Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5041-2545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5041-3526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5041-3545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5042-2526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5042-2545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5042-3526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5042-3545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5043-	Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance

			<p>2526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5043-2545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5043-3526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5043-3545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5044-2526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5044-2545/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5044-3526/ Item Name: DISPOSABLE GUIDE WIRE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5044-3545/ Specify grouping: Family Storage condition: Temperature of -10C° ~40C°</p>	
7	<p>Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e- Faisal Fee: Rs. 31000 /- Challan No.: 3223236783 Date of submission: 25 July 2025 MDMR- 20250725-00003</p>	<p>Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: DISPOSABLE SCLEROTHERAPY NEEDLE (DISPOSABLE SCLEROTHERAPY NEEDLE) Class B Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5311-2416-1904/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5311-</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>2423-1904/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5311-2416-1906/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5311-2423-1906/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5081-2416-2104/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5081-2423-2104/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5081-2416-2106/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5081-2423-2106/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5082-2416-2304/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5082-2423-2304/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5082-2416-2306/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5082-2423-2306/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years</p>	
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			<p>Codes/Sizes (if any): AG-5083-2416-2504/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5083-2423-2504/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5083-2416-2506/ Item Name: DISPOSABLE SCLEROTHERAPY NEEDLE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5083-2423-2506/ Specify grouping: Family Storage condition: Temperature of -10C° ≈40C°</p>	
8	<p>Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e-Faisal Fee: Rs. 31000 /- Challan No.: 7554803545 Date of submission: 25 July 2025 MDMR-20250725-00005</p>	<p>Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: DISPOSABLE STONE EXTRACTION BASKET (DISPOSABLE STONE EXTRACTION BASKET) Class B Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5061-N2024 / Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5061-N2524/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5061-N3024/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5062-N2024/ Item Name: DISPOSABLE STONE EXTRACTION</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5062-N2524/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5062-N3024/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5063-S2024/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5063-S2524/ Item Name: DISPOSABLE STONE EXTRACTION BASKET Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5063-S3024/ Specify grouping: Family Storage condition: Temperature of -10C° ≈40C°</p>	
9	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrach-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 356960463 Date of submission: 25 July 2025 MDMR-20250725-00039</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: HYSTO-TWO (REUSABLE CORE BIOPSY INSTRUMENT) Class B Shelf life/ service life: 59 months Codes/Sizes (if any): 10003 Specify grouping: Single Storage condition: Normal Room Temperature</p>	Approved
10	<p>KASBN INTERNATIONAL 41-K, Gulberg-III, Lahore 54660 -</p>	<p>Legal Manufacturer (as per FSC) BIO COMPRESSION SYSTEMS INC. Address: 120 West</p>	<p>Brand Name: BIO COMPRESSION SYSTEM INC (DVT PUMP) Class B Item Name: DVT PUMP</p>	Deferred. The need to submit legalized FSC of country of Origin.

	<p>Pakistan Fee: Rs. 31000 /- Challan No.: 6853546238 Date of submission: 24 July 2025 MDMR-20250724-00004</p>	<p>Commercial Avenue, Moonachie, New Jersey 07074, USA</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Not Submitted LOA: Submitted</p>	<p>Shelf life/ service life: 5 Years Codes/Sizes (if any): IC-1545-DL/ Specify grouping: System Storage condition: ROOM TEMPERATURE</p>	
11	<p>Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs. 31000 /- Challan No.: 8387446772 Date of submission: 23 July 2025 MDMR-20250723-00041</p>	<p>Manufacturer BONREE MEDICAL CO LTD Address: 1ST FLOOR OF BIULDING NO 2 BIULDING NO 4 LONGZHU VILLAGE ECONOMIC ESTATE, LONGZHU AVENUE NANTANG, 528451 ZHONGSHAN. GUANGDONG, CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Not Submitted LOA: Submitted</p>	<p>Brand Name: A1 SURGICS ENDOTRACHEAL TUBE CUFFED (ENDOTRACHEAL TUBE) Class B Shelf life/ service life: 59 months Codes/Sizes (if any): I.D. 2.0, I.D. 2.5, I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0 Specify grouping: Single Storage condition: ROOM TEMPERATURE</p>	<p>Deferred for provision of legalized FSC from regulatory authority of China.</p>
12	<p>Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e-Faisal Fee: Rs. 31000 /- Challan No.: 924939763 Date of submission: 24 July 2025 MDMR-20250724-00006</p>	<p>Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: DISPOSABLE BIOPSY FORCEPS (DISPOSABLE BIOPSY FORCEPS) Class B Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50121-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50122-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50123-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50124-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5019-1816/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5019-1823/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5019-2316/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5019-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50110-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50111-1816/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50111-1823/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50111-2316/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50111-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-50112-2323/ Item Name: DISPOSABLE</p>	
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			<p>BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5011-1816/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5011-1823/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5011-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5012-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5013-2323/ Item Name: DISPOSABLE BIOPSY FORCEPS Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5014-2323/ Specify grouping: Family Storage condition: Temperature of -10C° ~40C°</p>	
13	<p>SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrāh e Faisal, Fee: Rs. 31000 /- Challan No.: 69166430 Date of submission: 24 July 2025 MDMR-20250724-00035</p>	<p>Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: LKM-1-Ab ELISA (LKM-1-Ab ELISA) Class B Shelf life/ service life: 24 Months Codes/Sizes (if any): RE70911 Specify grouping: IVD Kit Storage condition: 2-8 0C</p>	Approved
14	<p>Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 31000 /-</p>	<p>Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing</p>	<p>Brand Name: H-80AS (Respiratory High-Flow Therapy Device) Class B Shelf life/ service life: 60 MONTHS Codes/Sizes (if any): H-80AS</p>	Approved

