

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

DECISIONS OF 92ND MEETING OF THE MEDICAL DEVICE BOARD (MDB)
TO BE HELD ON 30-06-2025

92nd 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 30th June, 2025. The meeting was chaired by Dr. Muhammad Fakhr-ud-Din Amir, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1	Dr. Muhammad Fakhr-ud-Din Amir, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
6	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
7	Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
8.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
9	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

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

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

S.#	Name of Establishment	Qualified person	Decision
1.	M/s Al Saad Pharmacy, Jans Arcad, Iqra Chowk University Town, Peshawar. Godown Address: House No B-2, Arbab Colony P.O Tehkal Bala, University Road Peshawar.	Mr. Imran Amir (Pharmacist) CNIC No. 11101-14732063-1	Approved for storage of room temperature medical devices.
2.	M/s Envision Medical Private Limited, Office No. 6, First Floor, Farhan Heights Banigala, Islamabad.	Mr. Yasir Imran (Pharm.D) CNIC No. 42501-4098429-5	Approved for storage of room temperature medical devices.
3.	M/s Seraph Healthcare, Plot No. 8 & 9, Judicial Colony, Rawalpindi.	Ms. Shereen Batool (Pharm.D) CNIC No. 33102-3754076-8	Approved for storage of room temperature medical devices.
4.	M/s Omni Tech, Plot # 241, Street # 8, Sector I-9/3, Industrial Area Islamabad.	Mr. Zubair Aziz (B.S Biomedical Engineer) CNIC No. 42301-9424983-5	Approved for storage of room temperature medical devices.
5.	M/s Medical Street Enterprises LLP, House No. R-12, Bage Jinnah Society, Jinnah Avenue, Malir Town Karachi. Godown Address: B-41, Block-D, North Nazimabad, Karachi	Mr. Shahid Hussain Khan (B.E. Biomedical) CNIC No. 42101-8387241-9	Approved for storage of room temperature medical devices.

Item No. II(b): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1	M/s Monitor Health International (Pvt) Ltd, Plot No.147, Iqbal Industrial City, Opposite M-3, Industrial City SEZ Sahianwala Interchange Motorway, M-4, Faisalabad.	Mr. Muhammad Assad Mehmood, (Pharm-D)	Miss Taania Aslam (Pharm-D)	The Board approved the grant of establishment license to M/s Monitor Health International (Pvt) Ltd, Plot No.147, Iqbal Industrial City, Opposite M-3, Industrial City SEZ Sahianwala Interchange Motorway, M-4, Faisalabad for the following sections of medical devices under Medical Devices Rules, 2017: 1. Auto Disable Syringes. 2. Hypodermic Needle.
2.	M/s Al-Shifa Medical Equipment, Plot No.28, Jaloza Economic Zone, Cherat Road, Jaloza,	Mr. Ahmad Zia Master of Science in	Mr. Muaaz Ismail Bachelor of Science in	The Board approved the grant of establishment license to M/s Al-Shifa Medical Equipment, Plot No.28, Jaloza Economic Zone, Cherat Road, Jaloza,

	Nowshera.	Electronics	Mechatronics Engineering	Nowshera for the following sections of medical devices under Medical Devices Rules, 2017: 1. X-Ray Machine (Assembling)
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Item No. II(c): APPLICATIONS FOR SITE APPROVAL FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

Case No.01:

M/s Pro.Gadge, Karachi 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 Plot No.711, Sector 11-1/2 Sheet N0.2, Ghaziabad, Orangi Town, Karachi.** 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, Sajjad Ahmad Abbasi, Deputy Director, CDL, DRAP, Karachi was nominated for inspection of proposed site. Panel conducted the inspection and submitted recommendations/report as under: -

- (i) The manufacturing site is situated at **at Plot No.711, Sector 11-1/2 Sheet N0.2, Ghaziabad, Orangi Town, Karachi measuring about 180 sq.yds.**
- (ii) The manufacturing facility has already been constructed and operational at above mentioned site address.
- (iii) The facility is located in commercial area with small units and godowns and is surrounded by wide road (around 60 ft) from front side while there was embroidery work (small textile) units located at right and left side of the facility and there is street of about 26 ft surrounds the back side of the facility.
- (iv) Relevant utilities were already available in facility.
- (v) The surrounding of the facility was found suitable for manufacturing of medical devices as per enclosed list of medical devices and the firm will have to submit the evidences of arrangements for necessary measures to avoid contamination, ensure cleaning and hygiene and other necessary measures based on risk-assessment, before issuance of establishment license to manufacture medical devices.

Keeping inn view the observations, location, surroundings and types of medical devices, **the above-mentioned manufacturing site is recommended for establishment of medical devices manufacturing unit.**

Submitted for consideration of MDB please.

Decision: The Board approved the site alongwith direction to applicant for arrangements/ necessary measures to avoid contamination, ensure cleaning and hygiene and other necessary measures based on risk-assessment while applying for establishment licence.

Item No. III(a): REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S#	Importer Name	Manufacturer Details	Name of Medical Device/ Class / Shelf life / Codes / etc	Decision
1.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 024371202033 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	Brand name: D Di Test Generic Name: Reagent 1: 1 x 1,3 mL vial (Latex) Reagent 2: 1 x 20 mL vial (Buffer) Reagent 3: 1 x 1 mL vial (Control -) Reagent 4: 1 x 1 mL vial (Control +) 10 test cards Mixing rods Models/ Specification <i>(as per Free sale certificate):</i> 00454 Class-B Shelf life: 24 Months Storage Conditions: 2 - 8°C	Approved. The firm shall submit the fee as per revised SRO for Cluster before the issuance of registration letter.
2.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 2159017678 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	Brand name: FDP Plasma Generic Name: Reagent 1: 1 x 1,3 mL vial Reagent 2: 1 x 20 mL vial Reagent 3: 1 x 0.5 mL vial Reagent 4: 1 x 0.5 mL vial 10 test cards Mixing rods Models/ Specification <i>(as per Free sale certificate):</i> 00540 Class-B LOA validity: 31-Dec-2025 Shelf life: 24 Months Storage Conditions: 2 - 8°C FSC country of origin validity: Date of Issue: 24-05-2024 FSC RRA validity: N/A	Approved. Firm shall submit differential fee as per revised SRO before issuance of Registration letter.

3.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 98950750620 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	Pool Norm Human Plasma Pool (12 x 1 ml vials) Models/ Specification <i>(as per Free sale certificate):</i> 00539 Class-B Shelf life: 24 Months	Approved.
4.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 8735471283 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	Brand name: PTT-LA Generic Name: IVD Test Kit (6 x 2 ml) Models/ Specification <i>(as per Free sale certificate):</i> 00599 Class-B Shelf life: 24 Months	Approved.
5.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 599499158085 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028	STA Control LA 1+2 Reagent 1: 3 x 1 mL vial Reagent 2: 3 x 1 mL vial Models/ Specification <i>(as per Free sale certificate):</i> 00599 Class-B LOA validity: 31-Dec-2025 Shelf life: 24 Months Storage Conditions: 2 - 8°C FSC country of origin validity: Date of Issue: 24-05-2024	Approved.

		CE Mark validity: N/A	FSC RRA validity: N/A	
6.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 277913779620 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	Brand name: STA – Deficient II & VII Generic Name: 6 x 1 mL vials (STA – Deficient II) 6 x 1 mL vials (STA – Deficient VII) Models/ Specification <i>(as per Free sale certificate):</i> STA – Deficient II: 00745 STA – Deficient VII: 00743 Class-B Shelf life: STA – Deficient II: 24 Months STA – Deficient VII: 24 Months	Approved. Firm shall submit fee and application form for Deficient VII before issuance of registration letter.
7.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 84786572 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA – FDP Calibrator & Control Generic Name: <ul style="list-style-type: none"> Reagent 1: (STA® - FDP Calibrator 1, human plasma containing a well-defined quantity of FDP, lyophilized.) Reagent 2: (STA® - FDP Calibrator 2, human plasma containing a well-defined quantity of FDP that is greater than that of Reagent 1, lyophilized). Reagent 3: (STA® - FDP Calibrator 3, human plasma containing a well-defined quantity of FDP that is greater than that of Reagent 2, lyophilized). Reagent 4: (STA® - FDP Calibrator 4, human plasma containing a well-defined quantity of FDP that is greater than that of Reagent 3, lyophilized) Reagent 5: (STA® - FDP Calibrator 5, human plasma containing a well-defined quantity of FDP that is greater than that of Reagent 4, lyophilized). 	Approved. The firm shall submit the fee as per revised SRO for Cluster before the issuance of registration letter.

			<ul style="list-style-type: none"> • Reagent 1 (Control): 6 x 1.5 mL vials • Reagent 2 (Control): 6 x 1.5 mL vials <p>Models/ Specification (as per Free sale certificate): Calibrator: 00655 Control: 00654</p> <p>Class-B LOA validity: 31-Dec-2025</p> <p>Shelf life: Calibrator: 24 months Control: 24 months</p> <p>Storage Conditions: Calibrator: 2 - 8°C Control: 2 - 8°C</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>FSC RRA validity: N/A</p>	
8.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 04-04-2025</p> <p>Fee: PKR 31,000/- Slip # 0073538400 Dated: 19-03-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>STA Immunodef VIII, IX, XI & XII</p> <ul style="list-style-type: none"> •STA® - ImmunoDef VIII (6 x 1 mL vials) •STA® - ImmunoDef IX (6 x 1 mL vials) •STA® - ImmunoDef XI (6 x 1 mL vials) •STA® - ImmunoDef XII (6 x 1 mL vials) <p>Models/ Specification (as per Free sale certificate):</p> <p>STA® - ImmunoDef VIII : 00728 STA® - ImmunoDef IX: 00734 STA® - ImmunoDef XI: 00759 STA® - ImmunoDef XII: 00315</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: STA® - ImmunoDef VIII : 24 Months STA® - ImmunoDef IX: 24 Months STA® - ImmunoDef XI:</p>	<p>Approved. Firm shall submit separate fee and application form for each of following before issuance of registration letter:</p> <ul style="list-style-type: none"> ImmunoDef IX (6 x 1 mL vials) •STA® - ImmunoDef XI (6 x 1 mL vials) •STA® - ImmunoDef XII (6 x 1 mL vials)

			24 Months STA® - ImmunoDef XII: 24 Months	
9.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 193405172130 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA® - Liatest FDP • Reagent 1: 6 x 5 mL vial • Reagent 2: 6 x 5 mL vial Models/ Specification <i>(as per Free sale certificate):</i> 00649 Class-B Shelf life: 24 Months	Approved
10.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 146433567749 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA® - Staclot® dRVV Screen ②, STA® - Staclot® dRVV Screen ⑤, STA® - Staclot® dRVV Confirm Generic Name: • Staclot® dRVV Screen ② (12 x 2 ml vials) • STA® - Staclot® dRVV Screen ⑤ (12 x 5 ml vials) • STA® - Staclot® dRVV Confirm (12 x 2 ml vials) Models/ Specification <i>(as per Free sale certificate):</i> • Staclot® dRVV Screen ② (12 x 2 ml vials): 00339 • STA® - Staclot® dRVV Screen ⑤ (12 x 5 ml vials): 00333 • STA® - Staclot® dRVV Confirm (12 x 2 ml vials): 00334 Class-B Shelf life: • Staclot® dRVV Screen ② (12 x 2 ml vials): 24 Months • STA® - Staclot® dRVV Screen ⑤ (12 x 5 ml vials): 24 Months	Approved. Firm shall submit separate fee and application form for each of following before issuance of registration letter: STA® - Staclot® dRVV Screen ⑤, STA® - Staclot® dRVV Confirm

			<ul style="list-style-type: none"> • STA® - Staclot® dRVV Confirm (12 x 2 ml vials): 24 Months 	
11.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 774780981600 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA® - Staclot® Protein C ① & S <ul style="list-style-type: none"> • STA® - Staclot® Protein C ① (Reagent 1: 3 x 1 mL vials) • STA® - Staclot® Protein C ① (Reagent 2: 3 x 1 mL vials) • STA® - Staclot® Protein S (Reagent 1: 2 x 1 mL vials) • STA® - Staclot® Protein S (Reagent 2: 2 x 1 mL vials) • STA® - Staclot® Protein S (Reagent 3: 2 x 1 mL vials) Models/ Specification <i>(as per Free sale certificate):</i> <ul style="list-style-type: none"> • STA® - Staclot® Protein C ① 00747 • STA® - Staclot® Protein S: 00746 Class-B Shelf life: <ul style="list-style-type: none"> • STA® - Staclot® Protein C ① - 36 Months • STA® - Staclot® Protein S - 24 Months 	Approved. Firm shall submit separate fee and application form for each kit before issuance of registration letter:
12.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 9910331717 Dated: 19-03-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA – Thrombin ② IVD Test Kit (12 x 2 ml vials) Models/ Specification <i>(as per Free sale certificate):</i> 00611 Class-B Shelf life: 24 Months	Approved
13.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France	Staclot LA • Reagent 1 (buffer): 2 x 1 mL vials	Approved

	Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 04-04-2025 Fee: PKR 31,000/- Slip # 87961783755 Dated: 19-03-2025	Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	• Reagent 2 (phospholipids): 2 x 0.250 mL vials • Reagent 3 (normal plasma): 4 x 0.5 mL vials • Reagent 4 (PTT-LS): 2 x 1 mL vials • Reagent 5 (solvent): 2 x 1.5 mL vials Models/ Specification <i>(as per Free sale certificate):</i> 00600 Class-B Shelf life: 24 Months	
14.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 91397192 Dated: 08-04-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérès - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA Deficient V IVD Test Kit (6 x 1 mL vials) Models/ Specification <i>(as per Free sale certificate):</i> 00744 Class-B Shelf life: 24 Months	Approved
15.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 842647429170 Dated: 08-04-2025	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérès - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny. LOA validity: 31-Dec-2025 FSC country of origin validity: Date of Issue: 24-05-2024 ISO 13485 certificate validity: 23-05-2028 CE Mark validity: N/A	STA Deficient X IVD Test Kit (6 x 1 mL vials) Models/ Specification <i>(as per Free sale certificate):</i> 00738 Class-B Shelf life: 24 Months	Approved
16.	M/s Martin Dow Specialties (Pvt) Limited	Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérès - 92600 Asnières sur Seine	STA® - Liatest® Free Protein S (2) • Reagent 1: 3 x 2ml vials	Approved

	<p>7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 05678257564 Dated: 08-04-2025</p>	<p>France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>• Reagent 2: 3 x 2ml vials</p> <p>Models/ Specification (as per Free sale certificate): 00527</p> <p>Class-B</p> <p>Shelf life: 12 Months</p>	
17.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 106099040600 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>STA Liatest VWF Ag</p> <ul style="list-style-type: none"> • Reagent 1: 4 x 5ml vials • Reagent 2: 4 x 2ml vials • Reagent 3: 4 x 4ml vials <p>Models/ Specification (as per Free sale certificate): 00518</p> <p>Class-B</p> <p>Shelf life: 18 Months</p>	Approved
18.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 80729058580 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>STA Stachrom ATIII ③</p> <ul style="list-style-type: none"> • Reagent 1: 4 x 3ml vials • Reagent 2: 4 x 3ml vials • Reagent 3: 4 x 3ml vials <p>Models/ Specification (as per Free sale certificate): 00518</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	Approved
19.	<p>M/s Martin Dow Specialties (Pvt)</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée</p>	<p>STA Stachrom Protein C</p> <ul style="list-style-type: none"> • Reagent 1: 6 x 3ml vials 	Approved

	<p>Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 2436682654 Dated: 08-04-2025</p>	<p>Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>• Reagent 2: 6 x 3ml vials</p> <p>Models/ Specification (as per Free sale certificate): 00671</p> <p>Class-B</p> <p>Shelf life: 18 Months</p>	
20.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 068731479816 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>STA Staclot APC-R</p> <ul style="list-style-type: none"> • Reagent 1: 4 x 2-mL vials • Reagent 2: 4 x 2-mL vials • Reagent 3: 4 x 2-mL vials • Reagent 4: 4 x 2-mL vials • Reagent 5: 4 x 2-mL vials <p>Models/ Specification (as per Free sale certificate): 00721</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	Approved
21.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 849282202 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 24-05-2024</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>STA VWF Ag Calibrator IVD Test Kit (6 x 1ml vials)</p> <p>Models/ Specification (as per Free sale certificate): 00520</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	Approved

22.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 486100869 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise: SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Brand name: Cardiolipin IgG Control Generic Name: Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC001 Class-B LOA validity: 31-Dec-2025 Shelf life: 24 Months Storage Conditions: 2 - 8°C FSC country of origin validity: 20-Dec-2026	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
23.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 8391162735 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise: SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Cardiolipin IgM Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC002 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
24.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site:	Brand name: Anti-Cardiolipin Control Generic Name: Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

	<p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 685420964 Dated: 26-03-2025</p>	<p>Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 20-Dec-2026</p> <p>ISO 13485 certificate validity: 14-Nov-2025</p> <p>CE Mark validity: N/A</p>	<p>(as per Free sale certificate): ZCC003</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	
25.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 77472614028 Dated: 26-03-2025</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 20-Dec-2026</p> <p>ISO 13485 certificate validity: 14-Nov-2025</p> <p>CE Mark validity: N/A</p>	<p>β2-Glycoprotein I IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml)</p> <p>Models/ Specification (as per Free sale certificate): ZCC004 Class-B</p> <p>Shelf life: 24 Months</p>	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
26.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/-</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong</p>	<p>β2-Glycoprotein I IgM Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml)</p> <p>Models/ Specification (as per Free sale certificate): ZCC005 Class-B</p> <p>Shelf life: 24 Months</p>	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

	Slip # 5743354991 Dated: 26-03-2025	Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A		
27.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 89386551801 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Anti-β2-Glycoprotein Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC006 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
28.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 7364479973 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025	ANA Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC007 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

		FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A		
29.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 79593760498 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	dsDNA IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC008 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
30.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 8877531957 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity:	Rheumatoid Arthritis Multi Control Immunoassay Controls (Negative: 2×2.0ml) (Positive: 2×2.0ml) Models/ Specification (as per Free sale certificate): ZCC009 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

		14-Nov-2025		
		CE Mark validity: N/A		
31.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 9809205832 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20- Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	MPO IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC010 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
32.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 2161617539 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20- Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	PR3 IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC011 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
33.	M/s Martin Dow Specialties (Pvt)	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd,	AMH Control Immunoassay Controls	Deferred for the provision of following:

	<p>Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 220039638 Dated: 26-03-2025</p>	<p>Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 20-Dec-2026</p> <p>ISO 13485 certificate validity: 14-Nov-2025</p> <p>CE Mark validity: N/A</p>	<p>(Low: 2×3.0ml) (High: 2×3.0ml)</p> <p>Models/ Specification (as per Free sale certificate): ZCC027</p> <p>Class-B</p> <p>Shelf life: 18 Months</p>	<p>Embassy attested/apostile FSC of reference country or notarized CE marked document</p>
34.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 511651218619 Dated: 26-03-2025</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 20-Dec-2026</p> <p>ISO 13485 certificate validity: 14-Nov-2025</p> <p>CE Mark validity: N/A</p>	<p>Inhibin B Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Models/ Specification (as per Free sale certificate): ZCC028</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document</p>
35.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal,</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p>	<p>PG I & PG II Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Models/ Specification (as per Free sale certificate):</p>	<p>Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document</p>

	Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 9763829370 Dated: 26-03-2025	Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20- Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	ZCC037 Class-B Shelf life: 18 Months	
36.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 76342670 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20- Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	GBM IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC038 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
37.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO.,	HA Control Immunoassay Controls (Low: 1×1.0ml) (High: 1×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC039 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

	Fee: PKR 31,000/- Slip # 26633480720 Dated: 26-03-2025	LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A		
38.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 0740447634 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Hepatic Fibrosis Related Marker Multi Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC049 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
39.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 9704173772 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.	Adiponectin Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC051 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

		LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A		
40.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 2321001849 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Autoimmune Diabetes Multi Control Immunoassay Controls (Negative: 2×2.0ml) (Positive: 2×2.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC052 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
41.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 84120563 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026	ICA Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC052 Class-B Shelf life: 18 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

		ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A		
42.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 990785393 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	ACTH Control Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC078 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
43.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 10228547563 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Anti-TSHR Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC080 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document

44.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 311427804971 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	17 α -Hydroxyprogesterone Control Immunoassay Controls (Low: 1 \times 1.0ml) (High: 1 \times 1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC080 Class-B Shelf life: 18 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
45.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 25733927 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	hGH Control Immunoassay Controls (Low: 1 \times 1.0ml) (High: 1 \times 1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC128 Class-B Shelf life: 24 Months	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or notarized CE marked document
46.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B,	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang	SHBG Control Immunoassay Controls (Low: 1 \times 1.0ml) (High: 1 \times 1.0ml)	Deferred for the provision of following: Embassy attested/apostile FSC of reference country or

	<p>Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025</p> <p>Fee: PKR 31,000/- Slip # 28493169392 Dated: 26-03-2025</p>	<p>District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 20-Dec-2026</p> <p>ISO 13485 certificate validity: 14-Nov-2025</p> <p>CE Mark validity: N/A</p>	<p>Models/ Specification (as per Free sale certificate): ZCC129</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>notarized CE marked document</p>
47.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Rs 31,030 Paid on 19/05/2025 Challan # 171288096</p> <p>Date of R& I 14th April 2025 4224-B</p>	<p>Legal Manufacturer: ZHUHAI LINTE MEDICAL INSTRUMENT CO., LTD</p> <p>Manufacturing Site: 501 BUILDING # 3 2 JINLIANG ROAD HONGQI TOWN JINWAN DISTRICT 519090 ZHUHAI GUANGDONG PRC</p> <p>LOA: Sole Agency Agreement (Notarized by CCPIT, submitted with file): Valid till Feb 2035</p> <p>FSC: CHINA FSC Valid Until: 29/07/2025</p> <p>ISO: Production Quality Management System Certificate (ISO 13485:2016) Valid till 2025-12-27 (Notarized by CCPIT, submitted along with the file)</p> <p>EU QMS certificate (MDR) validity 28-12-2027</p>	<p>ACCUMAX DIGITAL ARM BLOOD PRESSURE MONITOR</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes: LT-P31A</p>	<p>Approved</p>
48.	<p>Name M/S GHAZALI BROTHERS</p>	<p>Legal Manufacturer: M/S JIANGSU WEBEST MEDICAL PRODUCT CO., LTD</p>	<p>ACCUMAX EXTENSION TUBE</p> <p>Class B</p>	<p>Deferred for the provision of following: Original documents including notarized</p>

	<p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Date of R& I 14th April 2025</p> <p>Fees: Challan # 19425068411 Rs 31,000.00 submitted on 27/04/2025</p>	<p>Manufacturing Site: NO. 5 YINGCHUN ROAD INDUSTRIAL PARK, XUYI, JIANGSU, CHINA. Tel: +86-517-88296001 WWW.CNWEBEST.COM</p> <p>LOA: Sole Agency Agreement Valid till: 31-12-2029</p> <p>FSC: CHINA FSC Validity: 30-06-2025</p> <p>ISO: Production Quality Management System Certificate (ISO 13485:2016) Valid till: 2026-05-31</p>	<p>Shelf Life: 5 Years</p> <p>Codes/Sizes: SIZES: 150cm to 210cm, 300cm to 400cm</p>	<p>LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of ref country or notarized CE marked document and ISO 13485 certificate.</p> <p>The applied Brand name is not mentioned in the submitted LOA or FSC.</p>
49.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Challan # 80150949204 Rs 31,000 Date: 27/04/2025</p> <p>Date of R& I 14th April 2025</p>	<p>Legal Manufacturer: M/S JIANGSU WEBEST MEDICAL PRODUCT CO., LTD</p> <p>Manufacturing Site: NO. 5 YINGCHUN ROAD INDUSTRIAL PARK, XUYI, JIANGSU, CHINA. Tel: +86-517-88296001 WWW.CNWEBEST.COM</p> <p>LOA: Sole Agency Agreement Valid till: 31-12-2029</p> <p>FSC: CHINA FSC Validity: 30-06-2025</p> <p>ISO: Production Quality Management System Certificate (ISO 13485:2016) Valid till: 2026-05-31</p>	<p>EASYFLOW I.V. DIAFLOW REGULATOR</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes: Flow range from 5 to 250ml/hour</p>	<p>Deferred for the provision of following: Original documents including notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of ref country or notarized CE marked document and ISO 13485 certificate.</p> <p>The applied Brand name is not mentioned in the submitted LOA or FSC. Product codes</p>
50.	<p>Quintex Medical Lateef Manzal, 1st Floor, 100/B, Main Lyton road Lahore, Pakistan</p> <p>ELI No.: ELI- 00823 DRAP Fees: Rs: 31000/- Challan No. 977728636238 15-04-2025</p>	<p>Legal Manufacturer: Shenzhen Bi-Rich Medical Devices Co., Ltd The 1st Building Of No. 10, Xinqiao Gangzai Road, Xinqiao Street Bao'an District Shenzhen City China TEL. +86 75527464589 FAX +86 75527464595</p> <p>LOA Validity: 05-03-2030 FSC Valid till: 17-02-2026 EC Valid till: 31-12-2028 ISO Valid till: 14-07-2026</p>	<p>SHENZHEN BI-RICH MEDICAL DEVICES CO., LTD SUCTION MACHINE</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Model: BR-SM 153</p>	<p>Approved</p>

51.	<p>Quintex Medical Lateef Manzal, 1st Floor, 100/B, Main Lyton road Lahore, Pakistan</p> <p>ELI No.: ELI- 00823 DRAP Fees: Rs: 31000/- Challan No. 1883674192 15-04-2025</p>	<p><u>Legal Manufacturer:</u> Shenzhen Bi-Rich Medical Devices Co., Ltd The 1st Building Of No. 10, Xinqiao Gangzai Road, Xinqiao Street Bao'an District Shenzhen City China TEL. +86 75527464589 FAX +86 75527464595</p> <p>LOA Validity: 05-03-2030 FSC Valid till: 17-02-2026 EC Valid till: 31-12-2028 ISO Valid till: 14-07-2026</p>	<p>SHENZHEN BI-RICH MEDICAL DEVICES CO., LTD COMPRESSOR NEBULIZER</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>model: BR-CN143, BR-CN-116, BR-CN176</p>	<p>Approved.</p> <p>The firm shall submit fee and application form BR- CN-116, BR-CN176 before issuance of Registartion letter.</p>
52.	<p>Medico International B- 235, Block B, Satellite Town, Rawalpindi</p> <p>ELI-01038</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 312281800138</p>	<p>M/s Honsun (Nantong) Co., Ltd., No. 8, Tongxing Road, Economic & Technology Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 01-01-2030</p> <p>FSC copy: China Validity: 11-07-2025</p> <p>FSC: Germany Issue date: 01-05-2024</p> <p>ISO Validity: 08-03-2026</p> <p>EU QMS Certificate (MDR): Validity: 22-02-2029</p>	<p>Medico Compressor Nebulizer</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification NB-222C (NB-95)</p>	<p>Approved.</p>
53.	<p>Medico International B- 235, Block B, Satellite Town, Rawalpindi</p> <p>ELI-01038</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 69092521346</p>	<p>M/s Honsun (Nantong) Co., Ltd., No. 8, Tongxing Road, Economic & Technology Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 01-01-2030</p> <p>FSC copy: China Validity: 11-07-2025</p> <p>FSC: Germany Issue date: 01-05-2024</p> <p>ISO Validity: 08-03-2026</p> <p>EC Certificate: Validity: 22-02-2029</p>	<p>Medico Compressor Nebulizer NB-97</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification NB-97</p>	<p>Approved.</p>
54.	MBS Medical, F2, 1 st	M/s Dukwoo Medical Co., Ltd., 35,	3S Cath I.V Cannula	Deferred for the

	<p>Floor 51-1/C, PECHS Block 6, 75400, Karachi</p> <p>ELI-00035</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 522774425749</p>	<p>Hwaseong – ro 1616 Beongil, Bibong-Myeon, Hwaseong-Si Gyeonggil-Do, Korea</p> <p>LOA Issue date: 01-05-2024 valid for 5 years</p> <p>FSC: Korea Issue date: 02-05-2017</p> <p>ISO Validity: 10-04-2026</p> <p>EC Certificate: Validity: 26-05-2024</p>	<p>I.V Cannula Wing Type</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification 3S-Cath+ 16G 51 3S-Cath+ 18G 51 3S-Cath+ 22G 25 3S-Cath 16G 51 3S-Cath 18G 51 3S-Cath 22G 25 3S-Cath+ 18G 32 3S-Cath+ 20G 32 3S-Cath+ 24G 19 3S-Cath 18G 32 3S-Cath 20G 32 3S-Cath+24G 19</p>	<p>provision of following: Valid and notarized CE certificate.</p>
55.	<p>Applicant Name: Silpha Labs Pvt.Ltd., 99/6, Gulshan-e-Mehrun Nisa, Ibrahim Hyderi, Korangi Creek, Karachi</p> <p>(ELI-00650)</p> <p>Date of R&I 11-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 6971559111</p>	<p>M/s Winner Medical Co., Ltd., Winner Industrial Park, Bulong Road, Longhua, Shenzen City, China</p> <p>LOA Validity: 31-12-2026</p> <p>FSC: China Validity: 27-09-2025</p> <p>ISO Validity: 31-08-2026</p> <p>EC Certificate: Validity: 18-09-2023</p>	<p>Winject Sterile Hypodermic Syringe with Needle</p> <p>Class-B</p> <p>Shelf life: 03 years</p> <p>Models/ Specification 10cc & 20cc</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, notarized CE marked document and ISO 13485 certificate.</p>
56.	<p>Applicant Name: Silpha Labs Pvt.Ltd., 99/6, Gulshan-e-Mehrun Nisa, Ibrahim Hyderi, Korangi Creek, Karachi</p> <p>(ELI-00650)</p> <p>Date of R&I 11-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 10660070</p>	<p>M/s Winner Medical Co., Ltd., Winner Industrial Park, Bulong Road, Longhua, Shenzen City, China</p> <p>LOA Validity: 31-12-2026</p> <p>FSC: China Validity: 27-09-2025</p> <p>ISO Validity: 31-08-2026</p> <p>EC Certificate: Validity: 18-09-2023</p>	<p>Silget Sterile Insulin Syringe</p> <p>Class-B</p> <p>Shelf life: 03 years</p> <p>Models/ Specification 1cc</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, notarized CE marked document and ISO 13485 certificate.</p>
57.	<p>Applicant Name: Silpha Labs Pvt.Ltd., 99/6, Gulshan-e-Mehrun Nisa, Ibrahim Hyderi, Korangi Creek, Karachi</p> <p>(ELI-00650)</p>	<p>M/s Winner Medical Co., Ltd., Winner Industrial Park, Bulong Road, Longhua, Shenzen City, China</p> <p>LOA Validity: 31-12-2026</p>	<p>Silsafe Auto Disable Syringe</p> <p>Class-B</p> <p>Shelf life: 03 years</p> <p>Models/ Specification</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, notarized CE marked document and ISO</p>

	<p>Date of R&I 11-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 8664285855</p>	<p>FSC: China Validity: 27-09-2025</p> <p>ISO Validity: 31-08-2026</p> <p>EC Certificate: Validity: 18-09-2023 with extension notification</p>	<p>5cc & 3cc</p>	<p>13485 certificate.</p>
58.	<p>M/s Business Medical International</p> <p>Office No: Suite101& 102, Trade Centre, Plot#23-F Muhammad Ali Housing Society, Karachi.</p> <p>(ELI-00262) D.O.I: 22-10-2018</p> <p>Dy. No.: DRAP (R&I)</p> <p>Dated: 09-04-2025</p> <p>Fee Challan No.: 04059567</p> <p>PKR: 31,030 /-</p> <p>Dated: 4th APRIL, 2025</p>	<p>Legal Manufacturer: CORTEX TECHNOLOGY APS Cortex Technology ApS Niels Jernes Vej 6B 9220 Aalborg Denmark.</p> <p>LOA Validity: 19-03-2030</p> <p>FSC Validity (country of origin): 19-02-2027</p> <p>EU QMS Certificate MDR validity: 20-01-2030</p> <p>ISO 13485 Certificate validity: 30-09-2027</p>	<p>Cryo Pro Maxi and Cryo Pro Mini with Accessories & withdrawal device</p> <p>Class: B</p> <p>Service life: 10 Years</p> <p>Codes/models as per FSC</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, notarized CE marked document and ISO 13485 certificate.</p> <p>Multiple products applied along with accessories and withdrawal device, give your priority in current case and justification of grouping the accessories with the product applied.</p>
59.	<p>M/s Business Medical International</p> <p>Office No: Suite101& 102, Trade Centre, Plot#23-F Muhammad Ali Housing Society, Karachi.</p> <p>(ELI-00262) D.O.I: 22-10-2018</p> <p>Dy. No.: DRAP (R&I)</p> <p>Dated: 04-04-2025</p> <p>Fee Challan No.: 2860419821</p> <p>PKR: 31,030 /-</p> <p>Dated: 23RD MARCH, 2025</p>	<p><u>Legal Manufacturer:</u> CONMED CORPORATION 1311 Concept Blvd, Largo, FL 33773, USA,</p> <p>ISO 13485 Certificate validity: 15-03-2025</p>	<p>Electrosurgical Unit with Standard accessories</p> <p>Class: B</p> <p>Service life: 10 Years</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, notarized CE marked document and ISO 13485 certificate.</p> <p>Brand name and model/ codes.</p>