	Challan No.: 5094850834 Date of submission: 28 July 2025 MDMR- 20250728-00040	Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Specify grouping: Single Storage condition: -20°C to 70°C	
15	Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 50000 /- Challan No.: 04826969 Date of submission: 29 July 2025 MDMR- 20250729-00019	Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: G2S series (Continuous Positive Pressure Equipment) Class B Item Name: G2S B30VT Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B25VT Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B30AT Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B30T Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B25T Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B20T Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B25A Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B20A Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B25S Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Item Name: G2S B20S Shelf life/ service life: 5 Years Codes/Sizes (if any): 57817/ Specify grouping: Family Storage condition: -25°C to 70°C	Approved
16	Benchmark	Manufacturer	Brand Name: Aosaite Gold	Deferred for

	<p>Solutions Pakistan 28A, PCSIR, Phase 1, Canal Bank Road, Lahore Fee: Rs. 31000 /- Challan No.: 1049175868 Date of submission: 22 July 2025 MDMR- 20250722-00008</p>	<p>SHANDONG AOSAITE MEDICAL DEVICES CO.,LTD Address: No.3 North Ring Road,Chengwu County,Heze,274200 Shandong,P.R. China</p>	<p>(Disposable Blood Collection Needle) Class B Item Name: Aosaite Gold Disposable Blood Collection Needle Shelf life/ service life: 60 MONTHS Codes/Sizes (if any): 19G×3/4, 20G×3/4, 21G×3/4, 23G×3/4, 24G×3/4, 25G×3/4, 26G×3/4" Specify grouping: Family Storage condition: 4-35 C</p>	<p>provision of legalized FSC from regulatory authority</p>
17	<p>Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 50000 /- Challan No.: 8364635226 Date of submission: 29 July 2025 MDMR- 20250729-00038</p>	<p>Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: P series Pillow Mask (Nasal pillow mask) Class B Item Name: P2 Shelf life/ service life: 60 Months Codes/Sizes (if any): 36786/ Specify grouping: Family Storage condition: -25°C to 70°C</p>	<p>Approved</p>
18	<p>SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, Fee: Rs. 31000 /- Challan No.: 806396904492 Date of submission: 28 July 2025 MDMR- 20250728-00014</p>	<p>Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: dsDNA-Ab ELISA (dsDNA-Ab ELISA) Class B Shelf life/ service life: 18 MONTHS Codes/Sizes (if any): RE75201 Specify grouping: Single Storage condition: 2-8 0C</p>	<p>Approved</p>
19	<p>Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi Fee: Rs. 31000 /- Challan No.: 8950980560 Date of</p>	<p>Manufacturer BONREE MEDICAL CO LTD Address: 1ST FLOOR OF BIULDING NO 2 BIULDING NO 4 LONGZHU VILLAGE ECONOMIC ESTATE, LONGZHU AVENUE</p>	<p>Brand Name: A1 SURGICS ENDOTRACHEAL TUBE UNCUFFED (ENDOTRACHEAL TUBE UNCUFFED) Class B Shelf life/ service life: 60 MONTHS Codes/Sizes (if any):</p>	<p>Deferred for provision of FSC of regulatory authority</p>