60.	<p>Batla Impex, Shop No. 40 Namco Center, Cambell Street, Karachi</p> <p>(ELI-00170)</p> <p>Date of R&I 14-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 578049788</p>	<p>M/s Hangzhou Valued Medtech Co. Ltd.,289#, Gaojia Road, Tonglu County Zhejiang China</p> <p>LOA Validity: Validity not provided.</p> <p>FSC: China Validity: 17-01-2025</p>	<p>Super Absorbable Surgical Suture with Needle</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification: Surgical sutures (12-0, 11-0, 10-0, 9-0, 8-, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2)</p> <p>Surgical needles, Needle diameter: 0.2~1.3mm; Needle circle: 1/2circle, 3/8circle, Straight needle; Needle type: taper point round bodied, cutting, reverse cutting</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>The subject sutures fall in Class-D, no type is specified and revised the application and fee on the prescribed Form.</p>
61.	<p>Applicant Name: Batla Impex, Shop No. 40 Namco Center, Cambell Street, Karachi</p> <p>(ELI-00170)</p> <p>Date of R&I 14-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 5369944260</p>	<p>M/s Hangzhou Valued Medtech Co. Ltd.,289#, Gaojia Road, Tonglu County Zhejiang China</p> <p>LOA Validity: Validity not provided.</p> <p>FSC: China Validity: 17-01-2025</p>	<p>Super Non-Absorbable Surgical Suture with Needle</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification:</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>The subject sutures fall in Class-C, no type is specified and revised the application and fee on the prescribed Form.</p>
62.	<p>Applicant Name: Batla Impex, Shop No. 40 Namco Center, Cambell Street, Karachi</p> <p>(ELI-00170)</p> <p>Date of R&I 14-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- 8137827346</p>	<p>M/s Super Health Medical (Qingdao) Co., Ltd., No. 236 Heyuan Road, High-Tech Zone Qingdao, China</p> <p>LOA Validity: 17-02-2030</p> <p>FSC: China Validity: 27-04-2025</p> <p>ISO Validity: 29-03-2026</p> <p>EC Certificate: Validity:</p>	<p>B Care I.V Cannula</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification:14G, 16G, 18G, 20G, 22G, 24G, 26G</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
63.	Applicant Name:	M/s Spacelab Healthcare Ltd.,Unit B	Cardio Express SL 6A/12A	Deferred for the

	<p>Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road, Gulberg IV, Lahore, 54000</p> <p>(ELI-00554)</p> <p>Date of R&I 03-04-2025</p> <p>Fee Details: Paid Fee: 25,000/- 140154354892</p>	<p>Fox Holes Center Jhon Tate Road, USA. Manufacturing site: M/s Edan Instruments, Inc., #15 Jinui Road, Jinsha Community Kengzi Sub-District, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 04-12-2025</p> <p>FSC: USA Validity: 25-05-2023</p> <p>ISO Validity: 21-02-2025</p> <p>EC Certificate: Validity: 26-05-2024</p>	<p>Electrocardiograph</p> <p>Class-B</p> <p>Shelf life: 07 years</p> <p>Codes/model: 90478</p>	<p>provision of following:</p> <p>Credentials, Original, valid and Embassy attested/apostile FSC, notarized CE/FQA document and valid and notarized ISO 13485 certificate.</p> <p>Clarification is required since the site mentioned on application form is not reflecting in LOA and FSC.</p> <p>Submit fee for system as per revised SRO</p>
64.	<p>Applicant Name: Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road, Gulberg IV, Lahore, 54000</p> <p>(ELI-00554)</p> <p>Date of R&I 03-04-2025</p> <p>Fee Details: Paid Fee: 25,000/- 7200146033</p>	<p>M/s Spacelab Healthcare Ltd., Unit B Fox Holes Center Jhon Tate Road, USA.</p> <p>LOA Validity: 04-12-2025</p> <p>FSC: USA Validity: 25-05-2023</p> <p>ISO Validity: 21-02-2025</p> <p>EC Certificate: Validity: 26-05-2024</p>	<p>Xprezzon Bedside Monitor Physiological Monitor System</p> <p>Class-B</p> <p>Shelf life: 07 years</p> <p>Models/ Specification: 91393</p>	<p>Deferred for the provision of following:</p> <p>Credentials, Original, valid and Embassy attested/apostile FSC, notarized CE/FQA document and valid and notarized ISO 13485 certificate.</p> <p>Clarification is required since the site mentioned on application form is not reflecting in LOA and FSC.</p> <p>Submit fee for system as per revised SRO</p>
65.	<p>Applicant Name: M/s Melamine Emporium, 814, Star City Mall, Saddar, Karachi</p> <p>(ELI-00414)</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee:</p>	<p>M/s SWL Medizin GmbH, Havelstr. 16 64295 Darmstadt, Germany.</p> <p>LOA Validity: 16-01-2030</p> <p>FSC: Germany Issue date: 20-11-2024</p> <p>ISO Validity: 31-08-2026</p> <p>EC Certificate: Validity:</p>	<p>SWL Hemostasis Valve Set Hemostasis</p> <p>Class-B</p> <p>Shelf life: 03 years</p> <p>Models/ Specification: HV816102 HV816103 HV816104 HV816105 HV816106 HV816107 HV816108 HV816109 HV816200 HV816300 HV816110</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA, Embassy attested/apostile FSC, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Fee as per revised SRO for Family.</p>

			HV816111 HV816112 HV816113 HV816117 HV816118 HV816119 HV816120	
66.	<p>Applicant Name: M/s Mezan International, 59BRII Opp DCO House Haji Meherban Road, Bilal Town Jhelum</p> <p>(ELI-00096)</p> <p>Date of R&I 14-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Slip No. 2311299226</p>	<p>M/s Highgreen Medical Technology Co., Ltd., E6 Building No. 288 Shanhai Road Chucun Town, HI-Tech District Weihei Shandong PR China</p> <p>LOA Validity: 07-02-2030</p> <p>FSC: China Validity: 12-11-2025</p> <p>ISO Validity: 25-09-2026</p>	<p>Medical Sodlime Calcium Hydroxide, Water</p> <p>Class-B</p> <p>Shelf life: 3 years</p> <p>Models/ Specification: HG-A T4501 HG-A T4502</p>	<p>Deferred for the provision of following:</p> <p>Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification whether the applied product is a medical device in EU states or not.</p>
67.	<p>Applicant Name: M/s Biocare Enterprises, Plot No. 64/2 St#17, FECHS (NPF) 0-9 PWD Road, Islamabad</p> <p>(ELI-00220)</p> <p>Date of R&I 11-04-2025</p> <p>Fee Details: Paid Fee: 50000/- Slip No. 1165944563</p>	<p>M/s Shenzhen Cornley Bio-Medical Co., Ltd., 6/F Building 10, Block 3, Yangbei Industrial Park, Huangtian Community, Hangcheng Street, Bao'an 518128, China</p> <p>LOA Validity: 16-01-2030</p> <p>FSC: Germany Issue date: 28-02-2022</p> <p>FSC: China Validity: 04-08-2026</p> <p>ISO Validity: 08-12-2026</p>	<p>Cornley Vitagas 5 Series Blood Gas and Electrolyte Analyser and their related reagent, consumables, Accessories and Spare parts</p> <p>Class-B</p> <p>Shelf life: not mentioned</p> <p>Models/ Specification: Not specified</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>No model is specified; multiple products are included in single application.</p> <p>Shelf life is not mentioned, no stability data is provided.</p>
68.	<p>Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p>	<p>Name of Manufacturer: M/s. Haiyan Kangyuan Medical Instrument Co., Ltd. Address: Songpodong Rd., Shendang Town, Haiyan, Zhejiang 314311, China</p> <p>LOA Validity:</p>	<p>Pigeon Care Urinary Catheter for Single Use (Silicone Foley)</p> <p>Class-B</p> <p>Shelf Life: 05 years Models/Specifications:</p>	<p>Approved</p>

	<p>Date of R&I 08-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 34262205217 Dated: 25-03-2025</p>	<p>08-09-2029</p> <p>FSC: Country: CHINA Validity: 24-09-2025</p> <p>CE Certificate Validity: 01-02-2028</p> <p>ISO 13485 Validity: 25-08-2026</p>	<p>Two-way Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr</p>	
69.	<p>Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 0882246092 Dated: 25-03-2025</p>	<p>Legal Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024 EC Certificate Validity: 08-10-2023</p>	<p>Introducer set Vascular catheter Introduction Set Class-B Shelf life: 3 Years Models/ Specification: Introducer Set, 5 Fr, 90 cm Sheath / 970 mm Dilator / 18 g x 7 cm Needle, sterile Introducer Set, 5 Fr, 11 cm Sheath / 169 mm Dilator / 0.038" x 45 cm Guide Wire / 18g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 6 Fr, 11 cm Sheath / 169 mm Dilator / 0.038" x 45 cm Guide Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 7 Fr, 11 cm Sheath / 169 mm Dilator / 0.038" x 45 cm Guide Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 6 Fr, 11 cm Sheath / 169 mm Dilator/ 0.035 ^ prime prime *45 cm Gulde Wire / 18 g x 7 cm Dear Arterial Needle without Wings, sterile Introducer Set, 7 Fr, 11 cm Sheath / 169 mm Dilator/ 0.035 ^ prime prime *45 cm Guide Wire / 18g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 8 Fr, 11 cm Sheath / 169 mm Dilator / 0.038 ^ prime prime *45 cm Gulde Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile</p>	<p>Deferred for the provision of following: Brand name of the device. Valid and notarized CE marked document. Justification for applying all types in single application.</p>

			<p>Radial Introducer Set, 5 Fr, 11 cm Sheath /169 mm Dilator / 0.021 ^ prime prime *45 cm Guide Wire/21 g 1x4 cm Arterial Needle, sterile</p> <p>Radial Introducer Set, 6 Fr, 11 cm Sheath/169 mm Dilator/ 0.021^ prime prime * 45c Guide Wire/21 g 1x4 cm Arterial Needle, sterile</p> <p>Radial Introducer Set, 6 Fr, 16 cm Sheath / 219 mm Dilator/ 0.021 ^ prime prime *45 cm Guide Wire/21 g 1 x4 cm Arterial Needle, sterile</p>	
70.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 20130269101 Dated: 25-03-2025</p>	<p>Legal Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>Manifold Sets Manifold Sets (Fluid Transfer set general purpose)</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: Manifold Set, 3 Port, Right, ON, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Left, OFF, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / Control Syringe 12 ml LL / 180cm Vented Spike Line/180cm Vented Drip Chamber Line / 120cm Pressure Monitoring Line 500 psi, sterile</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device.</p> <p>Valid and notarized CE marked document.</p> <p>Justification for applying various sets in single application.</p>

			<p>Manifold Set, 3 Port, Right, ON, 500 psl / 180cm Vented Spike Line / 180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / 180cm Vented Spike Line / 180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, HP Stopcock, 3 Way, OFF, 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / Colour Coded Syringe 10 ml, LL, White / 180cm Vented Spike Line/180cm Vented Drip Chamber Line / 120cm Pressure Monitoring Line 500 psl, sterile</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / 275cm Vented Spike Line/275cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, 500 psi / 275cm Vented Spike Line/275cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, Green - Soft, 500 psi / Control Syringe 10 ml, Palm Pad/Finger Plate, LL/180cm Vented Spike Line/180cm Vented Drip Chamber Line /120cm Pressure Monitoring Line 500 psi, sterile</p>	
71.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p>	<p>Legal Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site:</p> <p>Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p>	<p>Pressure Monitoring Line</p> <p>Pressure Monitoring Line</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: Pressure Monitoring Line, 30 cm, DEHP free PVC, 500 psi,</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device.</p> <p>Valid and notarized CE marked document.</p>

	<p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 5822621260 Dated: 25-03-2025</p>	<p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 60 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 90 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 120 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 150 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 180 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p>	<p>Fee as per revised SRO for Family.</p>
72.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 808860841718 Dated: 25-03-2025</p>	<p>Legal Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>Manifold</p> <p>Manifold (Non-active devices for anesthesia, emergency and intensive care)</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: HP Manifold, 3 Port, Right, OFF, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, OFF, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, OFF, Green - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right,</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device.</p> <p>Valid and notarized CE marked document.</p> <p>Fee as per revised SRO for Family.</p>

			<p>ON, Blue, with Extension Line, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Left, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Left, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 4 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 4 Port, Right, OFF, White, RA, 500 psi, sterile</p>	
73.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 16400565854 Dated: 25-03-2025</p>	<p>Legal Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>High Pressure Extension lines Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: High Pressure Extension Line, 30 cm, PUR braided, 1200 psi, Male/Female LL, sterile</p> <p>High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, Male/Female LL, sterile</p> <p>High Pressure Extension Line, 90 cm, PUR braided, 1200 psi, Male/Female LL, sterile</p> <p>High Pressure Extension Line, 120 cm, PUR braided, 1200 psi, Male/Female LL, sterile</p> <p>High Pressure Extension Line, 30 cm, PUR braided, 1200 psi, RA, sterile</p> <p>High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, RA, sterile</p> <p>High Pressure Extension Line, 90 cm, PUR braided, 1200 psi, RA, sterile</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device.</p> <p>Valid and notarized CE marked document.</p> <p>Fee as per revised SRO for Family.</p>

			<p>High Pressure Extension Line, 120 cm, PUR braided, 1200 psi, RA, sterile</p> <p>High Pressure Extension Line, 150 cm, PUR braided, 1200 psi, RA, sterile</p> <p>High Pressure Extension Line, 150 cm, Balibraided, (Braided, 1200 psi, MRA-MRA, sterile</p>	
74.	<p>FM Health Care</p> <p>Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi</p> <p>License No: ELI-00082</p> <p>DRAP Application Submission Date: 28-Feb-2022</p> <p>DRAP Fees: Rs: 25,000/- Challan No. 5808194969 Dated: 18-02-2022</p>	<p>Legal Manufacturer: Well Lead Medical Co. Ltd. Address: C-4#JINHU INDUSTRIAL ESTATE, HUALONG, PANYU, GUANGZHOU, CHINA, 511434</p> <p>Tel: +86 20 84758878 Fax: +86 20 84758224 Website: http://www.welllead.com.cn/</p> <p>Free Sale Certificate Expiry: 27-09-2025</p> <p>LOA Expiry: 10-2027</p> <p>CE Certificate Expiry: 26-05-2024</p> <p>CE extension Confirmation Letter Reference No. GCN-SH24080A02</p> <p>ISO Certificate Expiry: 19-08-2025</p>	<p>Well lead PVC Stomach Tube</p> <p>Class: B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Code: 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr & 24Fr</p>	Approved
75.	<p>FM Health Care</p> <p>Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi</p> <p>License No: ELI-00082</p> <p>DRAP Application Submission Date: 28-Feb-2022</p> <p>DRAP Fees: Rs: 25,000/- Challan No. 2497296733 Dated: 18-02-2022</p>	<p>Legal Manufacturer: Well Lead Medical Co. Ltd. Address: C-4#JINHU INDUSTRIAL ESTATE, HUALONG, PANYU, GUANGZHOU, CHINA, 511434</p> <p>Tel: +86 20 84758878 Fax: +86 20 84758224 Website: http://www.welllead.com.cn/</p> <p>Free Sale Certificate Expiry: 27-09-2025</p> <p>LOA Expiry: 10-2027</p> <p>CE Certificate Expiry: 26-05-2024</p> <p>CE extension Confirmation Letter</p>	<p>Well lead Intubating Stylet</p> <p>Class: B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Code: 6Fr, 10Fr & 14Fr</p>	Approved

		Reference No. GCN-SH24080A02 ISO Certificate Expiry: 19-08-2025		
76.	FM Health Care Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi License No: ELI-00082 DRAP Application Submission Date: 30-01-2020 DRAP Fees: Rs: 25,000/- Challan No. 1996508 Dated: 09-01-2020	Legal Manufacturer: Well Lead Medical Co. Ltd. Address: C-4#JINHU INDUSTRIAL ESTATE, HUALONG, PANYU, GUANGZHOU, CHINA, 511434 Tel: +86 20 84758878 Fax: +86 20 84758224 Website: http://www.welllead.com.cn/ Free Sale Certificate Expiry: 27-09-2025 LOA Expiry: 10-2027 CE Certificate Expiry: 26-05-2024 CE extension Confirmation Letter Reference No. GCN-SH24080A02 ISO Certificate Expiry: 19-08-2025	Well Lead Clear Petra Suction-Evacuation Access Sheath Class: B Shelf Life: 5 Years Sizes Code: Ureteral Access Sheath 10 x 12 FR Length: 13,26,36,40,46,55 cm 11 x 13 FR Length: 13,26,36,40,46,55 cm 12 x 14 FR Length: 13,26,36,40,46,55 cm 13 x 15 FR Length: 13,26,36,40,46,55 cm 14 x 16 FR Length: 13,26,36,40,46,55 cm Nephrostomy Sheath 10 x 12 FR Length: 13,17,21 cm 12 x 14 FR Length: 13,17,21 cm 14 x 16 FR Length: 13,17,21 cm 16 x 18 FR Length: 13,17,21 cm 18 x 20 FR Length: 13,17,21 cm 20 x 22 FR Length: 13,17,21 cm 22 x 24 FR Length: 13,17,21 cm Cystoscope Sheath 18 x 20 FR Length: 21,24 cm 20 x 22 FR Length: 21,24 cm 22 x 24 FR Length: 21,24 cm Ureteral Access Sheath 10 Fr Length: 20,28,35,45,55 cm 12 FR Length: 20,28,35,45,55 cm 14 FR Length: 20,28,35,45,55 cm	Approved. Firm shall submit application form and fee for Nephrostomy Sheath and Cystoscope Sheath before issuance of registration letter.
77.	FM Health Care	Legal Manufacturer:	Well Lead	Approved.

	<p>Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi</p> <p>License No: ELI-00082</p> <p>DRAP Application Submission Date: 30-01-2020</p> <p>DRAP Fees: Rs: 25,000/- Challan No. 1996520 Dated: 23-12-2019</p>	<p>Well Lead Medical Co. Ltd. Address: C-4#JINHU INDUSTRIAL ESTATE, HUALONG, PANYU, GUANGZHOU, CHINA, 511434</p> <p>Tel: +86 20 84758878 Fax: +86 20 84758224 Website: http://www.welllead.com.cn/</p> <p>Free Sale Certificate Expiry: 27-09-2025</p> <p>LOA Expiry: 10-2027</p> <p>CE Certificate Expiry: 26-05-2024</p> <p>CE extension Confirmation Letter Reference No. GCN-SH24080A02</p> <p>ISO Certificate Expiry: 19-08-2025</p>	<p>Anesthetic Breathing Circuit</p> <p>Class: B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Code: Adult & Pediatric</p>	<p>The firm shall submit fee as per revised SRO for Family before the issuance of registration letter.</p>
78.	<p>FM Health Care</p> <p>Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi</p> <p>License No: ELI-00082</p> <p>DRAP Application Submission Date: 04-04-2022</p> <p>DRAP Fees: Rs: 25,000/- Challan No. 926878555 Dated: 22-03-2022</p>	<p>Legal Manufacturer: German Medical Technology (Beijing) Co., Ltd,</p> <p>Add: 68A, No.16 Huan Ke Zhong Lu, Jinqiao Science & Technology Industrial Base Zhongguancun Science Park Tongzhou Park Tongzhou District, Beijing 101102, P. R. China</p> <p>Tel: +86(10)5694 0198 Fax: +86(10)5694 0199 Website: http://www.germanmedtech.com/</p> <p>Free Sale Certificate Expiry: 11-07-2025</p> <p>LOA Expiry: 10-Jan-2029</p> <p>CE Certificate Expiry: 26-05-2024</p> <p>Notified Body extension Confirmation Letter Reference No. MDR CERBO0310124 Rev. 1</p> <p>ISO Certificate Expiry: 29-01-2028</p>	<p>Monarch Thru Cut Disposable Semi-Automatic Biopsy Instrument</p> <p>Class: B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Code: B-T041410 B-T041416 B-T041420 B-T041610 B-T041616 B-T041620 B-T041810 B-T041816 B-T041820 B-T042010 B-T042016 B-T042020 B-T061410 B-T061416 B-T061420 B-T061610 B-T061616 B-T061620 B-T061810 B-T061816 B-T061820 B-T062010 B-T062016</p>	<p>Approved.</p>

			B-T062020	
79.	FM Health Care Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi License No: ELI-00082 DRAP Application Submission Date: 04-04-2022 DRAP Fees: Rs: 25,000/- Challan No. 98546865264 Dated: 22-03-2022	<u>Legal Manufacturer:</u> German Medical Technology (Beijing) Co., Ltd, Add: 68A, No.16 Huan Ke Zhong Lu, Jinqiao Science & Technology Industrial Base Zhongguancun Science Park Tongzhou Park Tongzhou District, Beijing 101102, P. R. China Tel: +86(10)5694 0198 Fax: +86(10)5694 0199 Website: http://www.germanmedtech.com/ Free Sale Certificate Expiry: 11-07-2025 LOA Expiry: 10-Jan-2029 CE Certificate Expiry: 26-05-2024 Notified Body extension Confirmation Letter Reference No. MDR CERBO0310124 Rev. 1 ISO Certificate Expiry: 29-01-2028	Monarch Sure Anchor Mammography & Localization Needle Class: B Shelf Life: 5 Years Sizes Code: Sure Anchor1 20Gx5cmD 20Gx7cmD 20Gx10cmD 20Gx12cmD 20Gx15cmD Sure Anchor2 20Gx5cmS 20Gx7cmS 20Gx10cmS 20Gx12cmS 20Gx15cmS Sure Anchor1E 20Gx5cmD 20Gx7cmD 20Gx10cmD 20Gx12cmD 20Gx15cmD Sure Anchor2S 20Gx5cmS 20Gx7cmS 20Gx10cmS 20Gx12cmS 20Gx15cmS	Deferred for the provision of following: Clarification of grouping of Anchor Mammography & Localization Needle.
80.	FM Health Care Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi License No: ELI-00082 DRAP Application Submission Date: 04-04-2022 DRAP Fees: Rs: 25,000/- Challan No.	<u>Legal Manufacturer:</u> German Medical Technology (Beijing) Co., Ltd, Add: 68A, No.16 Huan Ke Zhong Lu, Jinqiao Science & Technology Industrial Base Zhongguancun Science Park Tongzhou Park Tongzhou District, Beijing 101102, P. R. China Tel: +86(10)5694 0198 Fax: +86(10)5694 0199 Website: http://www.germanmedtech.com/	Monarch Chiba Needle Class: B Shelf Life: 5 Years Sizes Code: BN-MAR-1/GA1 18G B-A301811 110mm B-A3010815 150mm B-A301820 200mm 20G B-A302011 110mm	Approved.

	412236553 Dated: 22-03-2022	Free Sale Certificate Expiry: 11-07-2025 LOA Expiry: 10-Jan-2029 CE Certificate Expiry: 26-05-2024 Notified Body extension Confirmation Letter Reference No. MDR CERBO0310124 Rev. 1 ISO Certificate Expiry: 29-01-2028	B-A302015 150mm B-A302020 200mm 22G B-A302211 110mm B-A302215 150mm B-A302220 200mm	
81.	FM Health Care Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi License No: ELI-00082 DRAP Application Submission Date: 04-04-2022 DRAP Fees: Rs: 25,000/- Challan No. 66285168 Dated: 22-03-2022	Legal Manufacturer: German Medical Technology (Beijing) Co., Ltd, Add: 68A, No.16 Huan Ke Zhong Lu, Jinqiao Science & Technology Industrial Base Zhongguancun Science Park Tongzhou Park Tongzhou District, Beijing 101102, P. R. China Tel: +86(10)5694 0198 Fax: +86(10)5694 0199 Website: http://www.germanmedtech.com/ Free Sale Certificate Expiry: 11-07-2025 LOA Expiry: 10-Jan-2029 CE Certificate Expiry: 26-05-2024 Notified Body Confirmation Letter Reference No. MDR CERBO0310124 Rev. 1 ISO Certificate Expiry: 29-01-2028	Monarch Accu Cut Coaxial Biopsy Needle Class: B Shelf Life: 5 Years Sizes Code: 13G B-T211305 50mm B-T121311 110mm B-T121315 150mm 15G B-T121505 50mm B-T121511 110mm B-T121515 150mm 17G B-T121705 50mm B-T121511 110mm B-T121515 150mm 19G B-T121905 50mm B-T121911 110mm B-T121915 150mm	Approved
82.	FM Health Care Address: 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi License No: ELI-00082 DRAP Application Submission Date: 04-04-2022	Legal Manufacturer: German Medical Technology (Beijing) Co., Ltd, Add: 68A, No.16 Huan Ke Zhong Lu, Jinqiao Science & Technology Industrial Base Zhongguancun Science Park Tongzhou Park Tongzhou District, Beijing 101102, P. R. China Tel: +86(10)5694 0198 Fax: +86(10)5694 0199 Website:	Monarch Disposable Bone Marrow Biopsy Needle Class: B Shelf Life: 5 Years Sizes Code: 9G B-B500910 100mm B-B500915 150mm 11G	Deffered for clarification of calss.

	DRAP Fees: Rs: 25,000/- Challan No. 33389503266 Dated: 22-03-2022	http://www.germanmedtech.com/ Free Sale Certificate Expiry: 11-07-2025 LOA Expiry: 10-Jan-2029 CE Certificate Expiry: 26-05-2024 Notified Body extension Confirmation Letter Reference No. MDR CERBO0310124 Rev. 1 ISO Certificate Expiry: 29-01-2028	B-B501110 100mm B-B501115 150mm 13G B-B501310 100mm B-B501315 150mm 14G B-B561428 28mm B-B561443 43mm B-B561458 58mm 15G B-B561528 28mm B-B561543 43mm B-B561558 58mm	
83.	Pakistan Hearing Aid Center, 4-5 Fatima Center, 14-A, Queens Road, Lahore. ELI-01271 5685-P	<u>Legal</u> Sivantos Pte Ltd 18 Tai Seng Street #08-08 Singapore 539775 <u>Manufacturer:</u> FSC: Detmold, Berlin Date of Issuance: 05-06-2023.	Audio Service Hearing Aids Class-B Shelf Life: N/A	Deferred for the provision of following: Original, valid and notarized LOA. The name of legal manufacturer on the, submitted copy of FSC, is different, clarify. Valid and notarized ISO 13485 and CE certificates. Brand name of the device. Models are not specified since the application includes all the types including In-the-ear air conduction hearing aid (ITE) Receiver-in-canal air-conduction hearing aid (RIC) Behind-the-ear air conduction. Specify the models and revised the application.
84.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038)	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification DH33	Deferred for the provision of following: Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy

	<p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 2913627227</p> <p>Dated: 08-04-2025</p>	<p>P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>		<p>attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
85.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 72626957</p> <p>Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DH36</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
86.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 1727532724</p> <p>Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DH21</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
87.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in</p>

	<p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 192399984077</p> <p>Dated: 08-04-2025</p>	<p>Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Models/ Specification DH26</p>	<p>the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
88.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 163372990814</p> <p>Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DH20</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
89.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 9292230090</p> <p>Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DH22</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
90.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza,</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street,</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy</p>

	<p>Blue area, Islamabad (ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 9821577607</p> <p>Dated: 08-04-2025</p>	<p>Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Models/ Specification DH36X</p>	<p>attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
91.	<p>Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 35816499523</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification UN73</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
92.	<p>Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 4854440718</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DF50</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
93.	<p>Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized</p>

	<p>Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 6861036810</p> <p>Dated: 08-04-2025</p>	<p>Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Shelf life: 8 Years</p> <p>Models/ Specification DF55</p>	<p>LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
94.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 6294326284</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification DH76</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
95.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 5976505618</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification D7 CRP</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
96.	<p>Applicant Name:</p> <p>Moody global services Address of Importer :</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original,</p>

	<p>Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 457747363674</p> <p>Dated: 08-04-2025</p>	<p>Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Shelf life: 8 Years</p> <p>Models/ Specification DF50-CRP</p>	<p>valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
97.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 915623711295</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification: DH615</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
98.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 5938033637</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification: DH-800 [T7] CS</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
99.	<p>Applicant Name:</p> <p>Moody global services</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address:</p>	<p>DYMIND Auto Hematology Analyzer</p>	<p>Deferred for the provision of following:</p>

	<p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 72877365432</p> <p>Dated: 08-04-2025</p>	<p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification: DH-800 [H7]</p>	<p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
100.	<p>Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 75022499169</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Auto Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification: DP-H10</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Clarification of Class of medical device since Analyzer falls in Class-A</p>
101.	<p>Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 85828755625</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Control</p> <p>Class-B</p> <p>Shelf life: 90 days</p> <p>Models/ Specification: DM-BF</p> <ul style="list-style-type: none"> • 3 mL×1 (H); 3 mL×2(H); • 3mL×3(H); • 3 mL×1 (N); • 3mL×2 (N); • 3 mL×3 (N); • 3 mL×1 (L); 3 mL×2 (L); • 3mL×3(L); • 3 mL (H) x1+3 mL (N) x1 +3 mL (L)×1 	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>

102.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 122740131648</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Control</p> <p>Class-B</p> <p>Shelf life: 90 days</p> <p>Models/ Specification: DM-6D</p> <ul style="list-style-type: none"> • 3 mL×1(H), 3 mL×2(H), • 3 mL×3(H), • 3 mL×1 (N), 3 mL×2 (N), • 3 mL×3(N), • 3 mL×1 (L), 3 mL×2 (L), • 3 mL×3(L), • 3 mL (H) x1+3 mL (N) x1 +3 mL (L)×1. 	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
103.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 94783283</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Control</p> <p>Class-B</p> <p>Shelf life: 90 days</p> <p>Models/ Specification: DM-RET</p> <p>Specification (as per FSC): 3 mL×1(H), 3 mL×2(H), 3 mL×3(H), 3 mL×1 (N), 3 mL×2 (N), 3 mL×3(N), 3 mL×1 (L), 3 mL×2 (L), 3 mL×3(L), 3 mL (H) x1+3 mL (N) x1 +3 mL (L)×1</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
104.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p>	<p>DYMIND Hematology Control</p> <p>Class-B</p> <p>Shelf life: 120 days</p> <p>Models/ Specification: DM-3D</p> <p>Specification (as per FSC):</p> <ul style="list-style-type: none"> • H:3mL×1,3mL×2,3mL×3 ; 	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>

	<p>Fee Challan No: 96350515</p> <p>Dated: 08-04-2025</p>	<p>ISO Validity: 30-05-2026</p>	<ul style="list-style-type: none"> • N:3mL×1,3mL×2,3mL×3 ; • L:3mL×1,3mL×2,3mL×3; • Control set:3mL,Hx1+N×1+L×1 	
105.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 77238331719</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Control</p> <p>Class-B</p> <p>Shelf life: 90 days</p> <p>Models/ Specification: DM-5D</p> <p>Specification (as per FSC):</p> <ul style="list-style-type: none"> • H:3mL×1,3mL×2,3mL×3; • N:3mL×1,3mL×2,3mL×3; • L:3mL×1,3mL×2,3mL×3; • Control set:3mL,Hx1+N×1+L×1 	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
106.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Fee Challan No: 7272857242</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 18-01-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Calibrator</p> <p>Class-B</p> <p>Shelf life: 60 days</p> <p>Model: DM-CAL-5E</p> <p>Specification: 3mL×1,3mL×2, 3mL×3</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
107.	<p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p>	<p>DYMIND Hematology Calibrator</p> <p>Class-B</p> <p>Shelf life: 60 days</p> <p>Model: DM-CAL-PF</p> <p>Specification:</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or</p>

	Fee Details: Paid Fee: 31,000/- Fee Challan No: 0351594624 Dated: 08-04-2025	FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	3mL×1, 3mL×2, 3mL×3	notarized CE marked document and valid and notarized ISO 13485 certificate.
108.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 3569997980 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DYMIND Hematology Calibrator Class-B Shelf life: 60 days Model: DM-CAL PLUS Specification: 3mL×1, 3mL×2, 3mL×3	Deferred for the provision of following: Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.
109.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 894698200747 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DYMIND Hematology Calibrator Class-B Shelf life: 60 days Model: DM-CAL Specification: 3mL×1, 3mL×2, 3mL×3	Deferred for the provision of following: Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and notarized ISO 13485 certificate.
110.	Applicant Name: AL-Hayat, Flat No. 18-A, 4 th Floor, Shan Arcade Bld No. 24, Civic Center Barket Market, New Garden Town, Lahore ELI-01298 Date of R&I 27-01-2025	Legal Manufacturer: Matek Medikal Aygitlar Tek. San. Ve Tic. A.S., Ivedik OSB Mah., 2273 Street NO. 10 06378, Yenimahalle, Ankara, Turkey LOA Issue date: 10-10-2018 FSC: Turkey Validity: 28-07-2027 ISO Validity:	Matek Biopsy Needle Class-B Shelf life: 5 years Models/specifications as per FSC	Deferred for the provision of following: Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or notarized CE marked document and valid and