	submission: 23 July 2025 MDMR- 20250723-00042	NANTANG, 528451 ZHONGSHAN. GUANGDONG, CHINA ISO 13485: Submitted EC Certificate: Submitted FSC: not Submitted LOA: Submitted	I.D. 2.0, I.D. 2.5, I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0 Specify grouping: Single Storage condition: ROOM TEMPERATURE	
20	KASBN INTERNATION AL 41-K, Gulberg-III, Lahore 54660 - Pakistan Fee: Rs. 31000 /- Challan No.: 01139810303 Date of submission: 26 July 2025 MDMR- 20250726-00002	Legal Manufacturer (as per FSC) Zimmer MedizinSysteme GmbH Address: Junkersstraße 9, 89231 Neu-Ulm, Germany ISO 13485: Submitted EC Certificate: not Submitted FSC: not Submitted LOA: Submitted	Brand Name: Zimmer MedizinSysteme GmbH (Shockwave Therapy Unit) Class B Shelf life/ service life: 120 months Codes/Sizes (if any): Specify grouping: Single Storage condition: ROOM TEMPERATURE	Deferred for provision of FSC and CE
21	Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 31000 /- Challan No.: 53546804 Date of submission: 29 July 2025 MDMR- 20250729-00010	Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: R-80S (High-Flow Oxygen Therapy Device with NIV) Class B Shelf life/ service life: 120 months Codes/Sizes (if any): R-80S Specify grouping: Single Storage condition: -25°C to 70°C	Approved
22	Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE	Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd.	Brand Name: NC11 (Pediatric Nasal Cannula to use with High Flow Oxygen Therapy Device) Class B Shelf life/ service life: 60 months Codes/Sizes (if any): NC11 (S, M, L)	Approved

	<p>Fee: Rs. 31000 /- Challan No.: 30678115446 Date of submission: 29 July 2025 MDMR-20250729-00032</p>	<p>2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Specify grouping: Single Storage condition: -25°C to 70°C</p>	
23	<p>DIA SCIENT INTERNATIONAL 11,12,13,14, EMAAN ARCADE, IQBAL STADIUM ROAD, NEW CIVIL LINE Fee: Rs. 31000 /- Challan No.: 304938923 Date of submission: 24 July 2025 MDMR-20250724-00025</p>	<p>Legal Manufacturer (as per FSC) Shenzhen Poweray Biotechnology Co. Ltd Address: Area C, 3rd Floor, Building 1, Mingrenju Furniture Industrial Factory, No 10, Maotian Road, Shatian Community, Kengzi Street, Pingshan District, Shenzhen City, Guangdong Province, 518118, P.R China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: Poweray Diagnostic kit for hemoglobin A1C (affinity chromatography) (HbA1c Kit) Class B Shelf life/ service life: 18 Codes/Sizes (if any): KO1 Specify grouping: Single Storage condition: Store in 2°C~30°C</p>	Approved
24	<p>SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, Fee: Rs. 31000 /- Challan No.: 40809382 Date of submission: 28 July 2025 MDMR-20250728-00018</p>	<p>Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: SS-A/Ro-Ab ELISA (SS-A/Ro-Ab ELISA) Class B Shelf life/ service life: 18 Months Codes/Sizes (if any): RE75231 Specify grouping: IVD Kit Storage condition: 2-8 0C</p>	Approved
25	<p>Medichem Enterprises 331/C, Block 3, D.M.C.H.S., Alamgir Road, Karachi Fee: Rs. 55000 /- Challan No.: 7622925890 Date of submission: 24</p>	<p>Legal Manufacturer (as per FSC) TSK LABORATORY JAPAN Address: 1510-1 Soja-Machi, Tochigi-Shi, Tochigi-Ken 328-0002 Japan ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: TSK Primecut II Biopsy Needle (Hypodermic Biopsy Needle) Class B Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-141001/ Item Name: TSK Prime cut II</p>	Approved