	Fee Details: Paid Fee: 31,000/- Fee Challan No:16874139 Dated:	17-04-2025		notarized ISO 13485 certificate. Stability studies data for the claimed shelf life.
111.	Applicant Name: Medequips SMC Pvt. Ltd., 30-Shahrah e Quaid e Azam Lahore ELI-00362 Date of R&I 27-02-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 7845896420	Legal Manufacturer: Medisono LLC. 3016 NW 82 nd Avenue, Doral, FL 33122 USA LOA Validity: 31-12-2025 FSC: USA Validity: 23-10-2026 ISO Validity: 14-09-2025 510K Certificate issue date: 23-02-2017	P3 Digital Ultrasonic System Class-B Service life: 7 years Models/specifications: Convex Array Probe Model: PB-C361-2 Linear Arrayd Probe Model: PB-L761-2 Linear Arrayd Probe Model: PB-L743-2 Micro-Convex Array Probe Model: PB-C611-2 Transvaginal Probe Model: PB-E-611-2 Endorectal Probe Model: PB-E741-2	Approved. The firm shall submit fee as per revised SRO for System.
112.	Applicant Name: Muslim Medical Services, 1 st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore ELI-00373 Date of R&I 13-02-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	Legal Manufacturer: Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany LOA Validity: 31-12-2025 FSC: Germany Issue date: 23-01-2025 ISO Validity: 29-11-2026 EC Certificate Validity: 26-05-2024	Beurer Blood Pressure Monitor Class-B Shelf life: Models/specifications: BM 23 BM 27	Deferred for the provision of following: Valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized FQA/ CE marked document and valid and notarized ISO 13485 certificate. Separate Fee and application form for BM-27 model.
113.	Applicant Name: Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad ELI-00442 Date of R&I	Legal Manufacturer: Zhejiang Oreint Gene Biotech, Co.Ltd., Street No. 3787 East Yungguang Avenue, Dipu Street, ANji 313300, Huzhou, Zhejiang LOA Validity: 04-01-2026 FSC: Spain Issue date: 05-12-2023	1) INST-ANSWER HIV 1/2 Ab Rapid Test, 2) INST-ANSWER HCV Rapid Test, 3) INST-ANSWER HBsAg Rapid Test, 4) INST-ANSWER Syphilis Ab Rapid Test,	Deferred for the provision of following: Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, Embassy attested/apostile FSC of reference country or

	<p>27-02-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 994691948 Dated:</p>	<p>ISO Validity: 16-03-2027</p>	<p>5) INST-ANSWER Typhoid IgG/IgM Rapid Test,</p> <p>6) INST-ANSWER H.Pylori Ag Rapid Test,</p> <p>7) INST-ANSWER H.Pylori Ab Rapid Test,</p> <p>8) INST-ANSWER Malaria Pf/Pan Ag Rapid Test,</p> <p>9) INST-ANSWER Toxoplasma Gondi IgG/IgM Rapid Test,</p> <p>10) INST-ANSWER TB IgG/IgM Rapid Test</p> <p>11) INST-ANSWER Dengue NS1 Ag Rapid Test,</p> <p>12) INST-ANSWER Dengue Ab Rapid Test,</p> <p>13) INST-ANSWER Malaria Pf/Pv Ab Rapid Test,</p> <p>14) INST-ANSWER One Step Pregnancy TestMonitor</p> <p>Generic Name:</p> <p>1) HIV 1/2 Ab Rapid Test,</p> <p>2) HCV Rapid Test,</p> <p>3) HBsAg Rapid Test,</p> <p>4) Syphilis Ab Rapid Test,</p> <p>5) Typhoid IgG/IgM Rapid Test,</p> <p>6) H.Pylori Ag Rapid Test,</p> <p>7) H.Pylori Ab Rapid Test,</p> <p>8) Malaria Pf/Pan Ag Rapid Test,</p> <p>9) Toxoplasma Gondi IgG/IgM Rapid Test,</p> <p>10) TB IgG/IgM Rapid Test,</p> <p>11) Dengue NS1 Ag Rapid Test,</p>	<p>notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Multiple products applied in single application. Separate the applications according to their Class of medical device.</p>
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			12) Dengue Ab Rapid Test, 13) Malaria Pf/Pv Ab Rapid Test, 14) One Step Pregnancy Test Applied as : Kits Class-B Shelf life: 24 months Models/specifications:	
114.	<p>Lab Diagnostic Systems (SMC) Pvt. Ltd., 111, Hali Road Westridge 1, Rawalpindi</p> <p>Warehouse: Plot No. 36-A PSIC, SIE, Taxila Rawalpindi</p> <p>ELI-00496</p> <p>Date of R&I 27-02-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 4015694103 Dated:</p>	<p><u>Legal Manufacturer:</u> Vircell, S.L. Vircell, S.L Parque Tecnologico de la Salud Avicena 8, 18016 Granada, Spain</p> <p>LOA Validity:</p> <p>FSC: China Validity:</p> <p>ISO Validity:</p> <p>EC Certificate Validity:</p>	<p>Helicobacter Pylori Ag Virclia Monotest Sandwich Chemiluminescent Immunoassay (CLIA)</p> <p>Class-B</p> <p>Shelf life: 15 months</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized CE marked document and valid and notarized ISO 13485 certificate.</p>
115.	<p><u>Applicant Name:</u> Allied Business System, Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi</p> <p>ELI-01118</p> <p>Date of R&I 12-02-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 93232976 Dated:</p>	<p><u>Legal Manufacturer:</u> Chronolab Systems S.L Spain, Travessia Prat De La Riba 34-B 08849 Sant Climent De Llobregat Bracelona, Spain</p> <p>LOA Issue date:07-04-2023</p> <p>FSC: Spain Issue: 21-03-2023</p> <p>ISO Validity: 11-02-2025</p>	<p>Clinical Chemistry (Electrolytes Reagents)</p> <p>Class-B</p> <p>Shelf life: 18-24 months</p> <p>Models/specifications: Size:</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Specify the names of Electrolyte Reagents along their codes and shelf life.</p> <p>Fee as per revised SRO for Cluster.</p> <p>Brand name of the device.</p>

116.	<p>Applicant Name: Allied Business System, Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi</p> <p>ELI-01118</p> <p>Date of R&I 21-01-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 81710213700 Dated:</p>	<p>Legal Manufacturer: Chronolab Systems S.L Spain, Travessia Prat De La Riba 34-B 08849 Sant Climent De Llobregat Bracelona, Spain</p> <p>LOA Issue date:07-04-2023</p> <p>FSC: Spain Issue: 21-03-2023</p> <p>ISO Validity: 11-02-2025</p>	<p>Clinical Chemistry (Enzymes)</p> <p>Class-B</p> <p>Shelf life: 18-24 months</p> <p>Models/specifications: Size:</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Specify the names of Enzymes along their codes and shelf life.</p> <p>Fee as per revised SRO for Cluster.</p> <p>Brand name of the device.</p>
117.	<p>Applicant Name: Allied Business System, Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi</p> <p>ELI-01118</p> <p>Date of R&I 21-01-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 81967908 Dated:</p>	<p>Legal Manufacturer: Chronolab Systems S.L Spain, Travessia Prat De La Riba 34-B 08849 Sant Climent De Llobregat Bracelona, Spain</p> <p>LOA Issue date:07-04-2023</p> <p>FSC: Spain Issue: 21-03-2023</p> <p>ISO Validity: 11-02-2025</p> <p>EC Certificate Validity:</p>	<p>Clinical Chemistry (Substrates)</p> <p>Class-B</p> <p>Shelf life: 18-24 months</p> <p>Models/specifications: Size:</p>	<p>Deferred for the provision of following:</p> <p>Credentials, original, valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized CE marked document and valid and notarized ISO 13485 certificate.</p> <p>Specify the names of Substrates along their codes and shelf life.</p> <p>Fee as per revised SRO for Cluster.</p> <p>Brand name of the device.</p>
118.	<p>Applicant Name: Muslim Medical Services, 1st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore</p> <p>ELI-00373</p> <p>Date of R&I 13-02-2025</p> <p>Fee Details:</p>	<p>Legal Manufacturer: Beurer GmbH, Soeflinger Strasse 218, 89077 Ulm Germany</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 23-01-2025</p> <p>ISO Validity: 29-11-2026</p>	<p>Beurer Nebulizer</p> <p>Class-B</p> <p>Shelf life: 7 years</p> <p>Models/specifications: IH 16 IH 51</p>	<p>Deferred for the provision of following:</p> <p>Valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized FQA/ CE marked document and valid and notarized ISO 13485 certificate.</p>

	Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	EC Certificate Validity: 26-05-2024		Clarification is required since the product mentioned on covering letter is blood pressure monitor but Form and rest of the documents are of Nebulizer. Separate Fee and application form for IH 51model
119.	Applicant Name: Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21 st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton Karachi ELI-00273 Date of R&I 10-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No:36801963 Dated:	Legal Manufacturer: Medtronic, Inc 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing site: 1. Medtronic Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic 2. Medtronic Neurosurgery 4620 North Beach Street FORT Worth, TX USA 76137 LOA Issue date: 15-01-2025 FSC: USA Validity: 10-06-2026 ISO Validity: 19-08-2024 EC Certificate Validity: 01-05-2025	Catheter Passer Disposable, 60cm Class-B Shelf life: 5 years Models/specifications 48409	Deferred for the provision of following: Valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, notarized FQA/ CE marked document and valid and notarized ISO 13485 certificate.
120.	Applicant Name: Hoor Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi ELI-00037 Date of R&I 14-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No:637417358908 Dated:	Legal Manufacturer: Cordis US Corp. 14201 North West 60th Avenue, Miami Lakes, FL USA 33014 LOA Issue date: 13-01-2025 FSC: USA Validity: 25-11-2026 ISO Validity: 07-02-2028 EC Certificate Validity: 26-05-2024	Brite Tip Radianz Guiding Sheath Vascular Catheter Introduction Set Class-B Shelf life: 2years Models/specifications: 687280110: 6Fr, Straight, 110cm 687280135: 6Fr, Straight, 135cm	Deferred for calss and clarification of type of product

121.	Applicant Name: ElectroMed Corporation, 53 Mall Avenue, 54 The Mall, Near Panorama Shopping Center, Lahore. ELI-00163 Date of R&I 14-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No:690725372246 Dated:	Legal Manufacturer: SysMed (China) Co., Ltd Address: No. 299, Baita Third Street, Hunnan District 110169 Shenyang, Liaoning, People's Republic of China LOA Issue date: 10-09-2029 FSC: China Validity: 07-05-2025 ISO Validity: 29-12-2027 EC Certificate Validity: 26-05-2024	OC Series Oxygen Concentrator Class-B Shelf life: 5 years Models/specifications: OC-E100 OC-E80 OC-E50	Deffered for valid free sae certificate ofchaina nad valid CE certificate. The firm shall submit separate fee and application form for OC-E80, OC-E50.
122.	Applicant Name: ElectroMed Corporation, 53 Mall Avenue, 54 The Mall, Near Panorama Shopping Center, Lahore. ELI-00163 Date of R&I 14-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No:690725372246 Dated:	Legal Manufacturer: Kunshan Dynmed medical Technology Co., Ltd, Address: No. 66, Shunxing road, Lujia Town, 215331 Kunshan Suzhou City, Jiangsu Province, People's Republic of China. LOA Issue date: 16-11-2028 FSC: China Validity: 11-10-2026 ISO Validity: 05-09-2025 EC Certificate Issue date: 08-05-2024	DO2-5E Oxygen Concentrator Class-B Shelf life: 5 years Models/specifications: DO2-5E DO2-5ED DO8-5EW	Approved. The firm shall submit valid CE certificate for applied models, fee and application form for DO2-5ED, DO8-5EW before the issuance of registration letter.
123.	Hospital Appliances, G274-Chishti Plaza, Gordon College Road, Rawalpindi, Pakistan. ELI-00271 7059-P Fee 31,000/- 07-04-2025	Legal Manufacturer: Guangdong TiDaKang Medical Technology Co, Ltd Address: 1, 4, 5 Floor of the Second Row, No 30 of Jin hong road ping nan Ind Town, Zhong Shan City China. FSC: China. Date of Validity: 22-07-2026.	TDK Sterile Wound Dressing, Non-woven Shelf Life: 3 Year Sizes as per FSC	Deferred for the provision of following: Valid and notarized LOA, Embassy attested/apostile FSC in the country of origin, embassy attested/apostile FSC of ref country, notarized and valid FQA/ CE marked document and valid &

		LOA validity 24-12-2029 ISO 13485 validity 25-05-2027		notarized ISO 13485 certificate.
124.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. ELI-00708 7150-P 31,000/-	<u>Legal Manufacturer:</u> Changsha Sinocare Inc. 265 Guyuan Roas, Hi-Tech Zone, Changsha, Hunan Province, 410205, People's Republic of China. Original FSC: China Date of Validity: 14-03-2026. LOA validity 07-02-2027 ISO 13485 validity 31-01-2028	Sinocare Blood Glucose Meter Class-B Service Life: 10 Years Model as per FSC	Deffered for Notarized valid CE certificate
125.	Treu-Dynamic International(Pvt) Ltd Office no.C-206,2 nd Floor, City Towers, Main Boulevard, Gulberg, Lahore. (Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)	<u>Legal Manufacture</u> Conmed Corporation 525 French Road, Utica, New York 13502,USA T+1404.855.4592 • F+1404.344.0283 • www.matrixsurgicalusa.com <u>LOA:</u> Validity 03-Year (Sept-2023 to Dec-2025). <u>FSC:</u> Country of Origin USA Validity: 31-12-2025 <u>ISO 13485:</u> March 2024 –March 2027.	Brand Name Knee Arthroscopy System Class C Shelf life: 05 Years Code Description 10K Arthroscopic for knee 10K150 Arthroscopic for knee AES-1 Arthroscopic for knee KFL100 Arthroscopic for knee 8750 Arthroscopic for knee AES-FC Arthroscopic for knee AES-90SN, PS8834 Arthroscopic for knee MR007C Arthroscopic for knee MR004C, Arthroscopic for knee KTB014,KFB035 Arthroscopic for knee H5100, DMS70 Arthroscopic for knee E9414, E9415A Arthroscopic for knee C8011, C8012, C8013, ACL Screw for Knee C8015, C8017, C8018, C8019 ACL Screw for Knee C8022, C8023, C8024, C8025 ACL Screw for Knee IA-2000-S, C7359 , C7368 ACL Screw for Knee	Deferred for the provision of following: Brand name of the product. Clarification of grouping the applied codes, as mentioned, in System
126.	Treu-Dynamic International(Pvt) Ltd Office no.C-206,2 nd Floor, City Towers, Main	<u>Legal Manufacture</u> Conmed Corporation 525 French Road, Utica, New York	Brand Name Shoulder Arthroscopy System Class C	Deferred for the provision of following:

	<p>Boulevard, Gulberg, Lahore.</p> <p>(Licence No.ELI-00175)</p> <p>File submitted on : 19.02.2025</p> <p>Fee challan No. 121540329(13.02.25)</p>	<p>13502, USA T+1404.855.4592 • F+1404.344.0283 • www.matrixsurgicalusa.com</p> <p>LOA: Validity 03-Year (Sept-2023 to Dec-2025).</p> <p>FSC: Country of Origin USA Validity: 31-12-2025</p> <p>ISO 13485: Validity 03-Years March 2024 –March 2027.</p>	<p>Shelf life: 05 Years</p> <p>Code Description</p> <p>H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT Anchor Suture 9971 anchor suture C7465 For anchor suture C7385 For anchor suture CKP-3500 Anchor suture CKP-4502 Anchor suture CF6140HB Anchor suture CF6140H Anchor suture C6140H Anchor suture Y1802A Anchor suture GKP-2801 Anchor suture GKP-3301 Anchor suture BKL-00M For Anchor Suture BGU-00M For Anchor Suture T50S Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture H5120 Anchor Suture C7480 For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture L3000L Advantage for Anchor Suture</p>	<p>Brand name of the product.</p> <p>Clarification of grouping the applied codes, as mentioned, in System</p>
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			5059532 Anchor Suture PRO6125 Anchor Suture MC5057 Universal Suture PRO2043 For Anchor Suture PRO203 For Anchor Suture PRO2041 For Anchor Suture PRO6228 For Anchor Suture PRO6240 For Anchor Suture PRO3011 For Anchor Suture PRO8500SB For Anchor Suture PRO6100 For Anchor Suture PRO3115 For Anchor Suture PRO3110 For Anchor Suture PRO3600 For Anchor Suture E8030LSO For Anchor Suture E8050LSO Anchor Suture E8130LSO Anchor Suture E8150LSO Anchor Suture E9011-2 Anchor Suture C8803 Anchor Suture D4240 For Anchor Suture D4000 For Anchor Suture 9299A, 9263A, 9247A For Anchor Suture 9599A, C9254, C9264 For Anchor Suture	
127.	Pak Punjab Cardex Medical System Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore ELI-00174 Product Fee Challan: 599262594,	<u>Legal Manufacturer:</u> Life Vascular Devices Camí de Can Ubach, 11 (Pol. ind. Les Fallulles) 08620 Sant Vinceç, dela Horts Barcelona, Spain Private Limited Tel: 91 822 54 99 Fax: 91 822 52 89 Website: https://ivascular.global/	<u>iVascular Angiolite</u> Sirolimus Eluting Coronary Stent System Class D Shelf Life: 3 Years Codes / Sizes SCCDSR14150200009, SCCDSR14150200014	Approved. Firm shall submit Differential fee of additional codes above 20 for system. Case will be referred to NICB.

	<p>PKR: 100,000/-</p>	<p>FSC: Spain Validity: 15-07-2029 LOA Validity: 15-07-2026 CE NOTIFIED BODY CONFIRMATION LETTER Attached REFERENCE: LVD013 DEX03 20240528v2 dated 28-05-24</p> <p>ISO 13485 Valid 08-03-2028</p>	<p>SCCDSR14150200016, SCCDSR14150200019, SCCDSR14150200024, SCCDSR14150200029, SCCDSR14150200034, SCCDSR14150200039, SCCDSR14150225009, SCCDSR14150225014, SCCDSR14150225016, SCCDSR14150225019, SCCDSR14150225024, SCCDSR14150225029, SCCDSR14150225034, SCCDSR14150225039, SCCDSR14150250009, SCCDSR14150250014, SCCDSR14150250016, SCCDSR14150250019, SCCDSR14150250024, SCCDSR14150250029, SCCDSR14150250034, SCCDSR14150250039, SCCDSR14150250044, SCCDSR14150250049, SCCDSR14150275009, SCCDSR14150275014, SCCDSR14150275016, SCCDSR14150275019, SCCDSR14150275024, SCCDSR14150275029, SCCDSR14150275034, SCCDSR14150275039, SCCDSR14150275044, SCCDSR14150275049, SCCDSR14150300009, SCCDSR14150300014, SCCDSR14150300016, SCCDSR14150300019, SCCDSR14150300024, SCCDSR14150300029, SCCDSR14150300034, SCCDSR14150300039, SCCDSR14150300044, SCCDSR14150300049, SCCDSR14150350009, SCCDSR14150350014, SCCDSR14150350016, SCCDSR14150350019, SCCDSR14150350024, SCCDSR14150350029, SCCDSR14150350034, SCCDSR14150350039, SCCDSR14150350044, SCCDSR14150350049, SCCDSR14150400009, SCCDSR14150400014, SCCDSR14150400016, SCCDSR14150400019, SCCDSR14150400024,</p>	
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			SCCDSR14150400029, SCCDSR14150400034, SCCDSR14150400039, SCCDSR14150400044, SCCDSR14150400049, SCCDSR14150450014, SCCDSR14150450016, SCCDSR14150450019, SCCDSR14150450024, SCCDSR14150450029, SCCDSR14150450034, SCCDSR14150450039	
128.	Pak Punjab Cardex Medical System Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore ELI-00174 DOI: 17.10.2018 DOE: 17.10.2023 Renewal Applied Product Fee Challan: 25994481964, PKR: 100,000/- Dated: 11-04-25	Legal Manufacturer: Life Vascular Devices Camí de Can Ubach, 11 (Pol. ind. Les Fallulles) 08620 Sant Vinceç, dela Horts Barcelona, Spain Private Limited Tel: 91 822 54 99 Fax: 91 822 52 89 Website: https://ivascular.global/ FSC: Spain Validity: 15-07-2029 LOA Validity: 15-07-2026 CE NOTIFIED BODY CONFIRMATION LETTER Attached REFERENCE: LVD013 DEX03 20240528v2 dated 28-05-24 ISO 13485 Valid 08-03-2028	iVascular Essential Pro Paclitaxel Eluting Coronary Balloon Dilatation Catheter Class D Shelf Life: 3 Years Codes / Sizes BCDPR14N150150010, BCDPR14N150150015, BCDPR14N150150020, BCDPR14N150150030, BCDPR14N150200010, BCDPR14N150200015, BCDPR14N150200020, BCDPR14N150200025, BCDPR14N150200030, BCDPR14N150200040, BCDPR14N150225010, BCDPR14N150225015, BCDPR14N150225020, BCDPR14N150225025, BCDPR14N150225030, BCDPR14N150225040, BCDPR14N150250010, BCDPR14N150250015, BCDPR14N150250020, BCDPR14N150250025, BCDPR14N150250030, BCDPR14N150250040, BCDPR14N150275010, BCDPR14N150275015, BCDPR14N150275020, BCDPR14N150275025, BCDPR14N150275030, BCDPR14N150275040, BCDPR14N150300010, BCDPR14N150300015, BCDPR14N150300020, BCDPR14N150300025, BCDPR14N150300030, BCDPR14N150300040, BCDPR14N150325010, BCDPR14N150325015, BCDPR14N150325020, BCDPR14N150325025,	Approved. Firm shall submit Differential fee of additional codes above 20.

			BCDPR14N150325030, BCDPR14N150325040, BCDPR14N150350010, BCDPR14N150350015, BCDPR14N150350020, BCDPR14N150350025, BCDPR14N150350030, BCDPR14N150350040, BCDPR14N150375010, BCDPR14N150375015, BCDPR14N150375020, BCDPR14N150375025, BCDPR14N150375030, BCDPR14N150375040, BCDPR14N150400010, BCDPR14N150400015, BCDPR14N150400020, BCDPR14N150400025, BCDPR14N150400030, BCDPR14N150400040, BCDPR14N150450010, BCDPR14N150450015, BCDPR14N150450020, BCDPR14N150450025, BCDPR14N150450030, BCDPR14N150450040	
129.	Pak Punjab Cardex Medical System Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore ELI-00174 Product Fee Challan: 42783486, PKR: 100,000/- Dated: 11-04-25	<u>Legal Manufacturer:</u> Life Vascular Devices Camí de Can Ubach, 11 (Pol. ind. Les Fallulles) 08620 Sant Vínçes, del Horts Barcelona, Spain Private Limited Tel: 91 822 54 99 Fax: 91 822 52 89 Website: https://ivascular.global/ FSC: Spain Validity: 15-07-2029 LOA Validity: 15-07-2026 CE NOTIFIED BODY CONFIRMATION LETTER Attached REFERENCE: LVD013 DEX03 20240528v2 dated 28-05-24 ISO 13485 Valid 08-03-2028	iVascular Naviscore Coronary Scoring Dilatation Balloon Catheter Class D Shelf Life: 3 Years Codes / Sizes BCSR14150150006, BCSR14150150008, BCSR14150150010, BCSR14150150012, BCSR14150150015, BCSR14150200006, BCSR14150200008, BCSR14150200010, BCSR14150200012, BCSR14150200015, BCSR14150250006, BCSR14150250008, BCSR14150250010, BCSR14150250012, BCSR14150250015, BCSR14150300006, BCSR14150300008, BCSR14150300010, BCSR14150300012, BCSR14150300015, BCSR14150350006, BCSR14150350008, BCSR14150350010, BCSR14150350012,	Approved. Firm shall submit Differential fee of additional codes above 20.

			BCSR14150350015	
130.	<p>Pak Punjab Cardex Medical System Ground Floor, 210-J/2 Block M.A. Johar Town, Lahore</p> <p>ELI-00174 Product Fee Challan: 100552893, PKR: 62,000/- Dated: 11-04-25</p>	<p>Legal Manufacturer: Life Vascular Devices Camí de Can Ubach, 11 (Pol. ind. Les Fallulles) 08620 Sant Vínçç, dela Horts Barcelona, Spain Private Limited Tel: 91 822 54 99 Fax: 91 822 52 89 Website: https://ivascular.global/</p> <p>FSC: Spain Validity: 15-07-2029 LOA Validity: 15-07-2026 CE NOTIFIED BODY CONFIRMATION LETTER Attached REFERENCE: LVD013 DEX03 20240528v2 dated 28-05-24</p> <p>ISO 13485 Valid 08-03-2028</p>	<p>iVascular Navitian Coronary Microcatheter</p> <p>Class D</p> <p>Shelf Life: 3 Years</p> <p>Codes / Sizes</p> <p>MCCC14135001 MCCC14150001</p>	<p>Approved.</p> <p>The firm shall submit differential fee as per revised SRO before the issuance of registration letter.</p>
131.	<p>S. Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi</p> <p>(ELI-00078)</p> <p>R&I Date: 08-4-2025</p> <p>Fee Rs 62,000/- vide Challan no. 1707745877</p>	<p>Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain.</p> <p>LOA validity: 30-09-2026 (Notarized copy)</p> <p>FSC Issued on 10-01-2025(Original Apostille FSC)</p> <p>EU QMS Certificate Validity:28-09-2026 (Notarized Copy)</p> <p>ISO-13485 Validity: 23-09-2025(Notarized copy)</p>	<p>DG Gel Anti-IgG Gel card for gel technique for Direct and Indirect antiglobulin test.</p> <p>Applied as : Not Mentioned</p> <p>Class: C</p> <p>Shelf life: 13 months</p> <p>Codes/Sizes: 210344</p>	<p>Deferred for provision of notarized copy of LOA mentioning product name.</p>
132.	<p>S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi</p> <p>(ELI-00078)</p> <p>R&I Date: 08-4-2025</p> <p>Fee Rs 62,000/- vide Challan no. 4764746874</p>	<p>Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain.</p> <p>LOA validity: 30-09-2026 (Notarized copy)</p> <p>FSC Issued on 10-01-2025(Original Apostille FSC)</p> <p>EU QMS Certificate Validity:28-09-2026 (Notarized Copy)</p> <p>ISO-13485 Validity: 23-09-2025(Notarized copy)</p>	<p>DG Gel DC Scan</p> <p>Applied as : Not Mentioned</p> <p>Class: C</p> <p>Shelf life: 25 months</p> <p>Codes/Sizes: 210345</p>	<p>Deferred for provision of notarized copy of LOA mentioning product name</p>

133.	<p>MBS Distributor, Flat 101, Shah Alam Arcade, Defence Road Rawalpindi. ELI-01287 R&I Date: 09-4-2025 Fee Rs 62,000/- vide Challan no. 462473176</p>	<p>Nanyang Major Medical Products Co., Ltd Address: No. 16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China. LOA validity: 31-12-2028 (Notarized copy) FSC (China) Valid upto 05-03-2027 (Original Apostille FSC) ISO-13485 Validity: 13-08-2025 (copy)</p>	<p>Neuro Surgical Patties Neuro Surgical Patties Applied as : Not Mentioned Class: C Shelf life: 3 year Codes/Sizes: 12x25mm, 12x50mm, 25x75mm,</p>	<p>Deferred for submission of the followings: i. Notarized copy of valid LOA wherein the applied product shall be mentioned. ii. Valid legalized FSc issued by concerned regulatory authority of the country of origin which clearly shows that the applied is on free sale in the country. iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) iv. Complete Stability study data.</p>
134.	<p>Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton Karachi ELI-00273 Fees: Rs 62000 Challan # 1758904284 Date of R& I 10-04-2025</p>	<p><u>Legal Manufacturer:</u> M/s Medtronic. Inc. 710 Medtronic Parkway, Minneapolis, MN USA 55432 <u>Manufacturing Site:</u> 1st Site: Name as per Form-7A: M/s Medtronic Covidien, Name as per FSC: M/s Covidien, Name as per ISO 13485: Covidien (Davis & Geck Caribe, Ltd.) dba Medtronic Dominicana (Manufactura) S.A., Address of the Site: Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic 2nd Site: Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 <u>LOA:</u> Issue date: 15-01-2025 (copy) <u>FSC (USFDA):</u> Valid Until: 10-06-2026 (Copy) EC Certificate valid until:01-05-2024 (Copy) <u>ISO 13485:</u> Valid till: 19-08-2024 (copy)</p>	<p>CSF-SNAP Shunt Assembly, Ultra Small, Medium Pressure Applied as: Not mentioned. Class C Shelf Life: 5 Years Codes/Sizes: 46564</p>	<p>Deferred for submission of the followings: i. Valid notarized copy of LOA ii. Valid legalized FSc of the country of origin iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) iv. Complete Stability study data. v. valid notarized ISO 13485 certificates for all the applied sites. vi. Clarification with evidence regarding the difference in the name of manufacturer in various documents like Form- 7A, FSC & ISO 13485. vii. Draft label of the applied product.</p>
135.	<p>Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st</p>	<p><u>Legal Manufacturer:</u> M/s Medtronic, Inc. 710 Medtronic</p>	<p>CSF-Ventricular Reservoir, Neonatal Bottom Inlet,</p>	<p>Deferred for submission of the followings:</p>

	<p>Floor Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton Karachi</p> <p>ELI-00273</p> <p>Fees: Rs 62000 Challan # 2945571402</p> <p>Date of R& I 10-04-2025</p>	<p>Parkway, Minneapolis, MN USA 55432</p> <p><u>Manufacturing Site:</u> 1st Site: Name as per Form-7A: M/s Medtronic Covidien, Name as per FSC: M/s Covidien, Name as per ISO 13485: Covidien (Davis & Geck Caribe, Ltd.) dba Medtronic Dominicana (Manufactura) S.A, Address of the Site: Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic</p> <p>2nd Site: Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137</p> <p><u>LOA:</u> Issue date: 15-01-2025 (copy)</p> <p><u>FSC (USFDA):</u> Valid Until: 10-06-2026 (Copy)</p> <p>EC Certificate valid until:01-05-2024 (Copy)</p> <p><u>ISO 13485:</u> Valid till: 19-08-2024 (copy)</p>	<p>10MM Ventricular Reservoir</p> <p>Applied as: Not mentioned.</p> <p>Class C</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes: 22104</p>	<p>i. Valid notarized copy of LOA ii. Valid legalized FSc of the country of origin iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) iv. Complete Stability study data. v. valid notarized ISO 13485 certificates for all the applied sites. vi. Clarification with evidence regarding the difference in the name of manufacturer in various documents like Form-7A, FSC & ISO 13485. vii. Draft label of the applied product.</p>
136.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#0583362272</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA :-validity:09/03/2026 (copy)</p> <p>FSC (Germany) issued on 04-03-2024 wherein the product (TD-4255) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p> <p>EC Certificate (FQA): 26-05-2025 (Copy)</p>	<p>Clever Chek Glucometer TD-4255 Glucometer</p> <p>Applied as: Single</p> <p>Class-C</p> <p>Shelf life: 7 years</p> <p>Models: -TD-4255</p>	<p>Deferred for submission of the followings: i. Valid notarized copy of LOA ii. Valid legalized FSc of the country of origin iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) vi. valid notarized ISO 13485 v. The product is a system in the RRA, so differential fee for system shall be submitted as per New SRO. vi. clarification required as Brand name as per FSC of Germany is AccuSure Fora and as per provided copy of Certificate of registration</p>

				the brand name is Clever Chek Active
137.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#30741466086</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA :-validity:09/03/2026 (copy)</p> <p>FSC (Germany) issued on 04-03-2024 wherein the product (TD-4255) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p> <p>EC Certificate (FQA): 26-05-2025 (Copy)</p>	<p>Clever Chek Glucometer Strips TD-4255</p> <p>Glucometer Strips</p> <p>Applied as: Single</p> <p>Class-C</p> <p>Shelf life: Strips:- 25.6 Months</p> <p>Codes/Sizes: Models: -TD-4255</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid notarized copy of LOA</p> <p>ii. Valid legalized FSc of the country of origin</p> <p>iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA)</p> <p>vi. valid notarized ISO 13485</p> <p>vi. clarification required as Brand name as per FSC of Germany is AccuSure Fora and as per provided copy of Certificate of registration the brand name is Clever Chek Active</p>
138.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#6188377559</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA: -validity:09/03/2026 (copy)</p> <p>FSC (Germany) issued on 20-01-2025 wherein the product (TD-4279) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p> <p>EC Certificate (FQA): 26-05-2025 (Copy)</p>	<p>CC Super Glucometer TD-4279</p> <p>Glucometer</p> <p>Applied as: Single</p> <p>Class-C</p> <p>Shelf life: Strips: - 7 Years</p> <p>Codes/Sizes: Models:-TD-4279</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid notarized copy of LOA</p> <p>ii. Valid legalized FSc of the country of origin</p> <p>iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA)</p> <p>vi. valid notarized ISO 13485</p> <p>v. The product is a system in the RRA, so differential fee shall be submitted as per New SRO.</p> <p>vi. clarification required as Brand name as per FSC of Germany is Uright and as per provided copy of Certificate of registration the brand name is CC Super & the product (TD-4279) is mentioned as Blood Glucose Monitoring System</p>
139.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA :-validity:09/03/2026 (copy)</p>	<p>CC Super Glucometer Strips Models: -TD-4279</p> <p>Glucometer Strips</p> <p>Applied as; Single</p> <p>Class-C</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid notarized copy of LOA</p> <p>ii. Valid legalized FSc of the country of origin</p> <p>iii. Valid legalized FSc of the RRA or notarized</p>

	<p>11-04-2025 Fee: PKR 62,000/- Slip#690230281078</p>	<p>FSC (Germany) issued on 20-01-2025 wherein the product (TD-4279) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p> <p>EC Certificate (FQA): 26-05-2025 (Copy)</p>	<p>Shelf life: Strips: - 25.6 Months</p> <p>Models:-TD-4279</p>	<p>copy of EC certificate (FQA)</p> <p>iv.valid notarized ISO 13485</p> <p>v. clarification required as Brand name as per FSC of Germany is Uright and as per provided copy of Certificate of registration the brand name is CC Super & the product (TD-4279) is mentioned as Blood Glucose Monitoring System</p>
140.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#6957780596</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA :-validity:09/03/2026 (copy)</p> <p>FSC (Germany) issued on 20-01-2025 wherein the product (TD-4267) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p> <p>EC Certificate (FQA): 26-05-2025 (Copy)</p>	<p>CC Fast Glucometer TD-4267 Glucometer</p> <p>Applied as: Single</p> <p>Class-C</p> <p>Shelf life: :- 7 Years</p> <p>Models: -TD-4267</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid notarized copy of LOA</p> <p>ii.Valid legalized FSc of the country of origin</p> <p>iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA)</p> <p>vi.valid notarized ISO 13485</p> <p>v.The product is a system in the RRA, so differential fee shall be submitted as per New SRO.</p> <p>v. clarification required as Brand name as per FSC of Germany is Uright and as per provided copy of Certificate of registration the brand name is CC Fast & the product (TD-4267) is mentioned as Blood Glucose Monitoring System</p>
141.	<p>Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore</p> <p>(ELI-00431)</p> <p>Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#8074211565</p>	<p>M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248.</p> <p>LOA :-validity:09/03/2026 (copy)</p> <p>FSC (Germany) issued on 20-01-2025 wherein the product (TD-4267) is mentioned as Blood Glucose Monitoring System. (Copy)</p> <p>ISO Certificate: 01-03-2026 (Copy)</p>	<p>CC Super Glucometer Strips TD-4267 (as per Form-7A)</p> <p>CC Fast Strips TD-4267 (as per covering letter & fee slip etc.)</p> <p>Glucometer</p> <p>Applied as: Single</p> <p>Class-C</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid notarized copy of LOA</p> <p>ii.Valid legalized FSc of the country of origin</p> <p>iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA)</p> <p>iv.valid notarized ISO 13485</p> <p>v. clarification required as Brand name as per FSC of Germany is</p>

		EC Certificate (FQA): 26-05-2025 (Copy)	Shelf life: :- 25.6 months Models: -TD-4267	Uright and as per provided copy of Certificate of registration the brand name is CC Fast & the product (TD-4267) is mentioned as Blood Glucose Monitoring System
142.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#05298657872	M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2 nd Road Wugu District, New Taipei City, Taiwan 248. LOA :-validity:09/03/2026 (copy) FSC not provided. ISO Certificate validity 01-03-2026 (Copy) EC Certificate (FQA): validity 26-05-2025 (Copy)	CC Glucometer Strips TD-4225 Glucometer Strips Applied as: Single Class-C Shelf life: Strips: - 25.6 Months Models: -TD-4225	Deferred for submission of the followings: i. Valid notarized copy of LOA ii. Valid legalized FSc of the country of origin iii. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) iv. valid notarized ISO 13485
143.	M/S Ghazali Brothers 1st Floor Azzainab Court Campbell Street, Karachi, Pakistan ELI-00240 Fees: Rs 31,030 Paid on 19/05/2025 Challan # 40821981214 Date of R& I 14 th April 2025	Guangdong Baihe Medical Technology Co., Ltd No.89, Taoyuan East Road, Nanhai Foshan Guangdong P.R. China LOA: Agency Agreement (Notarized copy): issued: 20-01-2025. (Validity for two years) FSC: CHINA FSC Valid Until: 30/08/2025 (Apostille copy) EC (FQA) Certificate: valid upto 26-05-2024 along with extension letter (Copy) ISO: ISO 13485:2016) Valid till: 2027-08-06 (Copy)	Hospital & Homecare Disposable Blood Lines Disposable Blood Lines Applied as : Single Class C Shelf Life: 3 Years Codes/Sizes: (as per dossier & same was confirmed from the FSC) Arterial Blood Line: A001, A002, A003, A004, A005, A006, A101, A102, A103, A104 Venous Blood Line: V01, V02, V03, V04, V05,V11,V12	Deferred for submission of the followings: i. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) ii. valid notarized ISO 13485. iii. Justification of Class of the applied product & submission of differential fee accordingly. iv. The current application shall be considered for Arterial Blood Line & the firm is advised to apply separately for Venous Blood Line.
144.	M/S Ghazali Brothers 1st Floor Azzainab Court Campbell Street, Karachi, Pakistan ELI-00240 Fees: Rs 31,030 Paid on 19/05/2025	Guangdong Baihe Medical Technology Co., Ltd No.89, Taoyuan East Road, Nanhai Foshan Guangdong P.R. China LOA: Agency Agreement (Notarized copy): issued: 20-01-2025. (Validity for two years)	Hospital & Homecare Disposable Fistula Needles Disposable Fistula Needles Applied as : Single Class C Shelf Life: Not mentioned	Deferred for submission of the followings: i. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) ii. valid notarized ISO 13485. iii. Justification of Class of the applied product & submission of

	Challan # 1036755964 Date of R& I 15 th April 2025	FSC: CHINA FSC Valid Until: 09/07/2025 (Apostille copy) EC (FQA) Certificate: valid upto 26-05-2024 along with extension letter (Copy) ISO: ISO 13485:2016) Valid till: 2027-08-06 (Copy)	Codes/Sizes: (as per dossier & same was confirmed from the FSC) 14G, 15G, 16G, 17G,	differential fee accordingly. iv. Revised Form-7 with demanded shelf life & complete stability study data.
145.	M/S Ghazali Brothers 1st Floor Azzainab Court Campbell Street, Karachi, Pakistan ELI-00240 Fees: Rs 62,030 Paid on 19/05/2025 Challan # 66660494286 Date of R& I 14 th April 2025	Ningbo Yingmed Medical Instruments Co., Ltd Address as per Form-7A: Yingsheng Building, No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China Address as per FSC (MHRA) & DOC: Room 705, Yingsheng Building, No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China. Address as per CE (FQA): Room 1201-9, No.456, Tai'an Middle RD, Yinzhou District, Ningbo, Zhejiang, China. LOA: Agency Agreement (Notarized copy): issued: 25-03-2025. (Validity for ten years) FSC: MHRA FSC Valid Until: 09/07/2025 (copy) FSC: China FSC issued on 18-12-2023 Valid for two years (Notarized copy) ISO: ISO 13485:2016) Valid till: 23-11-2026 (Copy) CE (FQA) valid up to 23-11-2028. (Notarized copy)	Yingmed Non-Absorbable Polypropylene Surgical Suture (with & without needles) Applied as : Single Class C Shelf Life: 5 years Codes/Sizes: (as per dossier but not mentioned in the FSC) PPL201, PPL202 PPL203, PPL204 PPL205, PPL206 PPL207, PPL208 PPL209, PPL210 PPL211, PPL212 PPL213, PPL214 PPL215, PPL216 PPL217, PPL218 PPL219, PPL220 PPL221, PPL222 PPL223	Deferred for submission of the followings: i. Valid legalized FSc of the RRA or notarized copy of EC certificate (FQA) ii. valid notarized ISO 13485. iii. Revised Form-7 with demanded shelf life & complete stability study data. iv. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC-MHRA & CE. v. legalized FSC of the country of origin mentioning the address of manufacturer
146.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per	Dymind C-Reactive Protein Reagent (Immuno nephelometric Method) Applied as : Kit Class-C Shelf life: 12 months	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china)

	09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 2099550207 Dated: 08-04-2025	Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. LOA Validity: 31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile) FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)	Models/ Specification 13mLR:1×13mL; 25mLR:1×25mL; 45mLR:1×45mL; 75mLR:1×75mL; 90mLR:1x90mL; 26mLR:2x13mL; 50mLR:2x25mL; 90mLR:2x45mL; 150mLR:2x75mL; 400μLR:1×400μL; 20000μLR: 50x400μL.	& ISO 13485. accordingly submit relevant documents.
147.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 29515198 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. LOA Validity: 31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)	Dymind Serum Amyloid A Protein Reagent (Immunonephelometric Method) Applied as : Kit Class-C Shelf life: 12 months Models/ Specification <ul style="list-style-type: none"> • 13 mL R: 1×13 mL; • 25 mL R: 1×25 mL; • 45 mL R: 1×45 mL; • 75 mL R: 1×75 mL; • 90 mL R: 1×90 mL; • 26 mL R: 2x13 mL; • 50 mL R: 2×25 mL; • 90 mL R: 2x45 mL; • 150 mL R: 2×75 mL; • 25tests R: 25×350 μL; • 50tests R: 50×350 μL. 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485. accordingly submit relevant documents.

		FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)		
148.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 8990653771 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. LOA Validity: 31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile) FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)	Dymind Serum Amyloid A Protein Reagent Model- SAA II (Immunonephelometric Method) Applied as : Kit Class-C Shelf life: 12 months Models/ Specification <ul style="list-style-type: none"> • 13mLR:1×13mL; • 25 mL R: 1×25 mL; • 45mLR:1x45mL; • 75mLR:1×75mL; • 90 mL R: 1×90 mL; • 26 mL R:2x13mL; • 50 mL R: 2×25 mL; • 90 mL R: 2x45 mL; • 150 mL R:2×75mL; • 25 test-kit: L: 25×300 µL, R: 25×350MI • 50 test-kit: L: 50×300 µL, R: 50×350µL; 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485. accordingly submit relevant documents.
149.	Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 48626699	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.	Dymind Activated Partial Thromboplastin Time Assay Kit (Coagulation Method) Model- CA-APTT Applied as : Kit Class-C Shelf life: 24 months Models/ Specification <ul style="list-style-type: none"> • R1:2.0 mL ×1,R2:2.0mL×1 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485. accordingly submit relevant documents.

	Dated: 08-04-2025	<p>Manufacturer Address (as per FSCs)</p> <p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<ul style="list-style-type: none"> • R1:4.0 mL×1,R2:4.0 mL×1 • R1:2.0 mL×10,R2:2.0 mL×10 • R1:4.0 mL×10,R2:4.0 mL×10 • R1: 1.0 mL×10,R2 1.0 mL×10 • 1 test/kit • 10 tests/kit • 15 tests/kit • 30 tests/kit 	
150.	<p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 97425628728</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs)</p> <p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Dymind Thrombin Time Assay Reagent (Coagulation Method) Models: CA-TT</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification: 5.0mL×10 3.0mL×1 3.0mL×10 1.5 mL×10 1 test/kit 10 tests/kit 15 tests/kit 30 tests/kit</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485. accordingly submit relevant documents.</p>
151.	<p>Moody global services Address of Importer :</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd.</p>	<p>Dymind Prothrombin Time Assay</p>	<p>Deferred for submission of the followings:</p>

	<p>Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 12219603</p> <p>Dated: 08-04-2025</p>	<p>Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Reagent (Coagulation Method) Models: CA-PT</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification: 4.0mL×10 2.0mL×10 4.0mL×1 2.0mL×1 1 test/kit 10 tests/kit 15 tests/kit 30 tests/kit</p>	<p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485. accordingly submit relevant documents.</p>
152.	<p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 1207607779</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen</p>	<p>Dymind Clotting Tetrachoric Combined Testing Kit (Coagulation Method)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Models/ Specification CA (PT+APTT+TT+FIB):</p> <ul style="list-style-type: none"> • 1 test/kit • 10 tests/kit • 15 tests/kit • 30 tests/kit <p>CA (PT+APTT):</p> <ul style="list-style-type: none"> • 1 test/kit 	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p> <p>ii. Valid legalized FSC of RRA or notarized CE (FQA) wherein he applied product is available in the country as kit.</p> <p>iii. Valid legalized FSC of concerned regulatory authority of the country of origin wherein he applied product is available in the country as kit.</p>

		<p>518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany Issued on 13-01-2025 (Embassy attested/apostile) But the applied product is not mentioned.</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy) But the applied product is not mentioned.</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<ul style="list-style-type: none"> • 10 tests/kit • 15 tests/kit • 30 tests/kit <p>CA (PT+APTT+FIB):</p> <ul style="list-style-type: none"> • 1 test/kit • 10 tests/kit • 15 tests/kit • 30 tests/kit 	<p>iv. the firm shall apply separately for each product .</p>
153.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 5313841340</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Dymind Fibrinogen Assay Kit (Modified Clauss Method) Models: CA-FIB(L)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification: R1:2.0 mL×10, R2:5.0 mL×12 R1:4.0 mL×10, R2:30.0mL×5 R1:1.0 mL x 10, R2:5.0 mL×6 R1:4.0 mL×1, R2:30.0mL×1 R1:1.0 mL×10 R1:2.0mL×10 R1:4.0 mL×10 1 test/kit 10 tests/kit 15 tests/kit 30 tests/kit</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>
154.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech</p>	<p>Dymind D-Dimer Assay Kit (Immunoturbidimetry) Models: CA D-Dimer</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the</p>

	<p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 794925262909</p> <p>Dated: 08-04-2025</p>	<p>Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification: R2: 2.0 mL×4, R1: 4.0 mL×4 R2:4.0 mL×4, R1:4.0 mL×8 R2:2.0 mL×1, R1:4.0 mL×1 R2: 1.0 mL×4, R1:4.0 mL×2 1.0mL×4 2.0mL×4 4.0mL×4 1 test/kit 10 tests/kit 15 tests/kit 30 tests/kit</p>	<p>difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>
155.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 91954041991</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity:</p>	<p>Dymind Serum Amyloid A Protein Control</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 12 months</p> <p>Specification: Control 1: 1×1.0mL; Control 2: 1×1.0mL; Control 1, Control 2: 2x1.0mL.</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>

		31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile) FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)		
156.	Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 10190530070 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. LOA Validity: 31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile) FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)	Dymind C-Reactive Protein Control Applied as : Kit Class-C Shelf life: 12 months Specification: <ul style="list-style-type: none"> Control 1: 1×1.0mL, 1×0.5mL; Control 2: 1×1.0mL, 1×0.5mL; Control 3: 1×1.0mL, 1×0.5mL; Control 1, Control 2, Control 3: 3× 1.0mL, 3 x 0.5mL 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485
157.	Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details:	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building	Dymind Coagulation Control (Model: CTRL Coagulation) Applied as : Kit Class-C Shelf life: 24 months Specification:	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485

	<p>Paid Fee: 62,000/-</p> <p>Fee Challan No: 2329945382</p> <p>Dated: 08-04-2025</p>	<p>B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office , Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs)</p> <p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<ul style="list-style-type: none"> • Specification 1 Coagulation control (level 1): 1x1.0 mL; • Specification 2 Coagulation control (level 2): 1x1.0 mL; • Specification 3 Coagulation control (level 1): 10x1.0 mL; • Specification 4 Coagulation control (level 2): 10x1.0 mL. 	
158.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 7819614744945</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office , Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs)</p> <p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China</p>	<p>Dymind D-Dimer Control (Model: CTRL-DD)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification:</p> <ul style="list-style-type: none"> • 1x0.5 mL (low value) • 1x0.5mL(high value) • 10x0.5mL(low value) • 10x0.5mL(high value) • 10x1.0mL(lowvalue) • 10x1.0mL(highvalue) 	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>

		Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)		
159.	Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 55209760039 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. LOA Validity: 31-12-2029 (notarized copy) FSC: Germany issued on 13-01-2025 (Embassy attested/apostile) FSC: China Validity: 18-01-2026 (Apostille copy) ISO Validity: 30-05-2026 (notarized copy)	Dymind Serum Amyloid A Protein Calibrator Applied as : Kit Class-C Shelf life: 12 months Specification: <ul style="list-style-type: none"> • 1x0.5mL Calibrator 1 • 1x0.5mL Calibrator 2 • 1x0.5mL Calibrator 3 • 1x0.5mL Calibrator 4 • 1x0.5mL Calibrator 5 • 1x0.5mL Calibrator 6 • 1x0.5mL Calibrator 7 • 5x0.5mL; Calibrator 1, Calibrator 2, Calibrator 3, Calibrator 4, Calibrator 5 • 7x0.5mL; Calibrator 1, Calibrator 2, Calibrator 3, Calibrator 4, Calibrator 5, Calibrator 6, Calibrator 7 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485
160.	Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 82010062586 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1 st , 2 nd , 4 th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per	Dymind C Reactive Protein Calibrator Applied as : Kit Class-C Shelf life: 12 months Specification: <ul style="list-style-type: none"> • Calibrator 1: 1x0.5mL; • Calibrator 2: 1x0.5mL; • Calibrator 3: 1x0.5mL; • Calibrator 4: 1x0.5mL; 	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485

		<p>FSCs)</p> <p>10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<ul style="list-style-type: none"> • Calibrator 5: 1×0.5mL; • Calibrator 6: 1×0.5mL; • Calibrator 1, Calibrator 2, Calibrator 3, Calibrator 4, Calibrator 5, Calibrator 6: 6×0.5mL 	
161.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 324054705773</p> <p>Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China. Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China. Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Dymind Fibrinogen Calibrator Model: CAL-FIB</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification:</p> <ul style="list-style-type: none"> • 1×1.0mL/kit • 6×1.0mL/kit 	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>
162.	<p>Moody global services No. 14, 2nd Floor, Mujahid Plaza, Blue</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Registered Address (as per Form-</p>	<p>Dymind D-Dimer Control (Model: CAL-DD)</p>	<p>Deferred for submission of the followings:</p>

	<p>area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 40560534974</p> <p>Dated: 08-04-2025</p>	<p>7A): 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>Manufacturing Site Address (as per Form-7A): 1st, 2nd, 4th Floors, Area-A, Building B, Yeming Mold Industrial Park, Genyu Road, Tian Liao Community, Yutang Sub district Office, Guang Ming District, Shenzhen 518132 P.R. China.</p> <p>Manufacturer Address (as per FSCs) 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China.</p> <p>LOA Validity: 31-12-2029 (notarized copy)</p> <p>FSC: Germany issued on 13-01-2025 (Embassy attested/apostile)</p> <p>FSC: China Validity: 18-01-2026 (Apostille copy)</p> <p>ISO Validity: 30-05-2026 (notarized copy)</p>	<p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Specification: 1×0.5 mL/kit 6×0.5mL/kit 1×1.0mL/kit 6×1.0mL/kit</p>	<p>i. Clarification with evidence regarding the difference in the address of manufacturer in various documents like Form-7A, FSC (Germany), FSC (china) & ISO 13485</p>
163.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 14-04-2025</p> <p>Fee: PKR 62,000/- Slip # 31982490737 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France.</p> <p>Manufacturing Site (as per FSC): Diagnostic Stago S.A.S ZAC des Chataigniers – 23/29 rue Constantin Pecqueur- 95150 Taverny- <u>France.</u></p> <p>Manufacturing Site (as per Form-7A): Diagnostic Stago S.A.S, 22-29 Rue Constantin Pecqueur ZAC “Les Chataigniers – 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025 (copy)</p> <p>ISO 13485 certificate validity: 23-05-2025 (Copy)</p> <p>FSC country of origin (France) validity: Date of Issue: 24-05-2024 (Copy)</p>	<p>CK Prest 2</p> <p>6 x 2-ml Vials of Reagent 1 (C.K. Prest® 2) 6 x 2-ml Vials of Reagent 2 (Activator)</p> <p>Models/ Specification: 00598</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 Months</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, & FSC. ii. Valid notarized LOA iii. Valid notarized ISO 13485 iv. Valid Legaized FSC (France)</p>
164.	<p>M/s Martin Dow</p>	<p>Legal Manufacturer:</p>	<p>Procalcitonin Control</p>	<p>Deferred for submission</p>

	<p>Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 62,000/- Slip # 8226727936 Dated: 08-04-2025</p>	<p>Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD.</p> <p>Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025 (Copy)</p> <p>FSC (China) validity: 20-Dec-2026 (Apostille))</p> <p>FSC (Germany) issued on 19-03-2025 (Embassay Attested)</p> <p>ISO 13485 certificate validity: 14- Nov-2025 (Copy)</p>	<p>Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 Months</p> <p>Models/ Specification:</p> <p>Low: 2x2.0mL, High: 2x2.0 mL</p>	<p>of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany). ii. Valid notarized LOA iii. Valid notarized ISO 13485</p>
165.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 62,000/- Slip # 6533457219 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD.</p> <p>Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025 (Copy)</p> <p>FSC (China) validity: 20-Dec-2026 (Apostille))</p> <p>FSC (Germany) issued on 19-03-2025 (Embassay Attested)</p> <p>ISO 13485 certificate validity: 14- Nov-2025 (Copy)</p>	<p>SCCA Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 18 Months</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany). ii. Valid notarized LOA iii. Valid notarized ISO 13485</p>

166.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 62,000/- Slip # 74958374905 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025 (Copy)</p> <p>FSC (China) validity: 20-Dec-2026 (Apostille))</p> <p>FSC (Germany) issued on 19-03-2025 (Embassy Attested)</p> <p>ISO 13485 certificate validity: 14-Nov-2025 (Copy)</p>	<p>BNP Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 Months</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany).</p> <p>ii. Valid notarized LOA</p> <p>iii. Valid notarized ISO 13485</p>
167.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R& I 14-04-2025</p> <p>Fee: PKR 62,000/- Slip # 1790232865 Dated: 08-04-2025</p>	<p>Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China.</p> <p>LOA validity: 31-Dec-2025 (Copy)</p> <p>FSC (China) validity: 20-Dec-2026 (Apostille))</p> <p>FSC (Germany) issued on 19-03-2025 (Embassy Attested)</p>	<p>CYFRA 21-1 Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml)</p> <p>Applied as : Kit</p> <p>Class-C</p> <p>Shelf life: 24 Months</p>	<p>Deferred for submission of the followings:</p> <p>i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany).</p> <p>ii. Valid notarized LOA</p> <p>iii. Valid notarized ISO 13485</p>

		ISO 13485 certificate validity: 14-Nov-2025 (Copy)		
168.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 25999604631 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassy Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)	HE4 Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml) Class-C Shelf life: 18 Months	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany). ii. Valid notarized LOA iii. Valid notarized ISO 13485
169.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 04694918 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025	NSE Control Immunoassay Controls (Low: 2×1.0ml) (High: 2×1.0ml) Models/ Specification (Low: 2×1.0ml) (High: 2×1.0ml) Class-C Shelf life: 24 Months	Deferred for submission of the followings: i. Clarification with evidence regarding the difference in the address of manufacturer in Form-7A, ISO 13485 & FSC of RRA (Germany). ii. Valid notarized LOA iii. Valid notarized ISO 13485

		(Embassy Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)		
170.	Essity Pakistan Limited, A/69, S.I.T.E. Manghopir Road, Karachi ELI-00011 Fee: 62000 Challan No. 966528885021 R&I date: 14-04-2024	Legal Manufacturer: BSN Medical GmbH, Schutzenstrabe, 1-3 22761 Hamburg, Germany Manufacturer (Site): BSN Medical (Pty) Ltd, 30 Gillits Road, 3610 Pinetown, South Africa LOA Issue date: 01-03-2023 (Copy) FSC (Germany) issue date: 07-03- 2023(copy) ISO Valid till: 16-06-2025 (Copy) for legal manufacturer only. EC Certificate valid till: 14-12-2025 (Copy)	Cuticell Classic Paraffin Gauze Dressing Applied as: Single Class C Shelf Life 3 years Code/Sizes (cmxcm) (cmxm): 5x5, 10x10, 10x40, 10x7, 15x2m, 5x5m, 10x10m, 40x10m	Deferred for submission of the followings: i. Valid legalized FSC of the country of origin (Germany) ii. Valid notarized LOA iii. Valid notarized ISO 13485 wherein the manufacturing site shall be mentioned.
171.	M/s Hospital Appliances, G-274, Chisti Plaza Gordon College Road, Rawalpindi ELI-00271 Date of R&I 07.04.2025 Fee: Rs.`62000/ through slip no. 259445864368	M/s Shenzhen Enmind Technology Co., Ltd., Room 201, Block-A No. 1, Qianhai Road 1, Qianhaishen Port Cooperative District, Shenzhen 518000 Guangdong, China LOA: Not provided FSC: Not provided ISO 13485 - Validity Date: 21-09- 2027 (copy) EC (FQA) Certificate Valid till: 17-05-2021 (copy)	Enmind Syringe Pump ENS7 Applied as: Class C Shelf Life : 10Years Code/sizes: ENS7	Deferred for submission of the followings: i. Valid legalized FSC of the country of origin. ii. Valid notarized LOA iii. Valid notarized ISO 13485 iv. Valid legalized FSC of RRA or valid notarized EC (FQA)
172.	Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road, Gulberg IV, Lahore, 54000 (ELI-00554) Date of R&I 04-04-2025 Fee Details: Paid Fee:	M/s Apelem 9 Avenue du Canal Philippe Lamour – 30660 – Gallargues-Le-Montueux-France Other site: Technix S.P.A (Societa per Azioni) Grassobbio(BG) Via Enrico/ Fermi 45 Cap 24050, Italy Manufacturer as per FSC: Technix S.P.A, Via Enrico Fermi 45 - 24050, Grassobbio (BG) Italy	Rafale (TMS 320) Rafale B32 (TMB 320) Rafale B40 (TMB 400) Mobile radiographic Unit Class-C Shelf life: 10 years Models/ Specification: Model as per FSC:	Deferred for submission of the followings: i. Valid legalized FSC of the country of origin or any RRA wherein all the manufacturing site shall be mentioned. ii. Valid notarized LOA issued by the product license holder. iii. Valid notarized ISO 13485 of the all the manufacturing sites.

		LOA Validity: 31-12-2025 (Copy) FSC: Italy Issue date: 28-03-2024 (copy) ISO Validity: 04-05-2027 (copy) EC Certificate: Validity: 04-05-2023 (copy)	Rafale (10500652) Rafale B32 (10500438) Rafale B40 (10500648) Applied as: Family	iv. Valid notarized EC (FQA) v. Prescribed fee for system (Rafale (TMS 320)) shall be submitted as per New SRO. vi. Only one System i.e. Rafale (TMS 320) shall be considered with the current application while for the rest of the systems Rafale B32 (TMB 320) & Rafale B40 (TMB 400) the firm shall apply separately with prescribed fee as per New SRO.
173.	Medequips SMC Pvt. LTd., 30-Shahrah e Quaid E Azam, Lahore (ELI-00362) Date of R&I 07-04-2025 Fee Details: slip No. 6873018112 Paid Fee: 62000/-	M/s Accuray Incorporated, 1209 Deming Way Madison, Wisconsin 53717 USA LOA Validity: 17-07-2026 (Notarized) FSC: USA Validity: 28-03-2026 (Apostille) ISO Validity: 05-07-2026 (copy)	Tomotherapy Treatment System TomoH TomoHD TomoHDA Hi-Art HD renew Tomotherapy Treatment System Class-C Shelf life: 10 years Models/ Specification: Applied as: Family	Deferred for submission of the followings: . i. Valid notarized ISO 13485 ii. Defferential fee for system per New SRO. vi. Only one System i.e. Tomotherapy Treatment System TomoH shall be considered with the current application while for the rest of the systems Tomotherapy Treatment System TomoHD, TomoHDA, Hi-Art & HD renew Tomotherapy Treatment System the firm shall apply separately with prescribed fee as per New SRO.
174.	Chemical House, 6C SKinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156	Bio-RAD Laboratories, Inc. 4000 Alfred Nobel Drive Hercules CA 94547, USA LOA Valid till: 31-12-2025(Copy) FSC (USFDA) Valid till: 18-08-2026	D-10 Hemoglobin A1C Program D-10 Hemoglobin A1C Program	Deferred for submission of the followings: i.Valid legalized FSC USFDA ii. Valid notarized LOA iii. Valid notarized ISO 13485

	<p>Fee. 62000</p> <p>Challan No 278491762457</p> <p>R&I date: 14-04-2025</p>	<p>(copy)</p> <p>ISO Valid till: 20-12-2027 (Copy)</p>	<p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life: 12months</p> <p>Code: 220-0109 D-10 Hemoglobin A1c Supplemental Program Reagent Pack 220-0110 D-10 Hemoglobin A1c-Program Elution Buffer 1 220-0111 D-10 Hemoglobin A1c Program Elution Buffer 2 220-0112 D-10 Wash/Diluent Solution 12005707 D-10 Hemoglobin A1c Program Analytical Cartridge 12005706 D-10 Hemoglobin A1c Program Calibrator/Diluent Set 220-0148 Whole Blood Primer 12002716 D-10 Hemoglobin A1c Program Floppy Diskette 12002715 D-10 Hemoglobin A1c Program CD-ROM 220- 0109 D-10 Hemoglobin A1c Supplemental Program Reagent Pack</p>	<p>iv. justification for applying as kit</p>
175.	<p>M/s Cabbot Surgicals, 09 Rose Lane 1, Gulberg Avenue New Lalazar Rawalpindi</p> <p>ELI-00415</p> <p>Fee Rs. 62000 Challan No. 3894447337</p> <p>R&I Date: 14-04-2025</p>	<p>Changzhou Haida Medical Equipment Co. Lt.d, Sanhekou Industrial Zone, Zhenglu Town, 213115, Tianning Dist. Changzhou City, Jiangsu Province China.</p> <p>LOA valid till: 01-03-2030 (Copy)</p> <p>FSC valid till: 06-08-2024 (copy)</p> <p>FSC (Germany) issue date:11-03-2024 (Copy)</p> <p>ISO Valid till: 28-02-2025</p> <p>EC Certificate valid till: 26-05-2024 with extension letter (copy)</p>	<p>Disposable Incision Retractor</p> <p>Applied as: not mentioned.</p> <p>Class C</p> <p>Shelf Life 5 years</p> <p>Code: HRA-60/70-60/150, HRA- 80/90-80/150, HRA-120/130- 120/250 HRA-150/160- 150/250, HRA-220/230- 220/250 HRA-180/190- 180/250, HRA-270/280- 270/250, HRA-320/330- 320/250, HRB-40/30--15/20 HRB-50/40--15/20, HRB- 50/40--25/25, HRB-60/50-- 25/25 HRB-60/50--25/50, HRB-60/25 HRB-120/120-- 60/25,</p> <p>70/60--35/50, HRB-70/70-- 35/25 HRB-70/70--35/40, HRB-100/50--35/50, HRB- 120/100--HRB-120/100--</p>	<p>Deferred for submission of the followings:</p> <p>i. Valid legalized FSC (China) wherein the product shall be on free sale.</p> <p>ii. Valid notarized LOA</p> <p>iii. Valid notarized ISO 13485</p> <p>iv. Valid legalized FSC of RRA or valid notarized CE (FQA)</p> <p>iv. justification for appling multiple codes in one application.</p>

			60/40, HRB-120/120--60/40HRB-120/100--60/70, HRB-150/70--60/50	
176.	M/s Cabbot Surgicals, 09 Rose Lane 1, Gulberg Avenue New Lalazar Rawalpindi ELI-00415 Fee Rs. 62000 Challan No. 3264355782 R&I Date: 14-04-2025	Changzhou Haida Medical Equipment Co. Lt.d, Sanhekou Industrial Zone, Zhenglu Town, 213115, Tianning Dist. Changzhou City, Jiangsu Province China. LOA valid till: 01-03-2030 (Copy) FSC valid till: 06-08-2024 (copy) FSC (Germany) issue date:11-03-2024 ISO Valid till: 28-02-2025 (Copy) EC Certificate valid till: 26-05-2024 (Copy)	Disposable Circular Stapler Applied as: Class C Shelf Life 5 years Code: HC-21, HC-24, HC-26, HC-29, HC-31, HC-32, HC-33, JC-34	Deferred for submission of the followings: i.Valid legalized FSC (China) wherein the product shall be on free sale. ii. Valid notarized LOA iii. Valid notarized ISO 13485 iv. Valid legalized FSC of RRA or valid notarized CE (FQA) iv. The firm shall submit differential fee for family as per new SRO along with justification for applying various codes in one application.
177.	M/s Cabbot Surgicals, 09 Rose Lane 1, Gulberg Avenue New Lalazar Rawalpindi ELI-00415 Fee Rs. 62000 Challan No. 251344112 R&I Date: 14-04-2025	Changzhou Haida Medical Equipment Co. Lt.d, Sanhekou Industrial Zone, Zhenglu Town, Tianning Dist. Changzhou City, Jiangsu Province China. LOA valid till: 01-03-2030 (Copy) FSC valid till: 06-08-2024 (copy) Reference country FSC issue date:11-03-2024 (Copy) ISO Valid till: 28-02-2025 (Copy) EC Certificate valid till: 26-05-2024 (Copy)	Disposable Endo Cutter Stapler Disposable Endo Cutter Stapler Applied as: Class C Shelf Life 5 years Code: HENDO-L, HENDO-S, HENDO-XL, HDQJ-60, HDQJ-160, HDQJ-260 HENDO-30-2.0A, HENDO-30-2.5A, HENDO-30-3.5A, HENDO-45-2.0A HENDO-45-2.5A, HENDO-45-3.5A, HENDO-45-4.8A, HENDO-60-2.5A, HENDO-60-3.5A, HENDO-60-4.8A, HENDO-30-2.0B, HENDO-30-2.5B HENDO-30-3.5B, HENDO-45-2.0B, HENDO-45-2.5B, HENDO-45-3.5B, HENDO-45-4.8B, HENDO-60-2.5B, HENDO-60-3.5B, B-type HENDO-60-4.8B; reloads(standard): HDQJ-30-2.5B, HDQJ-30-3.5B, HDQJ-30- 3.8B, HDQJ-30-4.0B, HDQJ-30-4.2B, HDQJ-45-2.5B, HDQJ-45-3.5B, HDQJ-45-3.8B, HDQJ-45-4.0B, HDQJ-45-4.2B, HDQJ-45-	Deferred for submission of the followings: i.Valid legalized FSC (China) wherein the product shall be on free sale. ii. Valid notarized LOA iii. Valid notarized ISO 13485 iv. Valid legalized FSC of RRA or valid notarized CE (FQA) iv. The firm applied different types/models of the products along with reloads in single application. Justification is required for classification all the products/its reloads/types/codes as family or system along with the documentary evidence & prescribed fee as per new SRO otherwise applying seperately.