	<p>July 2025 MDMR- 20250724-00008</p>		<p>Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-141002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-141502/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-142002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-142502/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-161001/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-161002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-161502/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-162002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-162502/</p> <p>Item Name: TSK Prime cut II</p>	
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			<p>Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-181001/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-181002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-181501/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-181502/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-181503/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182001/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182002/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182003/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182501/</p> <p>Item Name: TSK Prime cut II Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182502/</p> <p>Item Name: TSK Prime cut II</p>	
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			<p>Biopsy Needle Shelf life/ service life: 5 Years Codes/Sizes (if any): PRM-182503/ Specify grouping: Family Storage condition: Keep dry. Keep away from direct sunlight, high temperature, and humidity. Store in a clean place.</p>	
26	<p>Abbott Laboratories Pakistan Limited Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi Karachi-75120 Fee: Rs. 31000 /- Challan No.: 29556456686 Date of submission: 29 July 2025 MDMR-20250729-00020</p>	<p>Legal Manufacturer (as per FSC) Abbott GmbH Address: Max-Planck-Ring 2 65205, Wiesbaden, Germany ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: ARCHITECT Pepsinogen II (Pepsinogen II) Class B Item Name: ARCHITECT Pepsinogen II Reagent Kit Shelf life/ service life: 15 Months Codes/Sizes (if any): 9D65-28/ Item Name: ARCHITECT Pepsinogen II Reagent Kit Shelf life/ service life: 15 Months Codes/Sizes (if any): 9D65-38/ Item Name: ARCHITECT Pepsinogen II Calibrators Shelf life/ service life: 17 Months Codes/Sizes (if any): 9D65-01/ Item Name: ARCHITECT Pepsinogen II Controls Shelf life/ service life: 17 Months Codes/Sizes (if any): 9D65-10/ Specify grouping: IVD Kit Storage condition: 2 to 8°C</p>	<p>Deferred for clarification/ justification as multiple kits applied in single application as per FSC of Germany. Apply separately for each kit as per FSC of Germany and also inform which product to be considered for this application.</p>
27	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 83816480 Date of submission: 24 July 2025 MDMR-</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: SAMPLE MASTER (SEMI-AUTOMATIC BIOPSY SYSTEM) Class B Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1210/ Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1215/</p>	<p>Approved</p>

	20250724-00049		<p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1220/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1410/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1415/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1416/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1420/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1610/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1615/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1616/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1620/</p>	
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			<p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1810/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1815/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1816/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1820/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 1825/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 2010/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 2015/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 2016/</p> <p>Item Name: SAMPLE MASTER, SEMI-AUTOMATIC BIOPSY SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): SMA 2020/ Specify grouping: Family</p>	
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			Storage condition: Normal Room Temperature	
28	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 55568629686 Date of submission: 25 July 2025 MDMR-20250725-00012</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: MDS (BIOPSY NEEDLE) Class B Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1210/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1215/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1220/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1410/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1415/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1416/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1420/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1610/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1615/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1616/</p>	Approved

			<p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1620/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1810/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1815/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1816/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1820/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 1825/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 2010/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 2015/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 2016/</p> <p>Item Name: MDS BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDS 2020/ Specify grouping: Family Storage condition: Normal Room Temperature</p>	
29	Nassir Trading	Manufacturer	Brand Name: MDA (BIOPSY)	

	<p>Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e- Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 6038070996 Date of submission: 25 July 2025 MDMR- 20250725-00038</p>	<p>ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>NEEDLE) Class B Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1210/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1215/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1220/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1410/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1415/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1416/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1420/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1610/ Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA</p>	<p>Approved</p>
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			<p>1615/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1616/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1620/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1810/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1815/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1816/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1820/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 1825/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 2010/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA</p>	
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			<p>2015/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 2016/</p> <p>Item Name: MDA BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDA 2020/ Specify grouping: Family Storage condition: Normal Room Temperature</p>	
30	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 95000303322 Date of submission: 27 July 2025 MDMR-20250727-00004</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: MDM (BIOPSY NEEDLE) Class B Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1210/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1215/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1220/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1410/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1415/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1416/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1420/</p>	Approved