		<p>4.8B, HDQJ-60-2.5B, HDQJ-60- 3.5B, HDQJ-60-3.8B, HDQJ-60 4.0B, HDQJ-60-4.2B, HDQJ-60-4.8B</p> <p>D-Type reloads (with equal staple height): HDQJ-30-2.5D, HDQJ-30-3.5D, HDQJ-30-3.8D, HDQJ-30-4.0D, HDQJ-30- 4.2D, HDQJ-45-2.5D, HDQJ-45- 3.5D, HDQJ-45-3.8D, HDQJ-45 4.0D, HDQJ-45-4.2D, HDQJ-45-4.8D, HDQJ-60-2.5D, HDQJ-60-3.5D, HDQJ-60-3.8D, HDQJ-60- 4.0D, HDQJ-60-4.2D, HDQJ-60 4.8D, HDQJ-75-2 5D, HDQJ-75-35D, HDQJ-75-3.8D. HDQJ-75- 4.0D, HDQJ-75-4.2D, HDQJ-75-4.8D</p> <p>E type rotary reloads (with stepped staple height) HDQJ-30-2.0/2.5/3.0E, HDQJ-30-2.5/2.5/3.0E, HDQJ-30-3.0/3.5/4.0E, HDQJ-30-4.0/4.5/5.0E, HDQJ-45-2.0/2.5/3.0E, HDQJ-45-2.5/2.5/3.0E, HDQJ-45-3.0/3.5/4.0E, HDQJ-45-4.0/4.5/5.0E, HDQJ-60-2.0/2.5/3.0E, HDQJ-60-2.5/2.5/3.0E, HDQJ-60-3.0/3.5/4.0E, HDQJ-60-4.0/4.5/5.0E Ctype rotary reloads (Eagle-beak shaped reloads): HDQJ-30 2.0C, HDQJ-30-2.5C, HDQJ-30-3.5C, HDQJ-45-2.0C, HDQJ-45 2.5C, HDQJ-45-3.5C, HDQJ-60-2.0C, HDQJ-60-2.5C, HDQJ-60-3.5C, HDQJ-60-4.8C C(E) Type reloads (Eagle-beak shaped reloads with stepped staple height) HDQJ-30-2.0/2.5/3.0C(E), HDQJ-30-2.5/2.5/3.0C(E) HDQJ-30-2.0/2.5/3.0C(E), HDQJ-30-2.5/2.5/3.0C(E), HDQJ-30-3.0/3.5/4.0C(E), HDQJ-30-4.0/4.5/5.0C(E), HDQJ-45-2.0/2.5/3.0C(E), HDQJ-45-2.5/2.5/3.0C(E), HDQJ-45-3.0/3.5/4.0C(E), HDQJ-45-4.0/4.5/5.0C(E), HDQJ-60-2.0/2.5/3.0C(E), HDQJ-60-2.5/2.5/3.0C(E), HDQJ-60-3.0/3.5/4.0C(E), HDQJ-60-</p>	
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			4.0/4.5/5.0C(E)STAPLER: HDEC TYPE: HDEC-45S/M/L, HDEC-60S/M/L HDEC RELOADS: HDEC-45-2.5A, HDEC-45-3.5A, HDEC-45-3.8A, HDEC-45-4.1A, HDEC-45-4.3A, HDEC-60-2.5A, HDEC-60-3.5A, HDEC-60-3.8A, HDEC-60-4.1A, HDEC-60-4.3A	
178.	Applicant Name: Quintex Medical Lateef Manzal, 1 st Floor, 100/B, Main Lyton road Lahore, Pakistan (ELI No – 00823) Fee Details: Paid Fee: 6000 Challan No. 40995759610 Dated: 12-04-2025	Legal Manufacturer: Honsun (Nantong) Co. Ltd No. 8 Tongxing Road Economic & Technical Development Area Nantong Jiangsu China FSC Valid till: 14-02-2027 LOA Validity: 17-03-2030 ISO Certificate Validity: 08-03-2026	Brand name: HONSUN Aneroid Sphygmomanometer Generic Name: Aneroid Sphygmomanometer Class-A Shelf life: 5 Years Sizes: Codes: HS-20A, HS-20C, HS-20D, HS-60A, HS-60D, HS-60E, HS-70A, HS-70B, HS-70D	Deffered for clarification of various models applied in single application.
179.	Applicant Name: Quintex Medical Lateef Manzal, 1 st Floor, 100/B, Main Lyton road Lahore, Pakistan (ELI- 00823) DRAP Fees: Rs: 6000/- Challan No. 308014834 Dated: 12-04-2025	Legal Manufacturer: Honsun (Nantong) Co. Ltd No. 8 Tongxing Road Economic & Technical Development Area Nantong Jiangsu China FSC Valid till: 14-02-2027 LOA Validity: 17-03-2030 ISO Certificate Validity: 08-03-2026	Brand name: HONSUN Stethoscopes Class-A Shelf life: 5 Years Sizes: Codes: HS-30A, HS-30B, HS-30L, HS-30J, HS-30F, HS-30R	Deffered for clarification of various models applied in single application.
180.	Applicant Name: Quintex Medical Lateef Manzal, 1 st Floor, 100/B, Main Lyton road Lahore, Pakistan ELI No.: ELI- 00823 DRAP Fees: Rs: 6000/- Challan No. 52247913833 Dated: 12-04-2025	Legal Manufacturer: Honsun (Nantong) Co. Ltd No. 8 Tongxing Road Economic & Technical Development Area Nantong Jiangsu China FSC Valid till: 14-02-2027 LOA Validity: 17-03-2030 ISO Certificate Validity:	Brand name: Medical Crepe Papers/ Medical Packaging Material Class-A Shelf life: 5 Years Sizes: Codes: TRPR075, TRPR100, TRPRO150, TRPR200, TRPR250, TRPR300, TRPR350	Approved subject to brand name.

		08-03-2026	TRHFR050, TRHFR075, TRHFR100, TRHFR150, TRHFR200,	
181.	Applicant Name: Bio Indus, B-526, B Satellite Town, Rawalpindi. (ELI-00979)	Legal Manufacturer: M/s. ITL Asia Pacific Sdn. Bhd. Plot 17B, Lorong Bemban 2. Bemban Industrial Estate, 31000 Batu Gajah, Perak. Malaysia FSC Validity: 01-04-2026 ISO 13485 Validity: 31-07-2026	Brand name: Safety SubCulture Unit 2 17G Versatile dispensing unit for a safer subculture technique. Class: A Shelf life: 3 years Codes as per FSC: A100722	Deffered for the submission of the following. valid notarized LOA & evidence of submission of prescribed fee.
182.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 08-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 9738885061 Dated: 04-04-2025	Name of Manufacturer: M/s Hospital & Homecare Medical Device Co., Ltd. China Address: No. 12 Plant, Phase II, Standard Plant, Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China LOA Validity: 19-03-2030 FSC Validity: China 11-03-2027 ISO Certificate Validity: 07-12-2025	Brand name: Safety Med Hot & Cold Pack Generic Name: Hot & Cold Pack Class-A Models/ Specification 28 * 13.5cm	Approved
183.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 08-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 424113043213 Dated: 04-04-2025	Name of Manufacturer: M/s Hospital & Homecare Medical Device Co., Ltd. China Address: No. 12 Plant, Phase II, Standard Plant, Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China LOA Validity: 19-03-2030 FSC Validity: China 11-03-2027 ISO Certificate Validity: 07-12-2025	Brand name: Safety Med Tongue Depressor Generic Name: Tongue Depressor Class-A Models/ Specification 15 cm	Approved
184.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved

	<p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 08-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 9551180941 Dated: 04-04-2025</p>	<p>M/s Hospital & Homecare Medical Device Co., Ltd. China</p> <p>Address: No. 12 Plant, Phase II, Standard Plant, Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China</p> <p>LOA Validity: 19-03-2030</p> <p>FSC Validity: China 11-03-2027</p> <p>ISO Certificate Validity: 07-12-2025</p>	<p>Safety Med Cord Clamp</p> <p>Generic Name: Cord Clamp</p> <p>Class-A</p> <p>Shelf life: 5 years</p> <p>Models/ Specification 5cm, 5.5cm</p>	
185.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 08-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 222964360 Dated: 04-04-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Hospital & Homecare Medical Device Co., Ltd. China</p> <p>Address: No. 12 Plant, Phase II, Standard Plant, Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China</p> <p>LOA Validity: 19-03-2030</p> <p>FSC Validity: China 11-03-2027</p> <p>ISO Certificate Validity: 07-12-2025</p>	<p>Brand name:</p> <p>Safety Med I.D Band</p> <p>Generic Name: I.D Band</p> <p>Class-A</p> <p>Models/ Specification Write on type, pocket insert card type</p> <p>Sizes: Adult, child, infant</p>	<p>Approved. Firm shall submit differel fee as per revsed SRO for family.</p>
186.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 10-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 6731133401 Dated: 24-03-2025</p>	<p>Name of Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p>	<p>Brand name:</p> <p>Radial Compression Bandage</p> <p>Generic Name: Radial Artery Compression Device</p> <p>Class-A</p> <p>Shelf life: 03 years</p> <p>Models/ Specification 98217118- Radial Compression Bandage, 18cm, with scale indicator, sterile 98217122- Radial Compression Bandage, 22cm, with scale indicator, sterile 98217126- Radial Compression Bandage, 26cm,</p>	<p>Approve. Firm shall submit valid notarized ISO 13485 and brand name.</p>

			with scale indicator, sterile 982181INF- Radial Compression Bandage, inflating with syringe, sterile	
187.	Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 0568076152 Dated: 24-03-2025	Name of Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024	Brand name: Guide Wire Torquer Generic Name: Guide Wire Torquer Class-A Shelf life: 03 years Models/ Specification 0.014"-0.025" Wire, Metal Collar, Sterile 0.014" Wire, ABS Collar, Sterile 0.025" – 0.035" Wire, Metal Collar, Sterile 0.035" – 0.038" Wire, Metal Collar, Sterile	Approve. Firm shall submit valid notarized ISO 13485 nad brand name.
188.	Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 0568076152 Dated: 24-03-2025	Name of Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024	Brand name: Y Connector Set Generic Name: Hemostatic Valve and Accessories Class-A Shelf life: 03 years Models/ Specification	Deffered for the submission of the following. valid notarized ISO 13485 & provision of the details of codes / sizes of the product.
189.	Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025	Name of Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025	Brand name: Guide Wire Insertion Tool Generic Name: Guide Wire Insertion Tool Class-A Shelf life: 03 years Models/ Specification: Guide Wire Insertion Tool, 21g x 95mm, Blunt, Sterile	Approve. Firm shall submit valid notarized ISO 13485 and brand name.

	Fee Details: Paid Fee: 6,000/- Fee Challan No: 0568076152 Dated: 24-03-2025	FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024		
190.	Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 0216307278 Dated: 25-03-2025	Name of Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024	Brand name: Indeflation Syringe Generic Name: Catheter/Over Tube Balloon inflator, Single Use Class-A Shelf life: 03 years Models/ Specification: Indeflation Syringe, 20ml, 30atm, T Handle, HP STP, Sterile Indeflation Syringe, 20ml, 40 atm, T Handle, HP STP Sterile Indeflation syringe, 20ml, 30atm, HP STP, Sterile	Approve. Firm shall submit valid notarized ISO 13485 and brand name.
191.	Applicant Name: Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi ELI-01292 Date of R&I 07-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 9757711310 Dated: 25-03-2025	Name of Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024	Brand name: Y-PTCA Connector Generic Name: Hemostatic Valve Class-A Shelf life: 03 years Models/ Specification: Tuohy Borst Y PTCA Connector, sterile Push Rotate Y PTCA Connector, sterile Push Click Y PTCA Connector, sterile Push Pull Y PTCA Connector, sterile Tuohy Borst Y PTCA Connector, with 25 cm Extension line and STP 45 psi, sterile Push Click Y PTCA Connector, with 25 cm Extension line and STP 45 psi, sterile Push Click Y PTCA Connector, with 25 cm Extension line and MP STP 500 psi, sterile	Deffered for the submission of the following. valid notarized ISO 13485 brand name and justification for applying various types in single application..

			Push Pull Y PTCA Connector, with 25 cm Extension line and STP 45 psi, sterile Push Pull Y PTCA Connector, with 50 cm Extension line and STP 45 psi, sterile Tuohy Borst Y PTCA Connector, with 50cm Extension line and STP 45 psi, Sterile Push Rotate Y Connector with 50 cm Extension line and STP 45 psi, sterile Push Click Y PTCA Connector, with 50 cm Extension line and STP 45 psi, sterile Tuohy Borst Y PTCA Connector, with 50 cm Extension line and MP STP 500 psi, sterile Push Rotate Y connector with 50 cm Extension line and MP STP 500 psi, sterile Push Click Y PTCA Connector, with 50 cm Extension line and MP STP 500 psi, sterile	
192.	Applicant Name: M/s Tri Tech International, 10-C 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase II Ext. DHA, Karachi ELI-00247 Date of R&I 09-04-2025 Fee Details: Paid Fee: 25,000/- Fee Challan No: 4429419180 Dated: 08-04-2025	Name of Manufacturer: Wenzhou Longwan Medical Devices Factory China, Unit 4, Building 27, NO. 706 Yanyun Road, Oujiangkou Industrial Cluster District 325026, Wenzhou, Zhejiang, Peoples Republic of China LOA Validity: 13-01-2030 FSC: China Validity: 12-01-2027 ISO Validity: 24-11-2027	Brand name: Care Vision Aneroid Sphygmomanometer Generic name: Aneroid Sphygmomanometer (TY-P0 Series) Class-A Shelf life: 5 Years Models/ Specification: TY-P01, TY-P02, TY-P03, TY-P04, TY-P05, TY-P06	Deffered for Justification for applying various models in single application.
193.	Applicant Name: M/s Tri Tech International, 10-C 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase II Ext. DHA, Karachi ELI-00247	Name of Manufacturer: Wenzhou Longwan Medical Devices Factory China, Unit 4, Building 27, NO. 706 Yanyun Road, Oujiangkou Industrial Cluster District 325026, Wenzhou, Zhejiang, Peoples Republic of China LOA Validity: 13-01-2030	Brand name: Care Vision Aneroid Sphygmomanometer Generic name: Aneroid Sphygmomanometer (TY-A1 Series) Class-A	Deffered for Justification for applying various models in single application.

	<p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 81426256995 Dated: 08-04-2025</p>	<p>FSC: China Validity: 12-01-2027</p> <p>ISO Validity: 24-11-2027</p>	<p>Shelf life: 5 Years</p> <p>Models/ Specification: TY-A10, TY-A11, TY-A12</p>	
194.	<p>Applicant Name:</p> <p>M/s Tri Tech International, 10-C 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase II Ext. DHA, Karachi</p> <p>ELI-00247</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 34252382038 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Wenzhou Longwan Medical Devices Factory China, Unit 4, Building 27, NO. 706 Yanyun Road, Oujiangkou Industrial Cluster District 325026, Wenzhou, Zhejiang, Peoples Republic of China</p> <p>LOA Validity: 13-01-2030</p> <p>FSC: China Validity: 12-01-2027</p> <p>ISO Validity: 24-11-2027</p>	<p>Brand name:</p> <p>Care Vision Stethoscope</p> <p>Generic: Stethoscope</p> <p>Class-A</p> <p>Shelf life: 36 months</p> <p>Models/ Specification: TY-S01, TY-S02, TY-S03, TY-S04, TY-S05, TY-S06, TY-S07, TY-S08</p>	<p>Deffered for Justification for applying various models in single application.</p>
195.	<p>Applicant Name:</p> <p>M/s Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road, Rawalpindi</p> <p>ELI-01172</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 1349200518 Dated: 24-03-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Weaver and Company 565 Nucla Way, Unit B Aurora, Colorado 80011 United States of America</p> <p>LOA Validity: 17-03-2030</p> <p>FSC: USA Validity: 10-09-2026</p> <p>ISO Validity:</p>	<p>Brand name:</p> <p>Ten20 Conductive Paste</p> <p>Generic name: Ten20 Conductive Paste</p> <p>Class-A</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: 4oz Jar 3-pack (#10-20-4) 8oz Jar 3-pack (#10-20-8) 4oz Tube 3-pack (#10-20-4T) 4oz Tube Kit (#10-20-4TK) 50g Jar Sample (#10-20-2S) 50g Jar 3-pack (#10-20-2) Single-Use Cup 24-pack (#10-20-1) Single-Use Cup 3-pack (10-20-1S)</p>	<p>Deffered for the submission of the following. valid notarized ISO 13485, legalized FSC and justification of the model and codes.</p>
196.	<p>Applicant Name:</p> <p>M/s Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road, Rawalpindi</p>	<p>Name of Manufacturer:</p> <p>M/s Weaver and Company 565 Nucla Way, Unit B Aurora, Colorado 80011 United States of America</p> <p>LOA Validity: 17-03-2030</p>	<p>Brand name:</p> <p>Nuprep Skin Prep Gel</p> <p>Generic name: Abrasive Skin-Prepping Gel</p> <p>Class-A</p>	<p>Deffered for the submission of the following. valid notarized ISO 13485, legalized FSC and justification of the model and codes.</p>

	ELI-01172 Date of R&I 07-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 59506642 Dated: 24-03-2025	FSC: USA Validity: 10-09-2026 ISO Validity:	Shelf life: 3 Years Models/ Specification: 4oz Tube 3-pack (#10-30) 4oz Tube Kit (#10-30K) 25g Tube Sample (#10-25S) 25g Tube Kit (#10-25) 25g Tube 6-pack (#10-61) 25g Tube 20-pack (#10-65) Single use cup 24 pack (No. 10-91) Single use cup 3 pack (No. 10-91s)	
197.	Applicant Name: M/s Ghazali Brothers, 1st Floor Azzainab Court Campbell Street, Karachi ELI-00240 Date of R&I 03-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 82790069922 Dated: 24-03-2025	Name of Manufacturer: M/s Ningbo Yingmed Medical Instruments Co., Ltd., Room 1201-9, NO. 456 Tai'an Middle RD Yinzhou District 315199 Ningbo, Zhejiang China LOA Validity: 02-01-2029 FSC: UK Issue date: 09-02-2018 ISO Validity: 18-07-2027	Brand name: Careplus Night Drainage Bag Generic name: Urine Bag Class-A Shelf life: 5 Years Models/ Specification: 1000ml, 1500ml, 2000ml, 2200ml, 2500ml, 2800ml, 3000ml, 3100ml	Approved. Firm shall submit Valid FSC.
198.	Applicant Name: M/s Samerian's Enterprises, 4-First Floor, H.J. Centre, Kutchi Gali # 2, Marriot Road, Karachi ELI-00425 Date of R&I 14-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 668203804 Dated: 17-03-2025	Name of Manufacturer: M/s Yangzhou Bokang Medical Equipment Co., Ltd., 8-301, Liandong U-Valley Industrial Park, No. 17 Qianwan Road, Shiqiao Town, Yangzhou Development Zone. Yongzhou City Jiangsu Province China LOA Validity: 25-03-2030 FSC: China Validity: 3-07-2026 ISO Validity: 01-09-2027	Brand name: Master Alcohol Swabs Generic name: Alcohol Swabs Class-A Shelf life: 5 Years Models/ Specification: 5x5cm, 5x4.5cm, 5x4cm, 4x10cm, 6x6cm, 12x12cm	Approved
199.	Applicant Name: M/s Popular International Pvt. Ltd. House # 141 Justice Inamullah Road, Block 7 & 8 K.M.C.H.S, Near Hill Park, Karachi	Name of Manufacturer: M/s ACON Laboratories, Inc. 5850 Oberlin Drive, # 340 San Diego CA 92121 USA Manufacturing site: M/s ACON Biotech (Hangzhou) Co.,	Brand name: Flaflex TM Fluorescent Immunoassay Analyzer System Generic name:	Deffered for shelf life/service life, differential fee for system.

	(ELI-00091) Date of R&I 14-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 668203804 Dated: 17-03-2025	Ltd. No. 210 Zhengzhong Road, West Lake District, Hangzhou P.R. China, 310030 LOA Validity: 20-01-2027 FSC: China Validity: 28-10-2026 ISO Validity: 06-09-2025	Fluorescent Immunoassay Analyzer System Class-A Shelf life: N/a Models/ Specification: iFIA- 100	
200.	Applicant Name: M/s 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 10-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 6860150562 Dated: 21-03-2025	Name of Manufacturer: M/s Legal Manufacturer: GE Medical System Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI, 53226, USA Manufacturing Site: GE Medical Systems Information Technologies, Critikon de Mexico S. De R.L de C.V Calle Valle del cedro 1551, Juarez 32575 Chihuahua Mexico LOA Validity: 30-09-2025 FSC: France Issue date: 10-12-2020 ISO Validity: 03-04-2026	Brand name: Carescape Gateway Generic name: Network Server Class-A Shelf life: 7 Years Models/ Specification:	Deffered for the submission of the following. Valid legalized FSC and model/codes.
201.	Applicant Name: Tri Tech International, 10-C 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase II Ext, DHA Karachi (ELI-00247) Date of R&I 09-04-2025 Fee Details: Paid Fee: 25,000/- Fee Challan No: 90639579	Name of Manufacturer: Wenzhou Longwan Medical Devices Factory China, Unit 4, Building 27, NO. 706 Yanyun Road, Oujiangkou Industrial Cluster District 325026, Wenzhou, Zhejiang, Peoples Republic of China LOA Validity: 13-01-2030 FSC: China Validity: 12-01-2027 ISO Validity: 24-11-2027	Brand name: Care Vision Aneroid Sphygmomanometer Generic name: Aneroid Sphygmomanometer (TY-A0 Series) Class-A Shelf life: 5 Years Models/ Specification: TY-A01, TY-A02, TY-A03, TY-A04, TY-A05, TY-A06, TY-A07, TY-A08, TY-A09	Deffered for justification for applying various models in single application.
202.	Applicant Name:	Name of Manufacturer:	Brand name:	Deffered for justification

	<p>Medico International</p> <p>Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 242086013441 Dated: 08-04-2025</p>	<p>M/s. Honsun (Nantong) Co., Ltd.</p> <p>Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 11-07-2025</p> <p>FSC: Germany Issue Date: 15-05-2024</p> <p>ISO Validity: 08-03-2026</p>	<p>Medico Stethoscope</p> <p>Generic Name: Stethoscope ST-28</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification HS-30B1(ST-21), HS-30N(ST-11), HS-30A, HS-30F1, HS-30B2, HS-30R2, HS-107A, HS-108A, HS-109C, HS-30A, HS-30D, HS-30E, HS-30N, HS-30P, HS-30Q, HS-30T, HS-30V, HS-30X, HS-30Y, HS-30W, HS-710, HS-711, HS-101A, HS-102A, HS-30F, HS-30G, HS-30H, HS-30J(ST-28), HS-30K, HS-30L, HS-30M, HS-30R, HS-30S, HS-30U, HS-103A, HS-105A, HS-30C, HS-30C1, HS-30C2, HS-30C4, HS-30C5, HS-30C3, HS-30A1, HS-30A2, HS-30E1, HS-106A</p>	<p>for applying various models in single application, service / shelf life of applied product.</p>
203.	<p>Applicant Name:</p> <p>Medico International</p> <p>Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 412045772675 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>M/s. Honsun (Nantong) Co., Ltd.</p> <p>Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 14-12-2026</p> <p>FSC: Germany Issue Date: 15-05-2024</p> <p>ISO Validity: 08-03-2026</p>	<p>Brand name:</p> <p>Medico Aneroid Sphygmomanometer</p> <p>Generic Name: Aneroid Sphygmomanometer And-75</p> <p>Class-A</p> <p>Shelf life: N/A</p> <p>Models/ Specification HS-20A(AND-85), HS-20D(AND-75), HS-20F(AND-65), HS-20B, HS-20C, HS-20D, HS-20E, HS-20J, HS-20G, HS-20M, HS-20K, HS-201Z, HS-201A1, HS-201A2, HS-201B2, HS-201C1, HS-201C2, HS-201D1, HS-201M1, HS-201N1, HS-201J1, HS-201K1, HS-201K2, HS-201Q1, HS-201Q2, HS-201Q3, HS-201T, HS-201U, HS-201V, HS-201W, HS-201Y, HS-201X, HS-60A, HS-60D, HS-60B, HS-60C, HS-60E, HS-70A, HS-70B,</p>	<p>Deffered for justification for applying various models in single application, service / shelf life of applied product.</p>

			HS-70C, HS-70D	
204.	Applicant Name: Medico International Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 25853821 Dated: 08-04-2025	Name of Manufacturer: M/s. Honsun (Nantong) Co., Ltd. Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China LOA Validity: 31-12-2029 FSC: China Validity: 11-07-2025 FSC: Germany Issue Date: 15-05-2024 ISO Validity: 08-03-2026	Brand name: Medico Stethoscope ST-21 Generic Name: Stethoscope ST-21 Class-A Shelf life: N/A Models/ Specification HS-30B1(ST-21), HS-30N(ST-11), HS-30A, HS-30F1, HS-30B2, HS-30R2, HS-107A, HS-108A, HS-109C, HS-30A, HS-30D, HS-30E, HS-30N, HS-30P, HS-30Q, HS-30T, HS-30V, HS-30X, HS-30Y, HS-30W, HS-710, HS-711, HS-101A, HS-102A, HS-30F, HS-30G, HS-30H, HS-30J(ST-28), HS-30K, HS-30L, HS-30M, HS-30R, HS-30S, HS-30U, HS-103A, HS-105A, HS-30C, HS-30C1, HS-30C2, HS-30C4, HS-30C5, HS-30C3, HS-30A1, HS-30A2, HS-30E1, HS-106A	Deffered for justification for applying various models in single application, service / shelf life of applied product.
205.	Applicant Name: Medico International Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 88525789273 Dated: 08-04-2025	Name of Manufacturer: M/s. Honsun (Nantong) Co., Ltd. Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China LOA Validity: 31-12-2029 FSC: China Validity: 14-12-2026 FSC: Germany Issue Date: 15-05-2024 ISO Validity: 08-03-2026	Brand name: Medico Aneroid Sphygmomanometer And-85 Generic Name: Aneroid Sphygmomanometer And-85 Class-A Shelf life: N/A Models/ Specification HS-20A(AND-85), HS-20D(AND-75), HS-20F(AND-65), HS-20B, HS-20C, HS-20D, HS-20E, HS-20J, HS-20G, HS-20M, HS-20K, HS-201Z, HS-201A1, HS-201A2, HS-201B2, HS-201C1, HS-201C2, HS-201D1, HS-201M1, HS-201N1, HS-201J1, HS-201K1, HS-201K2, HS-201Q1, HS-201Q2, HS-201Q3, HS-201T, HS-201U, HS-201V, HS-201W, HS-	Deffered for justification for applying various models in single application, service / shelf life of applied product.

			201Y, HS-201X, HS-60A, HS-60D, HS-60B, HS-60C, HS-60E, HS-70A, HS-70B, HS-70C, HS-70D	
206.	<p>Applicant Name:</p> <p>Medico International</p> <p>Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 8835655876 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>M/s. Honsun (Nantong) Co., Ltd.</p> <p>Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 14-12-2026 FSC: Germany Issue Date: 15-05-2024</p> <p>ISO Validity: 08-03-2026</p>	<p>Brand name:</p> <p>Medico Aneroid Sphygmomanometer And-65</p> <p>Generic Name: Aneroid Sphygmomanometer And-65</p> <p>Class-A</p> <p>Shelf life: N/A</p> <p>Models/ Specification HS-20A(AND-85), HS-20D(AND-75), HS-20F(AND-65), HS-20B, HS-20C, HS-20D, HS-20E, HS-20J, HS-20G, HS-20M, HS-20K, HS-201Z, HS-201A1, HS-201A2, HS-201B2, HS201C1, HS-201C2, HS-201D1, HS-201M1, HS-201N1, HS-201J1, HS-201K1, HS-201K2, HS-201Q1, HS-201Q2, HS-201Q3, HS-201T, HS201U, HS-201V, HS-201W, HS-201Y, HS-201X, HS-60A, HS-60D, HS-60B, HS-60C, HS-60E, HS-70A, HS-70B, HS-70C, HS-70D</p>	Deffered for justification for applying various models in single application, service / shelf life of applied product.
207.	<p>Applicant Name:</p> <p>Medico International</p> <p>Address: B-235, Block B, Satellite Town, Rawalpindi Pakistan</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 9748628447 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>M/s. Honsun (Nantong) Co., Ltd.</p> <p>Address: No. 8, Tongxing Road, Economic & Technological Development Area 226009 Nantong City Jiangsu Province, China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 11-07-2025 FSC: Germany Issue Date: 15-05-2024</p> <p>ISO Validity: 08-03-2026</p>	<p>Brand name:</p> <p>Medico Stethoscope ST-11</p> <p>Generic Name: Stethoscope ST-11</p> <p>Class-A</p> <p>Shelf life: N/A</p> <p>Models/ Specification HS-30B1(ST-21), HS-30N(ST-11), HS-30A, HS-30F1, HS-30B2, HS-30R2, HS-107A, HS-108A, HS-109C, HS-30A, HS-30D, HS-30E, HS-30N, HS-30P, HS-30Q, HS-30T, HS-30V, HS-30X, HS-30Y, HS-30W, HS-710, HS-711, HS-101A, HS-</p>	Deffered for justification for applying various models in single application, service / shelf life of applied product.