			<p>Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1610/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1615/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1616/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1620/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1810/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1815/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1816/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1820/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 1825/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 2010/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM</p>	
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			2015/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 2016/ Item Name: MDM BIOPSY NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): MDM 2020/ Specify grouping: Family Storage condition: Normal Room Temperature	
31	Clifton Enterprises Ground Floor, 166 Shadman 1, Tehsil and District Lahore Fee: Rs. 31000 /- Challan No.: 948494055 Date of submission: 29 July 2025 MDMR- 20250729-00005	Manufacturer Tianchang City Anrui Medical Equipments Co., Ltd. Address: Renhe Industrial District 239331 Tianchang City, Anhui Province, China ISO 13485: Submitted EC Certificate: Submitted FSC: Not Submitted LOA: Submitted	Brand Name: Medi-Pro Plus (Sterile Surgical Gloves for Single Use Powdered) Class B Shelf life/ service life: 60 months Codes/Sizes (if any): 6, 6.5, 7, 7.5, 8, 8.5, 9 Specify grouping: Single Storage condition: Room Temperature Device	Deferred for provision of FSC
32	SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, Fee: Rs. 31000 /- Challan No.: 57048042422 Date of submission: 29 July 2025 MDMR- 20250729-00008	Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany	Brand Name: Modified Gliadin Peptide IgG ELISA (Modified Gliadin Peptide IgG ELISA) Class B Shelf life/ service life: 18 Months Codes/Sizes (if any): RE75751 Specify grouping: IVD Kit Storage condition: 2-8 0C	Approved
33	SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, Fee: Rs. 31000 /- Challan No.: 6935704670 Date of submission: 29 July 2025	Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany	Brand Name: Modified Gliadin Peptide IgA ELISA (Modified Gliadin Peptide IgA ELISA) Class B Shelf life/ service life: 18 Months Codes/Sizes (if any): RE75741 Specify grouping: IVD Kit Storage condition: 2-8 0C	Approved

	MDMR-20250729-00014			
34	Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 31000 /- Challan No.: 5835741547 Date of submission: 29 July 2025 MDMR- 20250729-00033	Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: NC12 (Adult High Flow Nasal Cannula) Class B Shelf life/ service life: 60 months Codes/Sizes (if any): NC12 (S, M, L) Specify grouping: Single Storage condition: -25°C to 70°C	Approved
35	SIND MEDICAL STORES 13-B, Block 6, PECHS, Shahrah e Faisal, Fee: Rs. 31000 /- Challan No.: 84815623612 Date of submission: 29 July 2025 MDMR- 20250729-00036	Manufacturer IBL INTERNATIONAL GMBH Address: Flughafenstrasse 52 A 22335 Hamburg, Germany	Brand Name: Myeloperoxidase- Ab ELISA (Myeloperoxidase- Ab ELISA) Class B Shelf life/ service life: 18 Months Codes/Sizes (if any): RE75601 Specify grouping: IVD Kit Storage condition: 2-8 °C	Approved
36	Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 50000 /- Challan No.: 151733929 Date of submission: 29 July 2025 MDMR- 20250729-00039	Legal Manufacturer (as per FSC) BMC (Tianjin) Medical Co., Ltd. 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted	Brand Name: N series Nasal Mask (Nasal mask) Class B Item Name: N5 Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/ Item Name: N5A Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/ Item Name: N5+ Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/ Item Name: N5A+ Shelf life/ service life: 60 Months	Approved

			<p>Codes/Sizes (if any): 36785/</p> <p>Item Name: N5H Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/</p> <p>Item Name: N5AH Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/</p> <p>Item Name: N6 Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/</p> <p>Item Name: N5BH Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/</p> <p>Item Name: N5B Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/ Item Name: N5B+ Shelf life/ service life: 60 Months Codes/Sizes (if any): 36785/ Specify grouping: Family Storage condition: -25°C to 70°C</p>	
37	<p>Electromed Corporation 53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE Fee: Rs. 50000 /- Challan No.: 55365268 Date of submission: 29 July 2025 MDMR- 20250729-00040</p>	<p>Legal Manufacturer (as per FSC)</p> <p>BMC (Tianjin) Medical Co., Ltd.</p> <p>2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: F series Oro-Nasal Mask (Oro-Nasal Mask) Class B Item Name: F5 Shelf life/ service life: 60 Months Codes/Sizes (if any): 57813/ Specify grouping: Family Storage condition: -25°C to 70°C</p>	Approved
38	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre,</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p>	<p>Brand Name: HYSTO SYSTEM II (DISPOSABLE AUTOMATIC SYSTEM) Class B Item Name: HYSTO SYSTEM</p>	Approved