			102A, HS-30F, HS-30G, HS-30H, HS-30J(ST-28), HS-30K, HS-30L, HS-30M, HS-30R, HS-30S, HS-30U, HS-103A, HS-105A, HS-30C, HS-30C1, HS-30C2, HS-30C4, HS-30C5, HS-30C3, HS-30A1, HS-30A2, HS-30E1, HS-106A	
208.	Applicant Name: MBS Distributor Address: Flat 101,Shah Alam road Arcade,Defence road Rawalpindi (ELI-01287) Date of R&I 15-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 229220895979 Dated: 26-04-2025	Name of Manufacturer: M/s. Nanyang Major Medical Products Co. Ltd. Address: No.16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China LOA Validity: 31-12-2028 FSC: China Validity: 04-03-2027 ISO Validity: 14-08-2026	Brand name: Sterile Surgical Tubing Cover Class-A Shelf life: 03 Years Models/ Specification 5.5x160cm, or customized	Approved
209.	Applicant Name: MBS Distributor Address: Flat 101,Shah Alam road Arcade,Defence road Rawalpindi (ELI-01287) Date of R&I 15-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 6205247180 Dated: 26-04-2025	Name of Manufacturer: M/s. Nanyang Major Medical Products Co. Ltd. Address: No.16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China LOA Validity: 31-12-2028 FSC: China Validity: 04-03-2027 ISO Validity: 14-08-2026	Brand name: Endoscope Camera Cover Class-A Shelf life: 03 Years Models/ Specification: 5.5x160cm, 12x200cm, 15x250cm, or customized	Approved
210.	Applicant Name: MBS Distributor Address: Flat 101,Shah Alam road Arcade,Defence road Rawalpindi (ELI-01287)	Name of Manufacturer: M/s. Nanyang Major Medical Products Co. Ltd. Address: No.16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China	Brand name: Surgical Pack Class-A Shelf life: 03 Years Models/ Specification: Spinal pack Craniotomy pack,	Deffered for justification for applying various types in single application,.

	<p>Date of R&I 15-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 735163614509 Dated: 26-04-2025</p>	<p>LOA Validity: 31-12-2028</p> <p>FSC: China Validity: 04-03-2027</p> <p>ISO Validity: 14-08-2026</p>	Cardiovascular pack, Biopsy pack, Universal pack, Cesarean pack, or customized	
211.	<p>Applicant Name:</p> <p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail 03/04/2025</p> <p>Fee: 6,000 Slip: 24653972 Dated: 26/03/2025</p>	<p>Name of Manufacturer:</p> <p>DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity : 15-02-2028</p> <p>FSC issue date : 18-08-2022</p> <p>ISO 13485 Validity: 21-11-2025</p> <p>DOC Issue date : 28-02-2025</p>	<p>Brand name:</p> <p>Respons ® 240c (Chemistry analyzer) 4110 1000</p> <p>Class: A</p> <p>Codes/Sizes: 4110 1000</p> <p>Shelf life: 10 years</p>	Approved
212.	<p>Applicant Name:</p> <p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail 03/04/2025</p> <p>Fee: 6,000 Slip: 166792380 Dated: 26/03/2025</p>	<p>Name of Manufacturer:</p> <p>DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity : 15-02-2028</p> <p>FSC issue date : 18-08-2022</p> <p>ISO 13485 Validity: 21-11-2025</p> <p>DOC Issue date : 28-02-2025</p>	<p>Brand name:</p> <p>Respons ® 420c (Chemistry analyzer) 4110 2000 -</p> <p>Respons ® 420c with ISE (Chemistry analyzer) 4110 3000 -</p> <p>Class: A</p> <p>Codes/Sizes: 4110 2000 4110 3000</p> <p>Shelf life: 4110 2000 – 10 years 4110 3000 - 10 years</p>	Approved Firm shal submit separate fee and application form for Respons ® 420c with ISE (Chemistry analyzer) 4110 3000 before issuance of regiatration letter.
213.	<p>Applicant Name:</p> <p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p>	<p>Name of Manufacturer:</p> <p>DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity : 15-02-2028</p> <p>FSC issue date :</p>	<p>Brand name:</p> <p>Respons ® 600c with ISE (Chemistry analyzer) 4110 4000</p> <p>Class: A</p> <p>Codes/Sizes: 4110 4000</p>	Approved

	R&I detail 03/04/2025 Fee: 6,000 Slip: 06277105672 Dated: 26/03/2025	18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 28-02-2025	Shelf life: 4110 4000 – 10 years	
214.	Applicant Name: M/s. Maher Apparels 182-Platinum Block, Park View Villas River Edge Society, OPP DHA EME, Multan Road, Lahore (ELI- 01330) R&I detail 14-04-2025 Fee: 6000 Slip: 05386647209 Dated: N/A	Name of Manufacturer: M/s Changzhou Major Medical Products Co., Ltd., No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, China. EU Quality Management Certificate (MDR) Validity: 14-07-2029 FSC issuance (China): 02-01-2027 ISO Validity: 14-07-2029	Brand name: MEDELAST Surgical Paper Tape. Generic Name: Medical Adhesive Tape Class: A Codes/Sizes: 1.25cm x 5y (10y), 2.5cmx5y (10y), 5cmx5y (10y). 7.5cmx5y (10y), 10cmx5y (10y). Shelf life: 05 Years	Approved
215.	Applicant Name: M/s. Maher Apparels 182-Platinum Block, Park View Villas River Edge Society, OPP DHA EME, Multan Road, Lahore (ELI- 01330) R&I detail 14-04-2025 Fee: 6000 Slip: 46809373385 Dated: 18-03-2025	Name of Manufacturer: M/s Changzhou Major Medical Products Co., Ltd., No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, China. EU Quality Management Certificate (MDR) Validity: 14-07-2029 FSC issuance (China): 02-01-2027 ISO Validity: 14-07-2029	Brand name: MEDELAST Surgical PE Tape Generic Name: Medical Adhesive Tape Class: A Codes/Sizes: 1.25cm x 5y (10y), 2.5cmx5y (10y), 5cmx5y (10y). 7.5cmx5y (10y), 10cmx5y (10y). Shelf life: 05 Years	Approved
216.	Applicant Name: M/s. Maher Apparels 182-Platinum Block, Park View Villas River Edge Society, OPP DHA EME, Multan Road, Lahore (ELI- 01330)	Name of Manufacturer: M/s Changzhou Major Medical Products Co., Ltd., No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, China. EU Quality Management Certificate (MDR) Validity: 14-07-2029	Brand name: MEDELAST Adhesive Wound Dressing Generic Name: Adhesive Wound Dressing Class: A Codes/Sizes:	Approved

	R&I detail 14-04-2025 Fee: 6000 Slip: 03010143 Dated: 18-03-2025	FSC issuance (China): 02-01-2027 ISO Validity: 14-07-2029	5x7cm, 6x 8cm, 8x10cm, 8x15cm, 10x10cm, 10x15cm, 10x20cm, 10x25cm, 10x30cm, 10x35cm. Shelf life: 05 Years	
217.	Applicant Name: M/s. Maher Apparels 182-Platinum Block, Park View Villas River Edge Society, OPP DHA EME, Multan Road, Lahore (ELI- 01330) R&I detail 14-04-2025 Fee: 6000 Slip: 027233530026 Dated: 18-03-2025	Name of Manufacturer: M/s Changzhou Major Medical Products Co., Ltd., No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, China. EU Quality Management Certificate (MDR) Validity: 14-07-2029 FSC issuance (China): 02-01-2027 ISO Validity: 14-07-2029	Brand name: MEDELAST Face Mask Generic Name: Medical Face Mask Class: A Codes/Sizes: 175x95mm Shelf life: 05 Years	Approved
218.	Applicant Name: M/s. Melamine Emporium, 814, Star City Mall, Saddar Karachi (ELI- 00414) R&I detail 07-04-2025 Fee: 6000 Slip: 2033382 Dated: 13-12-2020	Name of Manufacturer: M/s SWL Medizin GmbH, Havelstr. 16 64295 Darmstadt LOA Validity: 16-01-2030 FSC issuance (Germany): 20-11-2024 ISO Validity: 31-08-2026	Brand name: Balloon Inflation Devices Kit Generic Name: Balloon Inflation Devices Kit Class: A Codes/Sizes: BID817101, BID817102, BID817103, BID817104, BID817105, BID817106, BID817107, BID817108, BID817109, BID817110, BID817111, BID817112, BID817113, BID817114, BID817115, BID817116, BID817117, BID817118, BID817119, BID817120, BID817122, BID817123, BID817124, BID817125, BID817126, BID817127, BID817128, BID817129, BID817130, BID817131, BID817132, BID817133, BID817134, BID817135, BID817136 Shelf life: 03 Years	Deffered for class, brand name and fee challan.
219.	Applicant Name:	Name of Manufacturer:	Brand name:	Deffered for class, brand

	<p>M/s. Melamine Emporium, 814, Star City Mall, Saddar Karachi</p> <p>(ELI- 00414)</p> <p>R&I detail 07-04-2025</p> <p>Fee: 6000 Slip: 2033395</p> <p>Dated: 16-11-2020</p>	<p>M/s SWL Medizin GmbH, Havelstr. 16 64295 Darmstadt</p> <p>LOA Validity: 16-01-2030</p> <p>FSC issuance (Germany): 20-11-2024</p> <p>ISO Validity: 31-08-2026</p>	<p>TR Closure Band</p> <p>Generic Name: TR Closure Band</p> <p>Class: A</p> <p>Codes/Sizes: TRB829903, TRB829904, TRB829905, TRB829906, TRB829907, TRB829908, TRB829909, TRB829910,</p> <p>Shelf life: As per stability studies</p>	<p>name and fee challan and shelf life</p>
220.	<p>Applicant Name:</p> <p>M/s. Medichem Enterprises, Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi</p> <p>(ELI- 00252)</p> <p>R&I detail 09-04-2025</p> <p>Fee: 25000 Slip: 636432622704</p>	<p>Name of Manufacturer:</p> <p>M/s ABC Tip Saglik Spor Malzemeleri Tekst. Tur. Ins. San. Tic. Ltd. Sti. Located at Osmangazi Mah. Mehmet Deniz Kopuz Cad. No:20 K:3 Esenyurt – Istanbul/Turkey.</p> <p>LOA Validity: 02-07-2029</p> <p>FSC Validity (Turkey): 28-09-2026</p> <p>ISO Validity: 19-02-2025</p>	<p>Brand name:</p> <p>Throm-Med DVT/TED/Antiembolism Stockings</p> <p>Generic Name: DVT/TED/Antiembolism Stockings</p> <p>Class: A</p> <p>Codes/Sizes: Thigh Length (Supragenua): Small, Medium, Large, Extra Large, Extra Extra Large</p> <p>Shelf life: N/A</p>	<p>Deffered for the following. Submit valid ISO Certificate and provide shelf life details of the applied product.</p>
221.	<p>Applicant Name:</p> <p>M/s. Medichem Enterprises, Plot No. 331-C, Block 3, DMCH Society, Alamgir Road, Karachi</p> <p>(ELI- 00252)</p> <p>R&I detail 09-04-2025</p> <p>Fee: 25000 Slip: 2330058849</p>	<p>Name of Manufacturer:</p> <p>M/s ABC Tip Saglik Spor Malzemeleri Tekst. Tur. Ins. San. Tic. Ltd. Sti. Located at Osmangazi Mah. Mehmet Deniz Kopuz Cad. No:20 K:3 Esenyurt – Istanbul/Turkey.</p> <p>LOA Validity: 02-07-2029</p> <p>FSC Validity (Turkey): 28-09-2026</p> <p>ISO Validity: 19-02-2025</p>	<p>Brand name:</p> <p>Dual Med Medical Compression Stockings (Opened Toe)</p> <p>Generic Name: Medical Compression Stockings (Opened Toe)</p> <p>Class: A</p> <p>Codes/Sizes: Thigh Length (Supragenua): Small, Medium, Large, Extra Large, Extra Extra Large</p> <p>Shelf life: N/A</p>	<p>Deffered for the following. Submit valid ISO Certificate and provide shelf life details of the applied product.</p>
222.	<p>Applicant Name:</p> <p>ASTO Life Science (Pvt.) Ltd., Plaza No. 1,</p>	<p>Name of Manufacturer:</p> <p>M/s Becton, Dickinson and Company, 155 McCarthy Blvd, Milpitas CA</p>	<p>Brand name:</p> <p>BD FACS Lysing Solution-349202</p>	<p>Deffered. Justify the product details, as applied product contains</p>

<div>Block Orchard 1, Paragon City Barki Road, Lahore Cantt.</div> <div>(ELI- 00103)</div> <div>R&I detail 09-04-2025</div> <div>Fee: 25000 Slip: 18140360279</div>	<div>95035</div> <div>M/s Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland.</div> <div>LOA Issuance: 29-02-2024</div> <div>FSC Validity (U.S Food & Drug Administration): 12-09-2025</div> <div>ISO Validity: 17-09-2025</div>	<table><tr><td>3492 02</td><td>BD FACS Lysing Solution</td></tr><tr><td>3342 24</td><td>BD FACS Shutdo wn Solution</td></tr><tr><td>3369 11</td><td>BD FACS Sheath Solution</td></tr><tr><td>3403 45</td><td>BD FACS Cleanin g Solutin</td></tr><tr><td>3420 03</td><td>BD FACS Flow Sheath Fluid</td></tr><tr><td>3405 42</td><td>BD CD3 (SK7) FITC</td></tr><tr><td>3492 01</td><td>BD CD3 (SK7) FITC</td></tr><tr><td>3492 09</td><td>BD CD19 (4G7) PE</td></tr><tr><td>3402 98</td><td>BD Tritest CD4/C D8/CD3</td></tr><tr><td>3403 34</td><td>BD Trucoun t Tubes</td></tr><tr><td>3357 75</td><td>BD FAGS 7-Color Setup Beads</td></tr><tr><td>3445 63</td><td>Stem Cell Enumer ation Kit 50 Tests</td></tr><tr><td>3409 11</td><td>Multi- check CD4 control</td></tr></table>	3492 02	BD FACS Lysing Solution	3342 24	BD FACS Shutdo wn Solution	3369 11	BD FACS Sheath Solution	3403 45	BD FACS Cleanin g Solutin	3420 03	BD FACS Flow Sheath Fluid	3405 42	BD CD3 (SK7) FITC	3492 01	BD CD3 (SK7) FITC	3492 09	BD CD19 (4G7) PE	3402 98	BD Tritest CD4/C D8/CD3	3403 34	BD Trucoun t Tubes	3357 75	BD FAGS 7-Color Setup Beads	3445 63	Stem Cell Enumer ation Kit 50 Tests	3409 11	Multi- check CD4 control	<div>multiple types or apply seperaltely for each type.</div>
3492 02	BD FACS Lysing Solution																												
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			<table><tr><td></td><td>(BL)</td></tr><tr><td>3409 12</td><td>BD Multi- Check Control 2x2.5m L IVD</td></tr><tr><td>3409 13</td><td>BD Multi- Check Control 5x2.5m L IVD</td></tr><tr><td>3409 14</td><td>Multi- check CD4 control (BL) 2.5ml</td></tr><tr><td>3409 15</td><td>BD multi- check CD4 Low Ctrl 2x2.5m L IVD</td></tr></table> <p>Generic Name: Biosciences Reagents & IVD Kits</p> <p>Class: A</p> <p>Codes/Sizes:</p> <p>Shelf life: 24 Months</p>		(BL)	3409 12	BD Multi- Check Control 2x2.5m L IVD	3409 13	BD Multi- Check Control 5x2.5m L IVD	3409 14	Multi- check CD4 control (BL) 2.5ml	3409 15	BD multi- check CD4 Low Ctrl 2x2.5m L IVD	
	(BL)													
3409 12	BD Multi- Check Control 2x2.5m L IVD													
3409 13	BD Multi- Check Control 5x2.5m L IVD													
3409 14	Multi- check CD4 control (BL) 2.5ml													
3409 15	BD multi- check CD4 Low Ctrl 2x2.5m L IVD													
223.	<p>Applicant Name:</p> <p>M/s. Rehman Medicine Co, Shop No. 1 & 2, First Floor H.J. Centre, Kutchi Gali # 2, Marriot Road, Karachi-Pakistan</p> <p>(ELI- 01187)</p> <p>R&I detail 14-04-2025</p> <p>Fee: 6000 Slip: 67684062821</p>	<p>Name of Manufacturer:</p> <p>M/s Jinhua Jingdi Medical Supplies Co., Ltd. 88 Innovation Road, Xiaoshun, Jingdong 321000 Jinhua, Zhejiang Peoples Republic of China.</p> <p>LOA Validity: 17-03-2030</p> <p>FSC Validity (China): 19-11-2025</p> <p>EU Quality Assurance Certificate (MDR) Validity: 17-08-2028</p>	<p>Brand name:</p> <p>Masterpas Pain Relieving Plaster</p> <p>Generic Name: Pain Relieving Plaster</p> <p>Class: A</p> <p>Codes/Sizes: 110mm x 40mm x 110mm x 50mm, 120mm x 50mm, 150mm x 70mm, 200mm x 90mm</p> <p>Shelf life: 05 Years</p>	Approved										
224.	<p>Applicant Name:</p>	<p>Name of Manufacturer:</p>	<p>Brand name:</p>	Approved										

	<p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 2832906947 Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>FSC Germany: Issue date 13-01-2025</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Automatic Coagulation Analyzer</p> <p>Generic Name: Automatic Coagulation Analyzer</p> <p>Class-A</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification: (As per applied dossier also available in FSC).</p> <p>CA1200</p>	
225.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 158614130283 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Semi-auto Chemistry Analyzer</p> <p>Generic Name: Semi-auto Chemistry Analyzer</p> <p>Class-A</p> <p>Shelf life: 8 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <p>DP- C16</p>	Approved
226.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 090655900 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p>	<p>Brand name:</p> <p>DYMIND Cleanser</p> <p>Generic Name: Cleanser</p> <p>Class-A</p> <p>Shelf life: 24 monthhs</p> <p>Models/ Specification: (As per applied dossier also available in FSC)</p>	Approved

		ISO Validity: 30-05-2026	CLE-P Specification (as per FSC): 50mL, 10x4 mL, 2x25mL, 2x50 mL, 2x75 mL, 2x100ml"	
227.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 442521793162 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Diluent Generic Name: Hematology Analyzer Diluent Class-A Shelf life: 02 Years Models/ Specification (As per applied dossier also available in FSC) DIL-E Specification (as per FSC): 10L, 20L	Approved
228.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 7902570105 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Lyse Generic Name: Hematology Analyzer Lyse Class-A Shelf life: 02 Years Models/ Specification (As per applied dossier also available in FSC) LYE-1 Specification (as FSC): 200mL, 500mL, 1L	Approved
229.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao	Brand name: DYMIND Hematology Analyzer Diluent Generic Name: Hematology Analyzer Diluent Class-A	Approved

	(ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 4392563659 Dated: 08-04-2025	Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Shelf life: 02 Years Models/ Specification: (As per applied dossier also available in FSC) DIL-K Specification (as per FSC): 5L, 10L, 20L	
230.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 06173237536 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Lyse Generic Name: Hematology Analyzer Lyse Class-A Shelf life: 02 Years Models/ Specification (As per applied dossier also available in FSC) LYK-1 Specification (as FSC): 200mL, 500mL, 1L	Approved
231.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 3333902716 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Lyse Generic Name: Hematology Analyzer Lyse Class-A Shelf life: 02 Years Models/ Specification (As per applied dossier also available in FSC) L1 Specification (as FSC): 25×300μL, 50x300μL, 40mL , 75mL, 135mL, 200mL, 500mL, 1L, 2L	Approved
232.	Applicant Name: Moody global services	Name of Manufacturer: Shenzhen Dymind Biotechnology	Brand name: DYMIND Hematology	Approved

	<p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 5198549121249 Dated: 08-04-2025</p>	<p>Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <p>LYG-1</p> <p>Specification (as FSC): 200mL, 500mL, 1L</p>					
233.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 6945943655 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Diluent</p> <p>Generic Name: Hematology Analyzer Diluent</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <p>DIL-A</p> <p>Specification (as per FSC): 10L, 20L</p>	Approved				
234.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 7968396353 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity:</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <table><tr><td>Mod el</td><td>Specific ation</td></tr><tr><td>LY</td><td>200mL</td></tr></table>	Mod el	Specific ation	LY	200mL	Deffered for justification of applying in single application
Mod el	Specific ation							
LY	200mL							

		30-05-2026	<table><tr><td>A-1</td><td>、 500mL</td></tr><tr><td>LY A-2</td><td>100mL 、 200mL 、 500mL 、 1L</td></tr><tr><td>LY A-3</td><td>200mL 、 500mL 、 1L、 4L</td></tr></table>	A-1	、 500mL	LY A-2	100mL 、 200mL 、 500mL 、 1L	LY A-3	200mL 、 500mL 、 1L、 4L	
A-1	、 500mL									
LY A-2	100mL 、 200mL 、 500mL 、 1L									
LY A-3	200mL 、 500mL 、 1L、 4L									
235.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 98966439312 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Diluent</p> <p>Generic Name: Hematology Analyzer Diluent</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <p>DIL-C Specification (as per FSC): 10L, 20L</p>	Approved						
236.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 28314116878 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification (As per applied dossier also available in FSC)</p> <p>Model and Specification (as per FSC):</p> <table><tr><td>Mode 1</td><td>Speci ficati on</td></tr></table>	Mode 1	Speci ficati on	Deffered for justification of applying in single application				
Mode 1	Speci ficati on									

			<table><tr><td>LYC-1</td><td>50mL 、 100mL、 200mL、 500mL 、 1L 、 4L</td></tr><tr><td>LYC-2</td><td>100mL、 200mL、 500mL 、 1L 、 4L</td></tr></table>	LYC-1	50mL 、 100mL、 200mL、 500mL 、 1L 、 4L	LYC-2	100mL、 200mL、 500mL 、 1L 、 4L			
LYC-1	50mL 、 100mL、 200mL、 500mL 、 1L 、 4L									
LYC-2	100mL、 200mL、 500mL 、 1L 、 4L									
237.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 242941912 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification: (As per applied dossier also available in FSC)</p> <table><tr><td>Mode 1</td><td>Specifi cation</td></tr><tr><td>LYD-1</td><td>50mL 、 100mL 、 200mL 、 500mL 、 1L、 4L</td></tr><tr><td>LYD-2</td><td>100mL 、 200mL</td></tr></table>	Mode 1	Specifi cation	LYD-1	50mL 、 100mL 、 200mL 、 500mL 、 1L、 4L	LYD-2	100mL 、 200mL	Deffered for justification of applying in single application
Mode 1	Specifi cation									
LYD-1	50mL 、 100mL 、 200mL 、 500mL 、 1L、 4L									
LYD-2	100mL 、 200mL									

			、 500mL 、 1L 、 4L	
238.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 9635646786 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Diluent Generic Name: Hematology Analyzer Diluent Class-A Shelf life: 02 Years Models/ Specification: (As per applied dossier also available in FSC) DIL-N Specification (as per FSC): 10L, 20L	Approved
239.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 509905559141 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Diluent Generic Name: Hematology Analyzer Diluent Class-A Shelf life: 02 Years Models/ Specification: (As per applied dossier also available in FSC) DIN-R Specification (as per FSC): 200mL, 500mL, 1L, 4L	Approved
240.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China	Brand name: DYMIND Hematology Analyzer Dye Generic Name: Hematology Analyzer Dye Class-A	Approved

	09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 922229118627 Dated: 08-04-2025	LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Shelf life: 01 Year Models/ Specification: (As per applied dossier also available in FSC) Model: (As per applied dossier also available in FSC) FDN-D Specification: 22mL, 42mL	
241.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 41595298237 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Dye Generic Name: Hematology Analyzer Dye Class-A Shelf life: 01 Year Models/ Specification: (As per applied dossier also available in FSC) Model: FDN-R Specification: 6mL, 12mL, 24mL	Approved
242.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 9264261314 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Lyse Generic Name: Hematology Analyzer Lyse Class-A Shelf life: 02 Years Models/ Specification: (As per applied dossier also available in FSC) LYN-D Specification (as FSC): 500mL, 1L, 2L, 4L	Approved
243.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved

	<p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 857778322 Dated: 08-04-2025</p>	<p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Models/ Specification: (As per applied dossier also available in FSC)</p> <p>LYN-G</p> <p>Specification (as FSC): 200mL, 500mL, 1L</p>	
244.	<p>Applicant Name:</p> <p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 7207188687 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Cleanser</p> <p>Generic Name: Cleanser</p> <p>Class-A</p> <p>Shelf life: 12 months</p> <p>Models/ Specification: (As per applied dossier also available in FSC)</p> <p>CLR</p> <p>Specification (as per FSC): 500mL, 1L, 4L</p>	Approved
245.	<p>Applicant Name:</p> <p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 9953664131</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity:</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Diluent</p> <p>Generic Name: Hematology Analyzer Diluent</p> <p>Class-A</p> <p>Shelf life: 24 months</p> <p>Models/ Specification: (As per applied dossier also available in FSC)</p>	Approved

	Dated: 08-04-2025	30-05-2026	D-80DIL Specification (as per FSC): 10L, 20L	
246.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 445976005457 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Diluent Generic Name: Hematology Analyzer Diluent Class-A Shelf life: 02 Years Model: (As per applied dossier also available in FSC) D-80DR Specification (as per FSC): 1L, 2L, 4L	Approved
247.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 83895093 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Hematology Analyzer Dye Generic Name: Hematology Analyzer Dye Class-A Shelf life: 1 Year Model: (As per applied dossier also available in FSC) D-80FD Specification: 42mL, 22mL, 12 mL	Approved
248.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen	Brand name: DYMIND Hematology Analyzer Dye Generic Name: Hematology Analyzer Dye Class-A	Approved

	<p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 86930245 Dated: 08-04-2025</p>	<p>518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Shelf life: 01 Year</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80FR</p> <p>Specification: 24mL, 12mL, 6mL</p>	
249.	<p>Applicant Name:</p> <p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 4624822907 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Dye</p> <p>Generic Name: Hematology Analyzer Dye</p> <p>Class-A</p> <p>Shelf life: 01 Year</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80FN</p> <p>Specification: 42mL, 22mL, 12mL</p>	Approved
250.	<p>Applicant Name:</p> <p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 6151544248 Dated: 08-04-2025</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Dye</p> <p>Generic Name: Hematology Analyzer Dye</p> <p>Class-A</p> <p>Shelf life: 01 Year</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80FP</p> <p>Specification: 24mL, 12mL, 6mL</p>	Approved
251.	<p>Applicant Name:</p> <p>Moody global services</p> <p>Address of Importer : Office No. 14, 2nd</p>	<p>Name of Manufacturer:</p> <p>Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech</p>	<p>Brand name:</p> <p>DYMIND Hematology Analyzer Lyse</p>	Approved

	<p>Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 46042726098 Dated: 08-04-2025</p>	<p>Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 24 months</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80LH</p> <p>Specification (as FSC): 200mL, 500mL, 1L, 2L, 4L</p>	
252.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 935654166 Dated: 08-04-2025</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name: DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80LD</p> <p>Specification (as FSC): 500mL, 1L, 2L, 4</p>	Approved
253.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 72626930128 Dated: 08-04-2025</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name: DYMIND Hematology Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>D-80LN</p> <p>Specification (as FSC): 500mL, 1L, 2L, 4L</p>	Approved
254.	<p>Applicant Name: Moody global services</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology</p>	<p>Brand name: DYMIND Hematology</p>	Approved

	<p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 57170564255 Dated: 08-04-2025</p>	<p>Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Analyzer Lyse</p> <p>Generic Name: Hematology Analyzer Lyse</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>L2</p> <p>Specification (as FSC): 25×300μL、 50x300μL、 200mL、 500mL、 1L、 2L</p>	
255.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 531812119 Dated: 08-04-2025</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name: DYMIND Hematology Analyzer Reagent Kit (Diluent and Lyse)</p> <p>Generic Name: Hematology Analyzer Reagent Kit (Diluent and Lyse)</p> <p>Class-A</p> <p>Shelf life: 02 Years</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>PTD-1</p> <p>Specification: (as per FSC) 25tests/kit 50tests/kit</p>	Approved
256.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/-</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p>	<p>Brand name: DYMIND Sample Diluent</p> <p>Generic Name: Sample Diluent</p> <p>Class-A</p> <p>Shelf life: 01 Year</p> <p>Model: Model: (as per FSC)</p> <p>PTD-A</p>	Approved

	Fee Challan No: 080610681 Dated: 08-04-2025	ISO Validity: 30-05-2026	Specification: (as per FSC) <ul style="list-style-type: none"> • 25bottle/bag • 400µL×25 • 50bottle/bag • 400µL×50 	
257.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 985959902 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Sample Diluent Generic Name: Sample Diluent Class-A Shelf life: 01 Year Model: (As per applied dossier also available in FSC) PTD-B Specification: (as per FSC) <ul style="list-style-type: none"> • 25bottle/bag • 450µL×25 • 50bottle/bag 450µL×50	Approved
258.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 44931221 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Sample Diluent Generic Name: Sample Diluent Class-A Shelf life: 01 Year Model: (As per applied dossier also available in FSC) PTD-C Specification: (as per FSC) <ul style="list-style-type: none"> • 25bottle/bag • 600µL×25 • 50bottle/bag 600µL×50	Approved
259.	Applicant Name: Moody global services	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.	Brand name: DYMIND Sample Diluent	Approved

	<p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 52889862 Dated: 08-04-2025</p>	<p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Generic Name: Sample Diluent</p> <p>Class-A</p> <p>Shelf life: 01 Year</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>PTD-D</p> <p>Specification: (as per FSC)</p> <ul style="list-style-type: none"> • 25bottle/bag • 700µL×25 • 50bottle/bag • 700µL×50 	
260.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p> <p>Fee Details: Paid Fee: 6000/- Fee Challan No: 97125997 Dated: 08-04-2025</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p> <p>FSC: China Validity: 10-10-2026</p> <p>ISO Validity: 30-05-2026</p>	<p>Brand name: DYMIND Sample Diluent</p> <p>Generic Name: Sample Diluent</p> <p>Class-A</p> <p>Shelf life: 01 Year</p> <p>Model: (As per applied dossier also available in FSC)</p> <p>PTD-E</p> <p>Specification: (as per FSC)</p> <ul style="list-style-type: none"> • 25bottle/bag • 800µL×25 • 50bottle/bag 800µL×50 	Approved
261.	<p>Applicant Name: Moody global services</p> <p>Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 09-04-2025</p>	<p>Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd.</p> <p>Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China</p> <p>LOA Validity: 31-12-2029</p>	<p>Brand name: DYMIND Wash Solution</p> <p>Generic Name: Wash Solution</p> <p>Class-A</p> <p>Shelf life: 18 months</p>	Approved

	Fee Details: Paid Fee: 6000/- Fee Challan No: 5599047640 Dated: 08-04-2025	FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Model: (As per applied dossier also available in FSC) CLG-1 Specification: 5L, 10L, 20L	
262.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 04815339787 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 10-10-2026 ISO Validity: 30-05-2026	Brand name: DYMIND Cleanser Generic Name: Cleanser Class-A Shelf life: 18 months Model: (As per applied dossier also available in FSC) Model : CLG-2 Specification : 30mL, 20mL, 10mL, 8mL 1test/kit, 10test/kit, 15test/kit, 30test/kit	Approved
263.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 0448127326	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China LOA Validity: 11-03-2029 FSC: China Validity: 07-11-2025 ISO Validity: 22-11-2025	Brand name: Sansure Portable Molecule Workstation Generic Name: Portable Molecule Workstation Class-A Shelf life: 5 year Models/ Specification S-Q36B	Approved
264.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038)	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China	Brand name: Sansure Nucleic acid extraction (DNA/RNA) or purification kit Generic Name: Nucleic acid extraction (DNA/RNA) or purification kit	Deffered for calss, clarification of applied product, types and models.