	<p>Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 89169810842 Date of submission: 27 July 2025 MDMR-20250727-00006</p>	<p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1210/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1215/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1220/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1410/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1415/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1416/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1420/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1610/ Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1615/ Item Name: HYSTO SYSTEM</p>	
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			<p>II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1616/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1620/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1810/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1815/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1816/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1820/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 1825/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 2010/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 2015/</p> <p>Item Name: HYSTO SYSTEM</p>	
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			<p>II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 2016/</p> <p>Item Name: HYSTO SYSTEM II - DISPOSABLE AUTOMATIC SYSTEM Shelf life/ service life: 5 Years Codes/Sizes (if any): HSB 2020/ Specify grouping: Family Storage condition: Normal Room Temperature</p>	
39	<p>Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi. Fee: Rs. 31000 /- Challan No.: 4079295455 Date of submission: 25 July 2025 MDMR-20250725-00043</p>	<p>Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES (DISPOSABLE COAXIAL NEEDLE) Class B Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1210/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1215/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1220/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1410/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES /</p>	Approved

			<p>DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1415/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1416/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1420/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1610/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1615/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1616/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1620/</p> <p>Item Name: CO-AXIAL</p>	
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			<p>SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1810/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1815/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1816/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1820/ Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 1825/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 2010/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE Shelf life/ service life: 5 Years Codes/Sizes (if any): CPX 2015/</p>	
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			<p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE</p> <p>Shelf life/ service life: 5 Years</p> <p>Codes/Sizes (if any): CPX 2016/</p> <p>Item Name: CO-AXIAL SYSTEM FOR HSA, HSB, SMA BIOPSY DEVICES / DISPOSABLE COAXIAL NEEDLE</p> <p>Shelf life/ service life: 5 Years</p> <p>Codes/Sizes (if any): CPX 2020/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
40	<p>SIND MEDICAL STORES</p> <p>13-B, Block 6, PECHS, Shahrah e Faisal,</p> <p>Fee: Rs. 31000 /- Challan No.: 6481989068</p> <p>Date of submission: 28 July 2025</p> <p>MDMR-20250728-00004</p>	<p>Manufacturer IBL INTERNATIONAL GMBH</p> <p>Address: Flughafenstrasse 52 A 22335 Hamburg, Germany</p>	<p>Brand Name: beta 2-Glycoprotein 1 IgM ELISA (beta 2-Glycoprotein 1 IgM ELISA)</p> <p>Class B</p> <p>Shelf life/ service life: 12 Months</p> <p>Codes/Sizes (if any): RE75061</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: 2-8 0C</p>	Approved
41	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi.</p> <p>Fee: Rs. 31000 /- Challan No.: 09524274052</p> <p>Date of submission: 27 July 2025</p> <p>MDMR-20250727-00005</p>	<p>Manufacturer ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p> <p>EC Certificate: Submitted</p> <p>FSC: Submitted</p> <p>LOA: Submitted</p>	<p>Brand Name: SAMPLE MASTER SET (SEMI-AUTOMATIC BIOPSY NEEDLE SET)</p> <p>Class B</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET</p> <p>Shelf life/ service life: 5 Years</p> <p>Codes/Sizes (if any): SMAC 1210/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET</p> <p>Shelf life/ service life: 5 Years</p> <p>Codes/Sizes (if any): SMAC 1215/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET</p> <p>Shelf life/ service life: 5 Years</p>	Approved

			<p>Codes/Sizes (if any): SMAC 1220/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1410/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1415/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1416/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1420/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1610/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1615/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1616/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC</p>	
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			<p>BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1620/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1810/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1815/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1816/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1820/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 1825/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 2010/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 2015/</p>	
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			<p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 2016/</p> <p>Item Name: SAMPLE MASTER SET / SEMI-AUTOMATIC BIOPSY NEEDLE SET Shelf life/ service life: 5 Years Codes/Sizes (if any): SMAC 2020/ Specify grouping: Family Storage condition: Normal Room Temperature</p>	
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Evaluator Name: Zia Ullah (Evaluator-V)