	<p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 899850436546</p>	<p>LOA Validity: 11-03-2029</p> <p>FSC: China Validity: 25-10-2024</p> <p>ISO Validity: 22-11-2025</p>	<p>(Magnetic beads method)</p> <p>Class-A</p> <p>Shelf life: 12 months</p> <p>Models/ Specification S10013E-24 S10013E-48</p>	
265.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 68959163</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc</p> <p>Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China</p> <p>LOA Validity: 11-03-2029</p> <p>FSC: China Validity: 07-11-2025</p> <p>ISO Validity: 22-11-2025</p>	<p>Brand name:</p> <p>Sansure Portable Molecule Workstation</p> <p>Generic Name: Portable Molecule Workstation</p> <p>Class-A</p> <p>Shelf life: 5 years</p> <p>Models/ Specification model (as per FSC): S-Q36A</p>	Approved
266.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 43644881639</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc</p> <p>Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China</p> <p>LOA Validity: 11-03-2029</p> <p>FSC: China Validity: 25-10-2024</p> <p>ISO Validity: 22-11-2025</p>	<p>Brand name:</p> <p>Sansure Nucleic acid extraction (DNA) or purification kit</p> <p>Generic Name: Nucleic acid extraction (DNA) or purification kit(Magnetic beads method)</p> <p>Class-A</p> <p>Shelf life: 18 months</p> <p>Models/ Specification S10012E-48, S10012E-96,</p>	Deffered for calss, clarification of applied product, types and models.
267.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p>	<p>Name of Manufacturer:</p> <p>Shangai Hongshi Medicalk Technology Co.,Ltd</p> <p>Address: Floor 5, Building 5 No1181 Zhaoxian Road Jiading District 201821 Shanghai PEOPLS REPUBLIC OF CHINA</p>	<p>Brand name:</p> <p>Slan Real time PCR System</p> <p>Generic Name: Real time PCR System</p> <p>Class-A</p>	Deffered for calss and differential fee for system

	<p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 15196949</p>	<p>LOA Validity: 27-8-2029 FSC: China Validity: 14-4-2026</p> <p>ISO Validity: 31-7-2027</p>	<p>Shelf life: 7 Years</p> <p>Models/ Specification SLAN-96S</p>	
268.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 96930103</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc</p> <p>Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China</p> <p>LOA Validity: 11-03-2029</p> <p>FSC: China Validity: 25-10-2024</p> <p>ISO Validity: 22-11-2025</p>	<p>Brand name:</p> <p>Sansure iPo[aticIII Pro portable Molecular diagnostic system</p> <p>Generic Name: iPo[aticIII Pro portable Molecular diagnostic system - Class-A</p> <p>Shelf life: 5 Years</p> <p>Models/ Specification S-Q37A</p>	<p>Deffered for calss and differential fee for system valid and legalized FSC.</p>
269.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 30-01-2025</p> <p>Fee Details: Paid Fee: 6000/-</p> <p>Fee Challan No: 6371408010</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc</p> <p>Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China</p> <p>LOA Validity: 11-03-2029</p> <p>FSC: China Validity: 25-10-2024</p> <p>ISO Validity: 22-11-2025</p>	<p>Brand name:</p> <p>Sansure Sample storage reagent</p> <p>Generic Name: Sample storage reagent</p> <p>Class-A</p> <p>Shelf life: 1 year</p> <p>Models/ Specification X1001E-1, 1 X1001E-24, 24</p>	<p>Deffered. Submit valid and legalized FSC and justification for various modelsl in single application.</p>
270.	<p>Applicant Name:</p> <p>Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>(ELI-01038)</p> <p>Date of R&I 30-01-2025</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc</p> <p>Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China</p> <p>LOA Validity: 11-03-2029</p>	<p>Brand name:</p> <p>Sansure Nucleic Acid Extraction System</p> <p>Generic Name: Nucleic Acid Extraction System</p> <p>Class-A</p>	<p>Deffered. Submit valid and legalized FSC, differential fee for system, justification for class and various models.</p>

	Fee Details: Paid Fee: 6000/- Fee Challan No: 7363852829	FSC: China Validity: 25-10-2024 ISO Validity: 22-11-2025	Shelf life: 5 years Models/ Specification Natch 24 Natch 48 Natch 96	
271.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 6419242790	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China LOA Validity: 11-03-2029 FSC: China Validity: 25-10-2024 ISO Validity: 22-11-2025	Brand name: Sansure Nucleic acid extraction system Generic Name: Nucleic acid extraction system Class-A Shelf life: 5 years Models/ Specification Natch CS3	Deffered. Submit valid and legalized FSC, differential fee for system, justification for class
272.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 65594681	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China LOA Validity: 11-03-2029 FSC: China Validity: 25-10-2024 ISO Validity: 22-11-2025	Brand name: Sansure iPonatic® III Pro Portable Molecular diagnostic system Generic Name: iPonatic® III Pro Portable Molecular diagnostic system Class-A Shelf life: 5 years Models/ Specification S-Q37B	Deffered. Submit valid and legalized FSC, differential fee for system, justification for class
273.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details:	Name of Manufacturer: Shangai Hongshi Medicalk Technology Co.,Ltd Address: Floor 5, Building 5 No1181 Zhaoxian Road Jiading District 201821 Shanghai PEOPLS REPUBLIC OF CHINA LOA Validity: 27-8-2029 FSC: China	Brand name: Slan Real time PCR System Generic Name: Real time PCR System Class-A Shelf life: 7 Years Models/ Specification SLAN-96P	Deffered. Submit differential fee for system, justification for class

	Paid Fee: 6000/- Fee Challan No: 853605674	Validity: 14-4-2026 ISO Validity: 31-7-2027		
274.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 2261779566	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China LOA Validity: 11-03-2029 FSC: China Validity: 25-10-2024 ISO Validity: 22-11-2025	Brand name: Sansure Sample Release Reagent Generic Name: Sample Release Reagent Class-A Shelf life: 02 Years Models/ Specification S1013E-48	Deffered. Submit valid and legalized FSC.
275.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 30-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 4189645893	Name of Manufacturer: Sansure Biotech Inc Address: No. 680, Lusong Road, Yuelu District, 41025 Changsha, Hunan Province, People Republic Of China LOA Validity: 11-03-2029 FSC: China Validity: 25-10-2024 ISO Validity: 22-11-2025	Brand name: Sansure Natch S Pro fully Automated nucleic acid extraction system Generic Name: Natch S Pro fully Automated nucleic acid extraction system Class-A Shelf life: 5 Years Models/ Specification S-S14A	Deffered. Submit valid and legalized FSC, differebtial fee for system and justification of calss.
276.	Applicant Name: M/s. Flowtronix Systems, Flat No. 02, 1 st Floor Al-Ashraf Plaza, Range Road, Rawalpindi. (ELI- 00217) R&I detail 08-04-2025 Fee: 6000 Slip: 61103902674	Name of Manufacturer: M/s Alleva Medical Devices, 1050 W. Central Avenue, Unit B, Area, CA 92821, USA manufacutring site: M/s Alleva Medical Ltd. Suite M-Q, 12 th Floor, Kings Wing Plaza 2, 1 On Kwan St. Shek Mun, Shatin, N.T., Hong Kong	Brand name: Vide Wave Three Chamber Water Seal Chest Drain Generic Name: Three Chamber Water Seal Chest Drain Class: A Codes/Sizes: ST380-0001	Deffered for clarification as the Brand name / product already registered to M/s. Iqbal & Sons, Islamabad, bearing registration No. MDIR-0009163. Flowtronix systems shall provide original, valid and notarized LOA, ISO 13485 Certificate , legalized FSC of U

	Dated: N/A	LOA copy Validity: 14-01-2027 FSC copy Validity (FDA): 26-11-2026 ISO copy Validity: 22-02-2027	Shelf life: 03 Years	
277.	Applicant Name: M/s. Al Fajar Traders, Office:133, J Block, Sabzazar, Lahore. (ELI- 01247) R&I detail 07-04-2025 Fee: 6000 Slip: 4155069992 Dated: N/A	Name of Manufacturer: M/s Jiaxing Kenyue Medical Equipment Co., Ltd. Located at Add: No. 138, Lin Jiang Road, Ganyao Town, Jiashan County Jiaying City, Zhejiang Province China. LOA Validity: 24-12-2029 FSC Validity (China): 23-10-2026 ISO Validity: 18-10-2027	Brand name: MediSafe Generic Name: Hemostatic Sponge Class: A Codes/Sizes: KY-ZX003 (10*10*10mm), KY-ZX002 (70*50*10mm), KY-ZX001 (80*50*10mm), KY-ZX04 (80* ϕ 30mm) Shelf life: 05 Years	Approved
278.	Applicant Name: M/s. Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera. (ELI- 00120) R&I detail 07-04-2025 Fee: 6000 Slip: 91862081893 Dated: 25-03-2025	Name of Manufacturer: M/s. Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA M/s Boston Scientific Corporation, 302 Parkway Global Park, Heredia Costa Rica Agency Agreement Validity: 31-12-2025 FSC Validity (FDA): 25-06-2025 ISO Validity: 18-10-2027	Brand name: Electrophysiology Cables Generic Name: Medical Device Electrical Cable, Reusable Class: A Codes/Sizes: M0045441S0, M0045454S0, M004626S0, M00420S0, M0046130, M0046510, M004603S0, M004653S0, M0046200, M0046270, M0046210, M0046710 Shelf life: 03 Years	Deffered for clarification of calss and valid FSC.
279.	Applicant Name: M/s. S. Ejazuddin & Co. 237/B, Block II, P.E.C.H.S., Shahrah-e- Quaideen, Karachi. (ELI-00078) R&I detail 08-04-2025 Fee: 6000 Slip: 6979129900 Dated: 18-03-2025	Name of Manufacturer: M/s Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150, Parets del Valles Barcelona, Spain LOA Validity: 30-09-2026 FSC Issuance (Spain): 10-01-2025 ISO Validity:	Brand name: Grifols DG-Papain Generic Name: DG-Papain Class: A Codes/Sizes: 843658373PAPAINP7 Shelf life: 9 Months	Approved

		23-09-2025		
280.	Applicant Name: M/s. Biocare Pharma, B-175, Block H, North Nazimabad, Aziz Bhatti Road, Karachi. (ELI-00634) R&I detail 15-04-2025 Fee: 6000 Slip: 232836281188 Dated: 13-03-2025	Name of Manufacturer: M/s Cathay Manufacturer Crop. No. 328, Xishe Rd Maogang Town, Songjiang District, Shanghai, 20167 China. LOA Validity: 16-12-2027 FSC Validity (China): 31-01-2026 ISO Validity: 14-11-2027	Brand name: Disposable ECG Electrodes Generic Name: Disposable ECG Electrodes Class: A Codes/Sizes: GP202S, A;GP202S, A4;GP202D, A:GP202D, A1: GP202D, A2, GP202D, A3: GP202D, D; GP202S P;GP202D, P;GP202D, P4;GP202D, P2:GP2025, 1:GP2025, 11 GP2020, 1GP2000, E1 GP2025 1:CP2025, TB:GP2005, T4 GP2025, 16: GP2020, T: GP20D, T5 GP201D, TI GP20D, T56 GP202S AB: GP2020, AB GP2025, PB, GP202D, PB, GP202S, IB:GP202D, IB: GP202S, TB: GP202D, TB: GP202S AF GP202D, AF: GP202S, PF: GP202D, PF: GP202S, IF: GP202D, IF: GP202S, TF: GP202D, TF: GP202S AFB: GP202D, AFB:GP2025, PFB, GP202D, PFB: GP2025, IFB: GP202D, IFB: GP202S, TFB: GP202DTFB GP2025, AC: GP2020, AC: GP202S, PC: GP202D, PC: GP202S, IC: GP202D, IC: GP202S, TC; GP202D TC: GP202S, ACB: GP202D, ACB: GP202S, PCB: GP202D, PCB: GP202S, JCB: GP202D, ICB: GP202S TCB: GP202D, TCB: GP202S, ACF: GP202D, ACF: GP202S, PCF: GP202D, PCF: GP202S, ICF; GP202D ICF: GP202S, TCF: GP202D, TCF: GP202S, ACFB: GP202D, ACFB: GP202S, PCFB: GP202D, PCFB: GP202S ICFB: GP202D, ICFB: GP202S, TCFB: GP202D, TCFB Shelf life:	Deffered for justification of various types in single application.

			02 Years	
281.	Applicant Name: M/s. Acme Intertrade Health Care, Vision Clifton Shopping Arcade, Shop # 28, Khayaban-e-Roomi Road, Clifton Block 5, Karachi. (ELI-01097) R&I detail 04-04-2025 Fee: 6000 Slip: 25681892920 Dated: 15-03-2025	Name of Manufacturer: M/s Vacsax Limited, Western Wood Way Language Science Park Plymouth UK. LOA validity: 03-04-2025 FSC issuance (UK): 12-07-2023 ISO Validity: 09-07-2027	Brand name: Vacsax Bacticlear Liner Generic Name: suction liners Class: A Codes/Sizes: Shelf life: 05 Years	Deffered. Submit valid LOA AND codes and sizes of the applied product.
282.	Applicant Name: M/s. Batla Impex. Address: Shop No. 40, Namco center, Cambell street, Karachi. (ELI- 00170) R&I detail 14-04-2025 Fee: 6000 Slip: 769324142672 Dated: 08-04-2025	Name of Manufacturer: Ms. Zhejiang Bangli Medical Products Co., Ltd. Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Issuance date: 05-12-2024 FSC VALIDITY (China): 04-09-2026 ISO Validity: 25-11-2026	Brand name: Doctor + Face Mask Generic Name: Face Mask Class: A Codes/Sizes: Shelf life: 05 Years	Deffered. Submit valid and legalized FSC having applied product and product codes.
283.	Applicant Name: M/s. Batla Impex. Address: Shop No. 40, Namco center, Cambell street, Karachi. (ELI- 00170) R&I detail 07-04-2025 Fee: 6000 Slip: 8541833561 Dated: 03-04-2025	Name of Manufacturer: Ms. Zhejiang Bangli Medical Products Co., Ltd. Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Issuance date: 05-12-2024 FSC Validity (China): 04-09-2026 ISO Validity: 25-11-2026	Brand name: Doctor + Surgical Tape Generic Name: Surgical Tape Class: A Codes/Sizes: 1.25cm x 5m, 2.5cm x 5m, 5cm x 5m, 7.5cm x 5m, 10cm x 5m, 1.25 x 10 yards, 2.5cm x 10 yards, 5cm x 10 yards, 7.5cm x 10 yards, 10cm x 10 yards. Shelf life: 05 Years	Approved
284.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved

	M/s. Batla Impex. Address: Shop No. 40, Namco center, Cambell street, Karachi. (ELI- 00170) R&I detail 07-04-2025 Fee: 6000 Slip: 33050705 Dated: 03-04-2025	Ms. Zhejiang Bangli Medical Products Co., Ltd. Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Issuance date: 05-12-2024 FSC Validity (China): 04-09-2026 ISO Validity: 25-11-2026	Doctor + Cooling gel patch Generic Name: Cooling gel patch Class: A Codes/Sizes: 10^ * 4cm , 12^ * 5cm , 11*5cm Shelf life: 05 Years	
285.	Applicant Name: M/s. Batla Impex. Address: Shop No. 40, Namco center, Cambell street, Karachi. (ELI- 00170) R&I detail 07-04-2025 Fee: 6000 Slip: 0326921645 Dated: 03-04-2025	Name of Manufacturer: Ms. Zhejiang Bangli Medical Products Co., Ltd. Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Issuance date: 05-12-2024 FSC Validity (China): 04-09-2026 ISO Validity: 25-11-2026	Brand name: Doctor + Wound Dressing Generic Name: Wound Dressing Class: A Codes/Sizes: 70*18MM,72*19MM,76X15MM,38X38MM,40X20MM,70X110MM,65X25MM,56X19MM, 70X17MM,76X19MM,72X22MM,90X20MM,72x38MM Shelf life: 05 Years	Approved
286.	Applicant Name: M/s. Batla Impex. Address: Shop No. 40, Namco center, Cambell street, Karachi. (ELI- 00170) R&I detail 14-04-2025 Fee: 6000 Slip: 203640778 Dated: 08-04-2025	Name of Manufacturer: Ms. Zhejiang Bangli Medical Products Co., Ltd. Office No 118 Yuegui South Road, City West New District, Youngkang City 321300 Zhejiang P.R China. LOA Issuance date: 05-12-2024 FSC validity (China): 04-09-2026 ISO Validity: 25-11-2026	Brand name: Doctor + Self-Adhesive Bandages Generic Name: Self-Adhesive Bandages Class: A Codes/Sizes: 75CM*3200CM, 100CM*3200CM Shelf life: 05 Years	Approved
287.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China USFDA FSC Valid till: 03-04-2026	FLOWEASE (Non Compliant Coronary Dilatation Balloon Catheter) Shelf life 2 years Class D Code	Approved.

	(ELI-00691) Date of application 18.04.2025 Fee Rs 62000	510k premarket notification submitted issued on 29.06.2023 ISO valid till 19.06.2027 FQA valid till 27.05.2024 and having extension letter Notarized LOA valid till 25.02.2030 Design examination 27.05.2024	NC20010, NC20014, NC20018, NC20022, NC20026, NC20030, NC20034, NC20038, NC22510, NC22514, NC22518, NC22522, NC22526, NC22530, NC22534, NC22538, NC25010, NC25014, NC25018, NC25022, NC25026, NC25030, NC25034, NC25038, NC27510, NC27514, NC27518, NC27522, NC27526, NC27530, NC27534, NC27538, NC30010, NC30014, NC30018, NC30022, NC30026, NC30030, NC30034, NC30038, NC32510, NC32514, NC32518, NC32522, NC32526, NC32530, NC32534, NC32538, NC35010, NC35014, NC35018, NC35022, NC35026, NC35030, NC35034, NC35038, NC37510, NC37514, NC37518, NC37522, NC37526, NC37530, NC37534, NC37538, NC40010, NC40014, NC40018, NC40022, NC40026, NC40030, NC40034, NC40038	
288.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi (ELI-00691) Date of application 18.04.2025 Fee Rs 62000	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China Notarized LOA valid till 25.02.2030 Copy of Netherlands FSC Valid till: 31.12.2031 ISO valid till 19.06.2027 Copy of FQA valid till 27.05.2024 and complete extension letter having code not provided Notarized LOA valid till 25.02.2030 Copy of Design examination 27.05.2024	Restenix (Drug (Paclitaxel) Coated Balloon Catheter) Shelf life 02 years Fee 62000/- Challan no 303210117199 Class D PCB20010, PCB20014, PCB20018, PCB20022, PCB20026, PCB20030, PCB20034, PCB20038, PCB22510, PCB22514, PCB22518,	Deffered for following: Clarification that The name in the FSc is the Everflow Paclitaxel Coated Coronary balloon Catheter and applied is Restenix (Drug (Paclitaxe) Coated Balloon Catheter. Legalized and valid FSC of netherland or Notrized nad valid Design Examination and full quality assurance certificate with extension letter of applied product name/codes.

		FSC china Valid till: 08-04-2026	<p>PCB22522,</p> <p>PCB22526, PCB22530, PCB22534,</p> <p>PCB22538, PCB25010, PCB25014,</p> <p>PCB25018, PCB25022, PCB25026,</p> <p>PCB25030, PCB25034, PCB25038,</p> <p>PCB27510, PCB27514, PCB27518,</p> <p>PCB27522, PCB27526, PCB27530,</p> <p>PCB27534, PCB27538, PCB30010,</p> <p>PCB30014, PCB30018, PCB30022,</p> <p>PCB30026, PCB30030, PCB30034,</p> <p>PCB30038, PCB32510, PCB32514,</p> <p>PCB32518, PCB32522, PCB32526,</p> <p>PCB32530, PCB32534, PCB32538,</p> <p>PCB35010, PCB35014, PCB35018,</p> <p>PCB35022, PCB35026, PCB35030,</p> <p>PCB35034, PCB35038, PCB37510,</p> <p>PCB37514, PCB37518, PCB37522,</p> <p>PCB37526, PCB37530, PCB37534,</p> <p>PCB37538, PCB40010, PCB40014,</p> <p>PCB40018, PCB40022, PCB40026,</p>	
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			PCB40030, PCB40034, PCB40038 Codes AS per FSC of Netherlands	
289.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi (ELI-00691) Date of application 18.04.2025	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China apostille china FSC Valid till: 08-04- 2026 USFDA FSC Valid till: 03-04-2026 ISO valid till 19.06.2027 Notarized LOA valid till 25.02.2030	Valvoflex (Valvuloplasty Balloon Catheter) Shelf life 03 years VBC1540, VBC1840, VBC2140, VBC2340, VBC2640, VBC2940: Class D	Deffered. The firm shall submit clarification of brand name difference in USFDA free sale certificate and applied name.
290.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi (ELI-00691) Date of application 18.04.2025 Fee Rs 62000	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China Apostille China FSC Valid till: 08-08- 2026 ISO valid till 19.06.2027 FQA valid till 27.05.2024 and having extension letter Design examination 27.05.2024	Angioflex (Semi Compliant Coronary Dilatation Balloon Catheter) Shelf life 2 years Class D Codes SD25010 SD25014 SD25018 SD25022 SD25030 SD30010 SD30014 SD30018 SD30022 SD30026 SD30030 SD35010 SD35014 SD35018 SD35022 SD35026 SD35030 SD40010	Deferred for following: clarification of the Brand name in application form and China free sale certificate along with evidence. Nortized and valid CE certificate including FQA and Design examination certificate having name of applied product.

			SD40014 S040018 S040022 SD25026 SD40026 SD40030	
291.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostc Grifols, S.A. Passeig Fluvial 24, 08150, Parets del Valles (Barcelona), Spain FSC Spain issue date: 10-01-2025 LOA valid till 30.09.2026 ISO valid till 29.09.2025 EU technical documentation 17.01.2028 EU QMS valid till 29.09.2026	Serigrup Diana A ₁ /B code 213659 Class D Shelf life 60 days Fee 62000/-	Approved
292.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 29.09.2025 EU technical documentation 17.01.2028 EU QMS valid till 29.09.2026	Serigrup Diana A ₂ code 213658 Class D Shelf life 60 days Fee 62000/-	Approved
293.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 23.09.2025 EU technical documentation 8.05.2028 EU QMS valid till 28.09.2026	DG Gel Newborn Class D Shelf life 13 months Fee 62000/-	Approved
294.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Medion Grifols Diagnostic, A G. 9 bonn strassse, 3186 Duding Ch. Switzerland. FSC Apostille Switzerland validity date: 04.12.2027. LOA valid till 30.09.2026 ISO valid till 09.07.2025 EU technical documentation	Essential II Control Class D Shelf life 61 days Fee 62000/-	Approved

		03.10.2028 EU QMS valid till 07.09.2026		
295.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 29.09.2025 EU technical documentation 17.01.2028 EU QMS valid till 29.09.2026	Serigrup Diana 4 210215 Class D Shelf life 60 days Fee 62000/-	Approved
296.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 29.09.2025 EU technical documentation 17.01.2028 EU QMS valid till 28.09.2026	Identisera Diana Extend code 210212 Class D Shelf life 60 days Fee 62000/-	Approved
297.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 29.09.2025 EU technical documentation 28.05.2028 EU QMS valid till 28.09.2026	DG Gel Confirm P Code 210351 Class D Shelf life 13 months FSC issue date:10-01-2025	Approved The firm shall submit the stability study of 13 months with conclusion.
298.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078) Date of application 8.04.2025	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025 LOA valid till 30.09.2026 ISO valid till 23.09.2025 EU technical documentation 8.05.2028 EU QMS valid till 28.09.2026	DG Gel Rh Pheno+Kell Code 210350 Shel life 13 months Class D	Approved The firm shall submit the stability study of 13 months with conclusion.
299.	S.Ejazuddin & Co., 237/B Block II, P.E.C.H.S., Shahrah-e- Qaideen, Karachi (ELI-00078)	Diagnostic Grifols, S.A. Passeig Fluvial 24, 08150. Parets del Valles (Barcelona), Spain FSC Spain Apostille issue date: 10- 01-2025	DG Gel Rh Pheno Code 210349 Class D Shelf life 13 months Fee 62000/-	Approved The firm shall submit the stability study of 13 months with conclusion.

	Date of application 8.04.2025	LOA valid till 30.09.2026 ISO valid till 23.09.2025 EU technical documentation 8.05.2028 EU QMS valid till 28.09.2026		
300.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 07-04-2025 Fee Challan No.: 8222403708 PKR: 62,000/- Date of Fee Submission: 04-04-2025</p>	<p>Legal Manufacturer Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA.</p> <p>Manufacturing Sites:</p> <ol style="list-style-type: none"> 1. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California Mexico C.P. 22210. 2. Medtronic Ireland Parkmore Business Park West, Galway Ireland. <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA <i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>Copy of FSC: US FDA Issuance Date: 15-12-2023 Validity Date: 14-12-2025</p> <p>ISO: For Ireland Issuance Date: 09-08-2021 Validity Date: 16-07-2024</p> <p>FQA: Issuance Date: 12-12-2024 Validity Date: 01-06-2028 EU technical documentation Valid til 01.12.2029</p>	<p>Harmony™ Transcatheter Pulmonary Valve</p> <p>Generic Name: Transcatheter Pulmonary Valve</p> <p>Class: D</p> <p>Shelf life: 1 years</p> <p>Size & Model: Harmony-22 Harmony™ Transcatheter Pulmonary Valve (TPV) (22mm) Harmony-25 Harmony™ Transcatheter Pulmonary Valve (TPV) (25mm)</p> <p>Storage and Temperature conditions: Store the TPV at room temperature (5 °C to 25 °C [41 °F to 77 °F]).</p>	Deferred for submission of the Apostille/legalized FSC of USFDA and valid ISO 13485
301.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 07-04-2025 Fee Challan No.: 9455788000</p>	<p>Legal Manufacturer Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA</p> <p>Manufacturing Sites:</p> <ol style="list-style-type: none"> 1. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California Mexico C.P. 22210. 	<p>Harmony™ Delivery Catheter System</p> <p>Generic Name: Delivery Catheter System</p> <p>Class: D</p> <p>Shelf life: 1 years</p> <p>Size & Model: HARMONY-DSC</p> <p>Storage and Temperature</p>	Deferred for submission of the Apostille/legalized FSC of USFDA and valid ISO 13485

	<p>PKR: 62,000/- Date of Fee Submission: 04-04-2025</p>	<p>2. Medtronic Ireland, Parkmore Business Park West, Galway Ireland.</p> <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA</p> <p><i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>FSC: US FDA Issuance Date: 15-12-2023 Validity Date: 14-12-2025</p> <p>ISO: For Ireland Issuance Date: 09-08-2021 Validity Date: 16-07-2024</p> <p>FQA: Issuance Date: 21-11-2017 Validity Date: 20-11-2022</p> <p>EU quality management: Issuance Date: 12-12-2024 Validity Date: 01-06-2028 EU technical documentation Valid til 01.12.2029</p>	<p>conditions: Store the DCS at room temperature in a dry environment and away from direct sunlight</p>	
302.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 10-04-2025 Fee Challan No.: 44845704363 PKR: 62,000/- Date of Fee Submission: 26-03-2025</p>	<p>Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432</p> <p>Manufacturing sites</p> <ul style="list-style-type: none"> i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA</p> <p><i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>FSC: US FDA Issuance Date: 11-06-2024</p>	<p>CSF-SHUNT ASSEMBLY, CONTOURED REGULAR, HIGH PRESSURE</p> <p>Generic Name: Shunt Assembly</p> <p>Class: D</p> <p>Shelf life: 5 years</p> <p>Size & Model: 46646</p> <p>Storage and Temperature conditions: No specific storage conditions</p>	<p>Approved</p> <p>The firm shall submit valid ISO 13485</p>

		<p>Validity Date: 10-06-2026</p> <p><i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i></p> <p>ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024</p> <p>EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019</p>		
303.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 10-04-2025 Fee Challan No.: 865964360590 PKR: 62,000/- Date of Fee Submission: 26-03-2025</p>	<p>Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432</p> <p>Manufacturing sites i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137</p> <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA</p> <p><i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026</p> <p><i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i></p> <p>ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024</p> <p>EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019</p>	<p>CSF-SHUNT ASSEMBLY, CONTOURED REGULAR, MEDIUM PRESSURE</p> <p>Generic Name: Shunt Assembly</p> <p>Class: D</p> <p>Shelf life: 5 years</p> <p>Size & Model: 46644</p> <p>Storage and Temperature conditions: No specific storage conditions</p>	<p>Approved</p> <p>The firm shall submit valid ISO 13485</p>

304.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 10-04-2025 Fee Challan No.: 8777635352 PKR: 62,000/- Date of Fee Submission: 26-03-2025</p>	<p>Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432</p> <p>Manufacturing sites i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137</p> <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA</p> <p><i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026</p> <p><i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i></p> <p>ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024</p> <p>EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019</p>	<p>CSF-SHUNT ASSEMBLY, CONTOURED SMALL, MEDIUM PRESSURE</p> <p>Generic Name: Shunt Assembly</p> <p>Class: D</p> <p>Shelf life: 5 years</p> <p>Size & Model: 46624</p> <p>Storage and Temperature conditions: No specific storage conditions</p>	<p>Approved</p> <p>The firm shall submit valid ISO 13485</p>
305.	<p>M/s Medtronic Pakistan Private Limited</p> <p>License number: ELI-00273</p> <p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 10-04-2025 Fee Challan No.: 122669848 PKR: 62,000/- Date of Fee</p>	<p>Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432</p> <p>Manufacturing sites i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137</p> <p>LOA: Issuance Date: 15-01-2025</p>	<p>CSF-VENTRICULAR RESERVOIR, BURR HOLE, 12 MM</p> <p>Generic Name: Ventricular Reservoir</p> <p>Class: D</p> <p>Shelf life: 5 years</p> <p>Size & Model: 44111</p> <p>Storage and Temperature conditions: No specific</p>	<p>Approved</p> <p>The firm shall submit valid ISO 13485</p>

	Submission: 26-03-2025	Validity Date: NA <i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i> FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026 <i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i> ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024 EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019	storage conditions	
306.	M/s Medtronic Pakistan Private Limited License number: ELI-00273 Ocean Tower, 21 st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton. R&I Dated: 10-04-2025 Fee Challan No.: 5474523998 PKR: 62,000/- Date of Fee Submission: 26-03-2025	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 15-01-2025 Validity Date: NA <i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i> FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026 <i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i>	GUIDEWIRE, WITH ADJUSTABLE STOP, 10 CM Generic Name: General purpose non-vascular guidewire Class: D Shelf life: 5 years Size & Model: 21038 Storage and Temperature conditions: No specific storage conditions	Approved The firm shall submit valid ISO 13485

		ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024 EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019		
307.	M/s Medtronic Pakistan Private Limited License number: ELI-00273 Ocean Tower, 21 st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton. R&I Dated: 10-04-2025 Fee Challan No.: 587980721316 PKR: 62,000/- Date of Fee Submission: 26-03-2025	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 15-01-2025 Validity Date: NA <i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i> FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026 <i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i> ISO: For Dominican Republic site Issuance Date: 19-08-2021 Validity Date: 19-08-2024 EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019	NEONATE RESERVOIR, FLAT DOME WITH INTEGRAL VENTRICULAR CATHETER, SMALL, 2.0 CM Generic Name: Ventricular reservoir Class: D Shelf life: 5 years Size & Model: 22101E Storage and Temperature conditions: No specific storage conditions	Approved The firm shall submit valid ISO 13485
308.	M/s Medtronic Pakistan Private Limited License number: ELI-00273	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432	CSF- VENTRICULAR RESERVOIR, 12 MM, CONVERTIBLE Generic Name:	Approved The firm shall submit valid ISO 13485

	<p>Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.</p> <p>R&I Dated: 10-04-2025</p> <p>Fee Challan No.: 53191964276 PKR: 62,000/-</p> <p>Date of Fee Submission: 26-03-2025</p>	<p>Manufacturing sites</p> <p>i. Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic,</p> <p>ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137</p> <p>LOA: Issuance Date: 15-01-2025 Validity Date: NA</p> <p><i>(Original, Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025)</i></p> <p>FSC: US FDA Issuance Date: 11-06-2024 Validity Date: 10-06-2026</p> <p><i>(Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025)</i></p> <p>ISO: For Dominican Republic site</p> <p>Issuance Date: 19-08-2021 Validity Date: 19-08-2024</p> <p>EC Certificate: Issuance Date: 01-05-2024 Validity Date: 01-05-2019</p>	<p>Ventricular Reservoir</p> <p>Class: D</p> <p>Shelf life: 5 years</p> <p>Size & Model: 44100</p> <p>Storage and Temperature conditions: No specific storage conditions</p>									
309.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Rs 62,030 Paid on 19/05/2025 Challan # 89006840</p> <p>Date of R& I</p>	<p>Legal Manufacturer: NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD</p> <p>Address in FSC Room 1201-9, No.456 Tai'an Middle RD, Yinzhou District, Ningbo, Zhejiang, CHINA.</p> <p>Address in credential: YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS ZONE, 315199, NINGBO, CHINA</p> <p>Copy of FQA valid till 23.11.2028</p> <p>Copy of LOA: Sole Agency Agreement (Notarized by CCPIT, submitted with file): Valid till Jan. 2029</p>	<p>Brand Name: YINGMED ABSORBABLE POLYGLACTIN SURGICAL SUTURE</p> <p>Class D</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes:</p> <table><tr><th>S. No</th><th>DES CRI PTI ON</th><th>G B C O D E</th><th>Pa ck siz e(s)</th></tr><tr><td>1</td><td>Thre ad 75c m, 90c</td><td>P G L A 1</td><td>1 D oz en 2</td></tr></table>	S. No	DES CRI PTI ON	G B C O D E	Pa ck siz e(s)	1	Thre ad 75c m, 90c	P G L A 1	1 D oz en 2	<p>Deferred for submission of the following documents:</p> <p>Submit apostille or legalized FSC issued by concerned regulatory authority of China. Clarify the brand name applied and in the FSC. clarify the codes applied since it is neither present in the CE certificate nor in the FSC.</p> <p>Submit notarized and valid LOA, ISO 13485 and FQA and Design examination certificate.</p> <p>Submit Fee slip submitted in DRAP.</p>
S. No	DES CRI PTI ON	G B C O D E	Pa ck siz e(s)									
1	Thre ad 75c m, 90c	P G L A 1	1 D oz en 2									