S #	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>Rigel Health (Private) Limited Office # 911, Portway Trade Centre SMCHS Main Shahrah-e-Faisal Fee: Rs. 62000 /- Challan No.: 9779694992 Date of submission: 25 July 2025 MDMR-20250725-00002</p>	<p>Manufacturer Hangzhou AGS MedTech Co.,Ltd. Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA</p> <p>ISO 13485: Submitted EC Certificate: Submitted FSC: Submitted LOA: Submitted</p>	<p>Brand Name: POLYPECTOMY SNARE (POLYPECTOMY SNARE) Class C Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5071-241023 /</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5071-241523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5071-242523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5071-243223/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5072-</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC. Accordingly, add/amend codes in relevant field. Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>241023/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5072- 241523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5072- 242523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5075- 241023/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5075- 241523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5075- 242523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5076- 241023/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5076- 241523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5076- 242523/</p> <p>Item Name: POLYPECTOMY SNARE Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5078-</p>	
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			<p>241523/</p> <p>Item Name: POLYPECTOMY SNARE</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5078-242523/</p> <p>Specify grouping: Family</p> <p>Storage condition: Temperature of -10C° ~40C°</p>	
2	<p>Rigel Health (Private) Limited</p> <p>Office # 911, Portway Trade Centre SMCHS Main Shahrah-e-Faisal</p> <p>Fee: Rs. 62000 /- Challan No.: 137309565</p> <p>Date of submission: 25 July 2025</p> <p>MDMR-20250725-00004</p>	<p>Manufacturer</p> <p>Hangzhou AGS MedTech Co.,Ltd.</p> <p>Address: Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA</p> <p>ISO 13485: Submitted</p> <p>EC Certificate: Submitted</p> <p>FSC: Submitted</p> <p>LOA: Submitted</p>	<p>Brand Name: SPHINCTEROTOME (SPHINCTEROTOME)</p> <p>Class C</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5091-0520/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5091-0525/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5091-0530/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5093-0520/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5093-0525/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5093-0530/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5094-05/</p> <p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5096-0520/</p>	<p>Deferred. The firm need to apply those codes of applied product as per submitted catalogue or FSC.</p> <p>Accordingly, add/amend codes in relevant field.</p> <p>Furthermore, FSC of USFDA need to be legalized from country of its issuance</p>

			<p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5096-0520-U/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5096-0525/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5096-0525-U/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5096-0530/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5096-0530-U/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0520/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0520-U/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0525/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0525-U/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0530/</p> <p>Item Name: SPHINCTEROTOME Shelf life/ service life: 3 Years Codes/Sizes (if any): AG-5098-0530-U/</p>	
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			<p>Item Name: SPHINCTEROTOME</p> <p>Shelf life/ service life: 3 Years</p> <p>Codes/Sizes (if any): AG-5099-05/</p> <p>Specify grouping: Family</p> <p>Storage condition: Temperature of -10C° ~40C°</p>	
3	<p>Kamion Pharma</p> <p>Plot No. G/4-C, SITE, Super Highway, Phase-II</p> <p>Fee: Rs. 25000 /- Challan No.: 68720130098</p> <p>Date of submission: 21 July 2025</p> <p>MDMR-20250721-00004</p>	<p>Manufacturer</p> <p>Kamion Pharma</p> <p>Address: Plot No. G/4-C, SITE, Super Highway, Phase-II, Karachi</p>	<p>Brand Name: FUCITULLE (Sodium Fusidate Dressing)</p> <p>2% Sodium Fusidate B.P.</p> <p>Class D</p> <p>Shelf life/ service life: 36</p> <p>Codes/Sizes (if any):</p> <p>5 cm x 5 cm</p> <p>10 cm x 10 cm</p> <p>15 cm x 15 cm</p> <p>15 cm x 150 cm</p> <p>Specify grouping: Single</p> <p>Storage condition: Store at room temperature</p>	<p>Approved export purpose only.</p>
4	<p>Royal Medical</p> <p>Office No. 26th, 3rd Floor, United Trade Center, Plot No. 5, Block-6, Gulshan-e-Iqbal Karachi</p> <p>Fee: Rs. 62000 /- Challan No.: 1783656176</p> <p>Date of submission: 23 July 2025</p> <p>MDMR-20250723-00002</p>	<p>Manufacturer</p> <p>FIAB SpA</p> <p>Address: Via Paolo Costoli, 4 – 50039 Vicchio, Firenze – Italy.</p>	<p>Brand Name: DEFIPROPADS-Defibrillation Pads (Defibrillation pads)</p> <p>Class C</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG</p> <p>Shelf life/ service life: 30 Months</p> <p>Codes/Sizes (if any): RM-EP50U/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG</p> <p>Shelf life/ service life: 30 Months</p> <p>Codes/Sizes (if any): RM-EP51/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG</p> <p>Shelf life/ service life: 30 Months</p> <p>Codes/Sizes (if any): RM-EP52/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG</p> <p>Shelf life/ service life: 30 Months</p> <p>Codes/Sizes (if any): RM-EP61U/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG</p> <p>Shelf life/ service life: 30 Months</p>	<p>Approved</p>

			<p>Codes/Sizes (if any): RM-EP53/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP52PL/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP53P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP2750U/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN50UW/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN51W/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP2751/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN52W/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP2752/</p>	
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			<p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN55/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN55W/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP2755/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP50P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP50PW/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EPN51P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP51PW/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-EP2751P/</p>	
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			<p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EP2751PW/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EPN52P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EPN52WPL/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EP2752P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EP2752PW/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EPN55P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM- EP2755P/</p> <p>Item Name: Disposable Electrodes Defibrillation, cardioversion, cardiac stimulator, ECG Shelf life/ service life: 30 Months Codes/Sizes (if any): RM-</p>	
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			EPN61UW/ Specify grouping: Family Storage condition: The product should be stored in its original packaging in rooms with environment conditions of temperature and relative humidity, specified on the label.	
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Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

S #	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	Medilution Healthcare A - 322 (1st Floor), Gulshan-e-Iqbal Block 2, KDA Scheme No. 24 Fee: Rs. 62000 /- Challan No.: 68322846517 Date of submission: 25 July 2025 MDMR-20250725-00037	Manufacturer Jiangsu BANA Medical Technology Co. Ltd. Address: No. 28-3, Guihua Road, Zhonglou Economic Development Zone, Changzhou, 213013, Jiangsu, China	Brand Name: PolyTack (Hernia Stapler/Fixation Device) Class C Shelf life/ service life: 36 Codes/Sizes (if any): N/A Specify grouping: Single Storage condition: Room Temperature	Deferred. The firm need to clarify as generic name shows different types applied in single application and type of stapler applied in line with FSC of Germany. Accordingly fill all the relevant fields of application form, where required, along with product codes/models etc while submitting reply.

Import License Agenda

Evaluator Name: Muhammad Amin (Evaluator-IX)

S.#	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: SONO CARE(PRIVATE) LIMITED Office Address: G-17,GROUND FLOOR,KARACHI MARKET,KHYBER BAZAR,PESHAWAR	Name: MUHAMMAD KAMIL NASIR CNIC No: 1730147691687 Qualification: B.Sc (Hons) Medical Laboratory Technology Experience:	Name: AAMIR SHEHZAD Designation: CEO CNIC No(s): 1730134829975 Name: MAZHAR	Approved

	Godown Address: OFFICE NO,432 AND 433,4TH FLOOR,PAK MEDICAL CENTER,KHYBER BAZAR,PESHAWAR. Fee: Rs 25000 /- Date of Submission: 22 July 2025 Tracking ID: MDMC-20250723-00389	LAB TECHNICIAN (from June 2023 to December 2024)	SHEHZAD Designation: DIRECTOR CNIC No(s): 1730158119037 Name: MUHAMMAD ABDULLAH Designation: DIRECTOR CNIC No(s): 1730137575377	
2	Name of Establishment: AN BIOWARE (PRIVATE) LIMITED Office Address: Hamayoon Khan Plaza, Basement Office No 1, Mandi More, GT Road, Haripur Godown Address: Hamayoon Khan Plaza, Basement Office No 1, Mandi More, GT Road, Haripur Fee: Rs 25000 /- Date of Submission: 19 July 2025 Tracking ID: MDMC-20250728-00920	Name: Andleeb CNIC No: 1330293060942 Qualification: Doctor of Pharmacy Experience: Production officer (from April 2019 to February 2022)	Name: Asmara Atif Designation: Director CNIC No(s): 1330217640418 Name: Atif Nawaz Designation: Director CNIC No(s): 1330205157491	Approved

Local Manufacturer License Agenda

Evaluator Name: Muhammad Amin (Evaluator-IX)

S.#	Name of Establishment along with address	Details of Qualified Technical Person	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: Goldstar Medical Instruments Factory Address: Hayat Center, Khadim Ali Road Sialkot Tracking ID: MDSV-20250723-00375		Name(s): Sikandar Hayat Designation: partner CNIC No(s): 3460341752983 Name(s): Naheed Hayat Designation: partner CNIC No(s): 3460339487336	Approved

The meeting ended with vote of thanks to and from the chair.
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