	14 th April 2025	<p><u>FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health)</p> <p>Valid Upto: Dec, 2025</p> <p>Copy of FQA valid till 23.11.2028</p> <p>Copy of DEC valid till 23.11.2028</p> <p><u>Copy ISO:</u> ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026</p>		m, 0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	0 1	D oz en 3 D oz en
			2	Thre ad 75c m, 90c m, 0, Nee dle 35m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 2	1 D oz en 2 D oz en 3 D oz en
			3	Thre ad 75c m, 90c m, 0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 3	1 D oz en 2 D oz en 3 D oz en
			4	Thre ad 75c m, 90c m,1, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 4	1 D oz en 2 D oz en 3 D oz en

			5	Thre ad 75c m, 90c m, 1, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 5	1 D oz en 2 D oz en 3 D oz en
			6	Thre ad 75c m, 90c m, 2, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 6	1 D oz en 2 D oz en 3 D oz en
			7	Thre ad 75c m, 90c m, 2/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 7	1 D oz en 2 D oz en 3 D oz en
			8	Thre ad 75c m, 90c m, 2/0, Nee dle 30m	P G L A 1 0 8	1 D oz en 2 D oz en 3 D

				m, ½ Circl e Rou nd Bodi ed		oz en		
			9 .	Thre ad 75c m, 90c m, 2/0, Nee dle 35m m, ½ Circl e Rou nd Bodi ed	P G L A 1 0 9	1 D oz en 2 D oz en 3 D oz en		
			1 0 .	Thre ad 75c m, 90c m, 2/0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G L A 1 1 0	1 D oz en 2 D oz en 3 D oz en		
			1 1 .	Thre ad 75c m, 90c m, 3/0, Nee dle 20m m, ½ Circl e Rou nd Bodi ed	P G L A 1 1 1	1 D oz en 2 D oz en 3 D oz en		

			1 2 .	Thre ad 75c m, 90c m, 3/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed	P G L A 1 1 2	1 D oz en 2 D oz en 3 D oz en		
			1 3 .	Thre ad 75c m, 90c m, 3/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G L A 1 1 3	1 D oz en 2 D oz en 3 D oz en		
			1 4 .	Thre ad 75c m, 90c m, 4/0, Nee dle 16m m, ½ Circl e Rou nd Bodi ed	P G L A 1 1 4	1 D oz en 2 D oz en 3 D oz en		
			1 5 .	Thre ad 75c m, 90c m, 0, Nee dle	P G L A 2 0 1	1 D oz en 2 D oz en		

				30m m, ½ Circl e Rou nd Bodi ed		3 D oz en		
			1 6 .	Thre ad 75c m, 90c m, 0, Nee dle 60m m, Strai ght Cutti ng	P G L A 2 0 2	1 D oz en 2 D oz en 3 D oz en		
			1 7 .	Thre ad 75c m, 90c m, 1, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G L A 2 0 3	1 D oz en 2 D oz en 3 D oz en		
			1 8 .	Thre ad 75c m, 90c m,1, Nee dle 35m m, ½ Circl e Rou nd Bodi ed	P G L A 2 0 4	1 D oz en 2 D oz en L3 D oz en		
			1 9 .	Thre ad 75c m, 90c	P G L A 2	1 D oz en 2		

				m, 1, Nee dle 40m m, ½ Circl e Curv ed Cutti ng	0 5	D oz en 3 D oz en		
			2 0 .	Thre ad 75c m, 90c m, 2/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed	P G L A 2 0 6	1 D oz en 2 D oz en 3 D oz en		
			2 1 .	Thre ad 75c m, 90c m, 2/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G L A 2 0 7	1 D oz en 2 D oz en 3 D oz en		
			2 2 .	Thre ad 75c m, 90c m, 2/0, Nee dle 16m m, ½ Circl e Curv	P G L A 2 0 8	1 D oz en 2 D oz en 3 D oz en		

				ed Cutti ng			
			2 3 .	Thre ad 75c m, 90c m, 2/0, Nee dle 35m m, ½ Circl e Curv ed Cutti ng	P G L A 2 0 9	1 D oz en 2 D oz en 3 D oz en	
			2 4 .	Thre ad 75c m, 90c m, 2/0, Nee dle 60m m, Strai ght Cutti ng	P G L A 2 1 0	1 D oz en 2 D oz en 3 D oz en	
			2 5 .	Thre ad 75c m, 90c m, 2/0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G L A 2 1 1	1 D oz en 2 D oz en 3 D oz en	
			2 6 .	Thre ad 75c m, 90c m, 3/0,	P G L A 2 1 2	1 D oz en 2 D oz	

				Bodi ed			
			3 0 .	Thre ad 75c m, 90c m, 4/0, Nee dle 20m m, ½ Circl e Rou nd Bodi ed	P G L A 2 1 6	1 D oz en 2 D oz en 3 D oz en	
			3 1 .	Thre ad 75c m, 90c m, 4/0, Nee dle 16m m, ½ Circl e Rou nd Bodi ed	P G L A 2 1 7	1 D oz en 2 D oz en 3 D oz en	
			3 2 .	Thre ad 75c m, 90c m, 4/0, Nee dle 25m m, ½ Circl e Curv ed Cutti ng	P G L A 2 1 8	1 D oz en 2 D oz en 3 D oz en	
			3 3 .	Thre ad 75c m, 90c	P G L A 2	1 D oz en 2	

				m, 2, Nee dle 40m m, ½ Circl e Curv ed Cutti ng	1 9	D oz en 3 D oz en		
			3 4 .	Thre ad 75c m, 90c m, 0, Nee dle 40m m, ½ Circl e Curv ed Cutti ng	P G L A 2 2 0	1 D oz en 2 D oz en 3 D oz en		
			3 5	Thre ad 75c m, 90c m, 4/0, Nee dle 16m m, ½ Circl e Curv ed Cutti ng	P G L A 2 2 1	1 D oz en 2 D oz en 3 D oz en		
			3 6	Thre ad 75c m, 90c m, 4/0, Nee dle 20m m, ½ Circl e Curv ed	P G L A 2 2 2	1 D oz en 2 D oz en 3 D oz en		

			<table><tr><td></td><td>Cutting</td><td></td><td></td></tr><tr><td>37</td><td>Thread 75cm, 90cm, 4/0, Needle 16mm, 1/2 Circle Round Bodied</td><td>PGLA 22 D 3 en 3 D oz en</td><td>1</td></tr></table>		Cutting			37	Thread 75cm, 90cm, 4/0, Needle 16mm, 1/2 Circle Round Bodied	PGLA 22 D 3 en 3 D oz en	1					
	Cutting															
37	Thread 75cm, 90cm, 4/0, Needle 16mm, 1/2 Circle Round Bodied	PGLA 22 D 3 en 3 D oz en	1													
310.	<p>Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Rs 62,030 Paid on 19/05/2025 Challan # 07706326549</p> <p>Date of R& I 14th April 2025</p>	<p><u>Legal Manufacturer:</u> NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD</p> <p><u>Manufacturing Site:</u> YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS ZONE, 315199, NINGBO, CHINA</p> <p>Copy of FQA valid till 23.11.2028</p> <p>Copy of DEC valid till 23.11.2028</p> <p><u>Copy of LOA:</u> Sole Agency Agreement (Notarized by CCPIT, Valid till Jan. 2029</p> <p><u>Copy of FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health) REGISTRATION NUMBER: 2023YB2690 DATE OF REGISTRATION STATUS: 2024 Valid Upto: Dec, 2025</p> <p><u>Copy of ISO:</u></p>	<p>Brand Name: YINGMED ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE Class D</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes:</p> <table><tr><th>S . N o</th><th>DES CRI PTI ON</th><th>G B C O D E</th><th>Pa ck siz e(s)</th></tr><tr><td>1 .</td><td>Thread 75cm, 90cm, 0, Needle 30mm, 1/2 Circle Round Bodied</td><td>PGLA 101 D 3 D en</td><td>1 oz 2 D oz en</td></tr><tr><td>2 .</td><td>Thread 75cm, 90cm, 0, Needle</td><td>PGLA 102 D 2 oz</td><td>1 oz en</td></tr></table>	S . N o	DES CRI PTI ON	G B C O D E	Pa ck siz e(s)	1 .	Thread 75cm, 90cm, 0, Needle 30mm, 1/2 Circle Round Bodied	PGLA 101 D 3 D en	1 oz 2 D oz en	2 .	Thread 75cm, 90cm, 0, Needle	PGLA 102 D 2 oz	1 oz en	<p>Deferred for submission of the following documents:</p> <p>Submit apostille or legalized FSC issued by concerned regulatory authority of China. Clarify the brand name applied and in the FSC. clarify the codes applied since it is neither present in the CE certificate nor in the FSC.</p> <p>Submit notarized and valid LOA, ISO 13485 and FQA and Design examination certificate.</p> <p>Submit Fee slip submitted in DRAP.</p>
S . N o	DES CRI PTI ON	G B C O D E	Pa ck siz e(s)													
1 .	Thread 75cm, 90cm, 0, Needle 30mm, 1/2 Circle Round Bodied	PGLA 101 D 3 D en	1 oz 2 D oz en													
2 .	Thread 75cm, 90cm, 0, Needle	PGLA 102 D 2 oz	1 oz en													

		ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026		dle 35m m, ½ Circl e Rou nd Bodi ed		en 3 D oz en		
			3	Thre ad 75c m, 90c m, 0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 3	1 D oz en 2 D oz en 3 D oz en		
			4	Thre ad 75c m, 90c m,1, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 4	1 D oz en 2 D oz en 3 D oz en		
			5	Thre ad 75c m, 90c m, 1, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 5	1 D oz en 2 D oz en 3 D oz en		

			6	Thre ad 75c m, 90c m, 2, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 6	1 D oz en 2 D oz en 3 D oz en
			7	Thre ad 75c m, 90c m, 2/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 7	1 D oz en 2 D oz en 3 D oz en
			8	Thre ad 75c m, 90c m, 2/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 1 0 8	1 D oz en 2 D oz en 3 D oz en
			9	Thre ad 75c m, 90c m, 2/0, Nee dle	P G A 1 0 9	1 D oz en 2 D oz en 3

				35m m, ½ Circl e Rou nd Bodi ed		D oz en		
			1 0 .	Thre ad 75c m, 90c m, 2/0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G A 1 1 0	1 D oz en 2 D oz en 3 D oz en		
			1 1 .	Thre ad 75c m, 90c m, 3/0, Nee dle 20m m, ½ Circl e Rou nd Bodi ed	P G A 1 1 1	1 D oz en 2 D oz en 3 D oz en		
			1 2 .	Thre ad 75c m, 90c m, 3/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed	P G A 1 1 2	1 D oz en 2 D oz en 3 D oz en		

			1 3 .	Thre ad 75c m, 90c m, 3/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 1 1 3	1 D oz en 2 D oz en 3 D oz en		
			1 4 .	Thre ad 75c m, 90c m, 4/0, Nee dle 16m m, ½ Circl e Rou nd Bodi ed	P G A 1 1 4	1 D oz en 2 D oz en 3 D oz en		
			1 5 .	Thre ad 75c m, 90c m, 0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 2 0 1	1 D oz en 2 D oz en 3 D oz en		
			1 6 .	Thre ad 75c m, 90c m, 0, Nee dle 60m	P G A 2 0 2	1 D oz en 2 D oz en 3		

				m, Strai ght Cutti ng		D oz en		
			1 7 .	Thre ad 75c m, 90c m, 1, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 2 0 3	1 D oz en 2 D oz en 3 D oz en		
			1 8 .	Thre ad 75c m, 90c m, 1, Nee dle 35m m, ½ Circl e Rou nd Bodi ed	P G A 2 0 4	1 D oz en 2 D oz en 3 D oz en		
			1 9 .	Thre ad 75c m, 90c m, 1, Nee dle 40m m, ½ Circl e Curv ed Cutti ng	P G A 2 0 5	1 D oz en 2 D oz en 3 D oz en		
			2 0 .	Thre ad 75c m, 90c m,	P G A 2 0 6	1 D oz en 2 D		

				2/0, Nee dle 25m m, ½ Circl e Rou nd Bodi ed		oz en 3 D oz en		
		2 1 .	Thre ad 75c m, 90c m, 2/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 2 0 7	1 D oz en 2 D oz en 3 D oz en			
		2 2 .	Thre ad 75c m, 90c m, 2/0, Nee dle 16m m, ½ Circl e Curv ed Cutti ng	P G A 2 0 8	1 D oz en 2 D oz en 3 D oz en			
		2 3 .	Thre ad 75c m, 90c m, 2/0, Nee dle 35m m, ½ Circl e Curv	P G A 2 0 9	1 D oz en 2 D oz en 3 D oz en			

				ed Cutti ng			
			2 4 .	Thre ad 75c m, 90c m, 2/0, Nee dle 60m m, Strai ght Cutti ng	P G A 2 1 0	1 D oz en 2 D oz en 3 D oz en	
			2 5 .	Thre ad 75c m, 90c m, 2/0, Nee dle 40m m, ½ Circl e Rou nd Bodi ed	P G A 2 1 1	1 D oz en 2 D oz en 3 D oz en	
			2 6 .	Thre ad 75c m, 90c m, 3/0, Nee dle 30m m, ½ Circl e Rou nd Bodi ed	P G A 2 1 2	1 D oz en 2 D oz en 3 D oz en	
			2 7 .	Thre ad 75c m, 90c m, 3/0,	P G A 2 1 3	1 D oz en 2 D oz	

				Bodi ed			
			3 1 .	Thre ad 75c m, 90c m, 4/0, Nee dle 16m m, ½ Circl e Rou nd Bodi ed	P G A 2 1 7	1 D oz en 2 D oz en 3 D oz en	
			3 2 .	Thre ad 75c m, 90c m, 4/0, Nee dle 25m m, ½ Circl e Curv ed Cutti ng	P G A 2 1 8	1 D oz en 2 D oz en 3 D oz en	
			3 3 .	Thre ad 75c m, 90c m, 2, Nee dle 40m m, ½ Circl e Curv ed Cutti ng	P G A 2 1 9	1 D oz en 2 D oz en 3 D oz en	
			3 4 .	Thre ad 75c m, 90c m, 0,	P G A 2 2 0	1 D oz en 2 D	

					Bodi ed				
311.	Schazoo SPL Consumer Healthcare, 71 B/C2, Gulberg 3, Lahore, Pakistan. ELI-00095	Legal Manufacturer: Biopharma S.r.l Address: Via Castelliere, 2, 33036, Metro di tomba UD, Italy. Original FSC: Italy. Date of Issuance: 03-12-2024. Notarized Copy of LOA 09.01.2024 issue date DEC valid till 26.05.2024 FQA valid till 26.05.2024	Vijoint Hyaluronic Acid Shelf Life: 36 months at 25 ⁰ C +/- 2 ⁰ C Class D Fee 62000/-	Approved. The firm shall submit notarized and original LOA.					
312.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120	M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA M/s Boston Scientific Corporation 302 Parkway, Global Park, Heredia, Costa Rica Copy of FSC od USFDA valid till 05.11.2025. Copy of 3 FSC of Ireland two issued on 10.06.2024 Third FSC issued on 15.7.2024 EU technical documentation 2.09.2027 EU QMS valid till 2.09.2027 ISO 13485 Valid till 01.09.2026	Farapulse™ Pulsed Field Ablation System Pulse Field Ablation Catheter Catheter Connection Cable Class D 24 Months(2) N/A FARASTAR Pulsed Field Ablation Generator M004PFCE61M401 M004PFCE61M407 Electronic Components- Shelf Life Not Applicable FARAWAVE Catheter M004PFCE41M401 M004PFCE41M402 24 months FARASTAR Connection Cable M004PF41M434 24 months ACCESSORIES M004PF61M404 M004PF61M405 M004PF61M409	Deferred for submission of the following: Submit apostille/ legalized FSC of USFDA or reference country for the applied products. multiple products applied in single application. Identify which product to be considered for this application and apply other products separately along with applicable fee. Clarify and Align the brand name applied and present in the FSC on revised Form7-A. Submit stability studies for this product mentioning name of product.					

			M004PF61M408 M004PF61M410 M004PF61M411 M004PF61M412 M004PF61M413 M004PF61M415 M004PF61M416 M004PF61M417 M004PF61M420 M004PF61M421 Electronic Components- Shelf Life Not Applicable (Attached as annexure: 04) Fee 100000/-	
313.	Melamine Emporium, 814, Star City Mall, Saddar Karachi (ELI-00414)	Lepu Medical Technology (Beijing) Co, No. 37 Chaoqian Road, Changping District Beijing 102200, China <u>Copy of FSC of china:</u> . <u>Date of Issuance:</u> valid till 28.09.2024 <u>Copy of FSC of netherlands:</u> . <u>Date of Issuance:</u> valid till 27.05.2024 Notarized Copy of LOA 31.12.2026 issue date ISO 13485 valid till 6.03.2026 DEC valid till 27.05.2024 FQA valid till 27.05.2024 Fee Rs 50000	GuReater™ CoCr Sirolimus-eluting Coronary Stent System shelf life 02 years Codes LPRPC2208 LPRPC2508 LPRPC2708 LPRPC2212 LPRPC2512 LPRPC3008 LPRPC3508 LPRPC4008 LPRPC4512 LPRPC2712 LPRPC3012 LPRPC3512 LPRPC4012	Deferred for submission of the Apostille/ legalized and valid FSC of country of origin. Apostille/ legalized and valid FSC of reference country or Notarized and valid Design examination certificate and ISO 13485 certificate Notrized LOA. Differential fee as per new SRO for system and for additional codes more than 20.

			LPRPC4515	
			LPRPC2215	
			LPRPC2515	
			LPRPC2715	
			LPRPC3015	
			LPRPC3515	
			LPRPC4015	
			LPRPC4518	
			LPRPC2221	
			LPRPC2218	
			LPRPC2518	
			LPRPC2718	
			LPRPC3018	
			LPRPC3518	
			LPRPC4018	
			LPRPC4521	
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			LPRPC3024	
			LPRPC3524	
			LPRPC4024	
			LPRPC4529	
			LPRPC2729	
			LPRPC3029	
			LPRPC3529	

			LPRPC2224 LPRPC2524 LPRPC2229 LPRPC2529 LPRPC4029 LPRPC4533 LPRPC2233 LPRPC2533 LPRPC2733 LPRPC3033 LPRPC3533 LPRPC4033 LPRPC4536 LPRPC2236 LPRPC2536 LPRPC2736 LPRPC3036 LPRPC3536 LPRPC4036	
314.	Applicant Name: M/s ACP Systems 13&23 Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi ELI-00001 Date of R& I 18.04.2025 Fee: PKR 62000/- Slip: 573709244	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028 Shelf Life: not provide	Brand name: HeartMate Touch Communication System (Touch Communication System) Model: HMT1150 Components: 1- Power Adapter for HeartMate Touch Communication System HMT2133. 2- USB Cable for HeartMate Touch Communication System HMT2166. 3- Flash Drive for HeartMate Touch Communication System HMT2900. Fee 62000/-	Deferred for following: submission of the differential fee of RS 38000/- The components mentioned are not present in the FSC. The HeartMate Touch™ Communication System (Model: HMT1150) was subject to a Class I recall by USFDA initiated by Abbott on January 3, 2024. This recall was due to a software issue in version 1.0.32, which could lead to unintended pump start or stop events.

			Class D	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205152 Therefore, provide following details: - What is the exact product model and software version currently installed on the device(s) intended for import? - Provide evidence that the units proposed for import are compliant with post-recall updates. - Current software version and how does it prevent the known issue (unintended pump start/stop) which was the reason of Class I recall by USFDA? - Copy of the latest Instructions for Use (IFU) and software release notes. Has this product been cleared for use post-recall in its country of origin? If yes, please provide the evidence
315.	Applicant Name: M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18-04-2025 Fee: Rs.62000 Slip: 31788176	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028	Brand name: HeartMate 3 Surgical Hand Tools – 10002222INT Class D Shelf Life: nil years	Deferred for clarification of recall as given below. The HeartMate 3 Surgical Hand Tools used in HeartMate 3 Left Ventricular Assist System (LVAS) via the HeartMate Touch Wireless Adapter was subject to a Class I recall by USFDA initiated by Abbott on January 3, 2024. This recall was due to a software issue in version 1.0.32, which could lead to unintended pump start or stop events. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205152

				s/cfres/res.cfm?id=205152 <p>therefore provide details including provision of Current status of recall of HeartMate 3 Left Ventricular Assist System (LVAS) via the HeartMate Touch Wireless Adapter in which these hand tools will be used. Has this product been cleared for use post-recall in its country of origin? If yes, please provide the evidence</p>
316.	Applicant Name: M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18.04.2025 Fee: Rs.62000 Slip: 4909987157	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028	Brand name: HeartMate Apical Coring Knife Model: 1050 Class D Shelf Life: 03 years Fee 62000/- DOC: 26.04.2024	Deferred for clarification of recall as given below HeartMate Apical Coring Knife used in HeartMate 3 Left Ventricular Assist System (LVAS) was subject to a Class I recall by USFDA initiated by Abbott on January 3, 2024. This recall was due to a software issue in version 1.0.32, which could lead to unintended pump start or stop events. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205152 <p>therefore following details be provided: Current status of recall with all details for HeartMate 3 Left Ventricular Assist System (LVAS) via the HeartMate Touch Wireless Adapter in which Apical Coring Knife will be used. Has this product been cleared for use post-recall in its country of origin? If yes, please provide the evidence</p>
317.	Applicant Name:	Legal Manufacturer:	Brand name:	Deferred for clarification of recall as given below:

	<p>M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18.04.2025</p> <p>Fee: Rs.62000 Slip: 673039094464</p>	<p>Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA</p> <p>Apostille FSC: (US FDA) Validity:12/06.2026</p> <p>Notarized LOA: valid date: 31.12.2026</p> <p>ISO 13485 Validity: 20-02-2028</p> <p>QMSC validity: 30.03.2028 EU technical documentation 25.07.2028</p>	<p>HeartMate 3 Tunneling Lance and Handle – 10010372GB</p> <p>Class D</p> <p>Shelf Life: nil years Fee 62000/-</p>	<p>HeartMate 3 Tunneling Lance and Handle used in HeartMate 3 Left Ventricular Assist System (LVAS was subject to a Class I recall by USFDA initiated by Abbott on January 3, 2024. This recall was due to a software issue in version 1.0.32, which could lead to unintended pump start or stop events.</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205152</p> <p>therefore following details required: Current status of recall with all details of HeartMate 3 Left Ventricular Assist System (LVAS) via the HeartMate Touch Wireless Adapter in which HeartMate 3 Tunneling Lance and Handle will be used. Has this product been cleared for use post-recall in its country of origin? If yes, please provide the evidence</p>
318.	<p>Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad.</p> <p>ELI-00442</p>	<p>Legal Manufacturer: Assure Tech (Hangzhou) Co., Ltd</p> <p>Address: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China.</p> <p>FSC: Date of Issuance: 19-02-2025. Apostille china FSC: Validity:19.02.2027</p> <p>Notarized LOA: valid date: 18.02.2028</p> <p>ISO 13485 Validity: 08.02.2025</p>	<p>INST ANSWER HBsAg Rapid Test</p> <p>HBsAg Rapid Test</p> <p>Shelf Life: 24 month 2-30°C</p> <p>Fee 62000/-</p>	<p>Deferred for submission of the following:</p> <p>Legalized and valid FSC of country o origin clearly reflecting the Free Sale Status of the product.</p> <p>Legalized and valid FSC of any Refrence country OR Notarized and valid FQA and Design examination certificate.</p> <p>Product codes not mentioned.</p>
319.	Mian Scientific	Legal Manufacturer:	INST ANSWER Hepatitis C	Deferred for submission

	Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad. ELI-00442	Assure Tech (Hangzhou) Co., Ltd <u>Address:</u> Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China. <u>FSC:</u> China. <u>Date of Issuance:</u> 19-02-2025. Apostille china FSC: Validity:19.02.2027 Notarized LOA: valid date: 18.02.2028 ISO 13485 Validity: 08.02.2025	Virus-HCV Rapid Test Hepatitis C Virus-HCV Rapid Test <u>Shelf Life:</u> 24 month 2-30°C Fee 62000/-	of the following: Legalized and valid FSC of country o origin clearly reflecting the Free Sale Status of the product. Legalized and valid FSC of any Refrence country OR Notarized and valid FQA and Design examination certificate. Product codes not mentioned.
320.	Mian Scientific Corporation (Pvt) Ltd, 534-Jinnah Colony Faisalabad. ELI-00442	<u>Legal Manufacturer:</u> Assure Tech (Hangzhou) Co., Ltd <u>Address:</u> Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China. <u>Original FSC:</u> China. <u>Date of Issuance:</u> 19-02-2025. Apostille china FSC: Validity:19.02.2027 Notarized LOA: valid date: 18.02.2028 ISO 13485 Validity: 08.02.2025	INST ANSWER Human Immunodeficiency Virus-HIV Rapid Test kit Human Immunodeficiency Virus-HIV Rapid Test Class D Fee 62000/- <u>Shelf Life:</u> 24 month 2-30°C	Deferred for submission of the following: Legalized and valid FSC of country o origin clearly reflecting the Free Sale Status of the product. Legalized and valid FSC of any Refrence country OR Notarized and valid FQA and Design examination certificate. Product codes not mentioned.

Item No. III(b): REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURING

S#	Importer Name	Name of Medical Device/ Class / Shelf life / Codes / etc	Decision
1.	Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate	Silon (Silver Coated Dressing)	Deferred for following.

	<p>Sargodha Road Faisalabad (ELM-0019 valid till 06-04-2025) [623-7L] R & I: 21265 dated 11-12-2024</p> <p>Approved Sections/Medical devices: 1. Gauze Section (Sterile/Non-Sterile) 2. Eye Pad Section (Sterile) 3. Tulle Section (Sterile) 4. Surgical Bandage Section 5. Sponge Section (Sterile) 6. Crepe Bandage Section</p>	<p>Strength: Silver.....1.0g/m² Class: C Sizes: 4 inch × 4 inch 4 inch × 8 inch 8 inch × 16 inch 16 inch × 16 inch 4 inch × 48-inch Roll 2 inch × 2 inch 5 inch × 5 inch</p> <p>Shelf Life: 3 Years Fee: 25,000/- Fee Slip No. 3915283854</p>	<ul style="list-style-type: none"> • Submission of sample label • Clarification of manufacturing steps to be performed by the applicant
2.	<p>Caraway Diagnostics, Plot No. 12, Street N-3, National Industrial Zone Rawat, Rawalpindi (ELM-0092) [959-6L] D. No. 13316 dated 16-05-2025. License permits the manufacture of following medical devices in Liquid Section for IVD Products; 1. Diluent for Hematology Analyzer, 2. Cleaning Solution for hematology analyzer 3. Lyse (IVD) 4. Reagent for quantitative determination of Hemoglobin (Hb) 5. -Reagent for quantitative determination of Total Protein 6. Reagent for quantitative determination of Creatinine 7. Reagent for quantitative determination for Bilirubin.</p>	<p>Lyse-CA (Cell Diluent or Erythrocyte / Lysis Diluent)</p> <p>INGREDIENTS: Surfactants.....<3.5% Buffers ... <1.0 % Preservative...<0.5% Stabilizers...<0.5% in ion-free water Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 6312751844</p>	<p>Approved with shelf life of 2 years. The firm will submit Sample label of the product before issuance of enlistment letter.</p>
3.	<p>M/s Renacon Pharma Ltd. Plant Address: Plot No. 6, Phase-II, Faisalabad Industrial Estate, Development & Management Company (FIEDMC), Faisalabad. (ELM-0024 valid till 19-09-2025.) [929-7L] D. No. 13326 dated 16-05-2025</p> <p>Approved Section: 1. Hemodialysis Concentrate Section</p>	<p>RENACARB-C Hemodialysis Concentrate Composition: Part A: (Before Dilution). Sodium chloride...210.89 g/l Potassium chloride....5.22 g/l Calcium chloride.... 6.43 g/l Magnesium chloride....5.33g/l Glucose Acetic acid....10.5 g/l L-Ascorbic acid.... 0.5 g/l Glucose....34.65 g/l Part B: (After reconstitution) Sodium Bicarbonate...84 g/l</p> <p>Class: C Shelf Life: 3 Years</p> <p>Fee: 25000 Fee Slip No. 81176633</p>	<p>Approved with shelf life of 2 years.</p>
4.	<p>Sayyed Healthcare Limited, 37 Allama Iqbal Industrial City, Faisalabad (ELM-0079 valid till 18-04-2029.) [930-7L]</p>	<p>Healthcare + Disposable Syringes 1cc (Needle dimension: 26G × 1/2inches TW (0.45 mm × 13 mm) Class: B</p>	<p>Deferred for confirmation of manufacturing facility for 1 cc disposable syring.</p>

	D. No. 13327 dated 16-05-2025 Approved Sections: 1. Syringes (Auto-disposable Syringe) Section 2. IV Set Section	Shelf Life: 5 Years Fee: 25000 Fee Slip No. 620916212567	
5.	Surgi Plast, Plot No.78, Road L-4, Industrial Estate, Gadoon Amazai, Swabi, KPK (ELM-0030 valid till 10-06-2021, Renewal application submitted dated 02-06-2021) [928-7L] D. No. 13532 dated 19-05-2025 Additional Sections approved vide letter No.F.4-13/2025-Md (M-89 dated 13-05-2025). 1. Butterfly Needle Section/Facility 2. IV cannula (Packing, Labelling, Sterilization and Testing) Section/Facility	Clinic IV Cannula with Different Gauge Needle (16G/18G/20G/21G/22G/24G/26G) IV Disposable Cannula with different Gauge needle (16G/18G/20G/21G/22G/24G/26G) Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 2064126991	Deferred for following; • No sign/stamp on application form. • Sample label not provided. • Type of cannula
6.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097 valid till 14-05-2030) [931-6L] D. No. 13943 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Doctor Cap Doctor Cap Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 9253346351	Approved with a shelf-life of two (02) years.
7.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [932-6L] D. No. 13944 dated 20-05-2025 Approved Sections: Approved Sections:	Medi Plus Abdominal Binder Abdominal Binder Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 10813028346	Approved with a shelf-life of two (02) years.

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
8.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [933-6L] D. No. 13945 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Digital Thermometer Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 47202210	Deferred for confirmation of manufacturing facility (Section) in which the applied product to be manufactured.
9.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [934-6L] D. No. 13946 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section	Medi Plus Philadelphia Collar Class: A Model: PC-1125 Size: S, M, L, XL, XXL Shelf Life: 5 Years Fee Slip Not attached	Approved with a shelf-life of two (02) years. The firm shall submit evidence of fee submitted.

	iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
10.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [935-6L] D. No. 13947 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Shoe Cover Class: A Model: SC-1790 (Non-woven) SC-1690 (Polythene) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 93461489	Approved with shelf-life of two (02) years.
11.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [936-6L] D.No. 13948 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag	Medi Plus Adhesive Plaster Class: A Model: AP-2000 (1inch, 2 inch, 3 inch, 4 inch) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 9383608032	Deferred for confirmation of requisite manufacturing facility (section) in which the applied product to be manufactured.

	<p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clam</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
12.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [937-6L]</p> <p>D. No. 13949 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clam</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Face Mask KF-94</p> <p>Size: Adult Size (Standard)</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 8074109034</p>	<p>Approved with shelf-life of two (02) years.</p>
13.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [938-6L]</p> <p>D. No. 13950 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clam</p>	<p>Medi Plus Drape Sheet</p> <p>Class: A</p> <p>Model: DS-1690</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 8743439330</p>	<p>Approved.</p> <p>The firm shall submit exact configurations.</p>

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
14.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [939-6L] D. No. 13951 dated 20-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clam vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Abdominal Support Class: A Model: AB-1220 Size: S, M, L, XL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 833689379	Approved with shelf-life of two (02) years.
15.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [940-6L] D. No. 13952 dated 20-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clam vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only)	Medi Plus Disposable Isolation Gown Class: A Model: IG-1690 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 35612223827	Approved with shelf-life of two years.

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
16.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [941-6L] D. No. 13953 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clam</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Stethoscope</p> <p>Class: A Model: DHS-3330 (Stethoscope Dual Head), DHS-3320 (Stethoscope Single Head) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3633121355</p>	<p>Deferred for confirmation of requisite manufacturing facility (Section) in which applied product to be manufactured and steps of manufacturing need to be clarified.</p>
17.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [942-6L] D. No. 13954 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clam</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Ankle Support</p> <p>Class: A Model: AP-2000 Size: S, M, L, XL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 09833737802</p>	<p>Approved with shelf-life of two (02) years.</p>
18.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad</p>	<p>Medi Plus Nurse Cap</p> <p>Class: A</p>	<p>Deferred for justification of the applied product claimed</p>

	(ELM-0097) [943-6L] D. No. 13955 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Model: NC-1690 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 13005433061	to be a medical device with evidence.
19.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [944-6L] D. No. 13956 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Face Mask Class: A Model: FM-1125 (Adult STD) FM-1128 (Adult STD) CFM-1125 (Child) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1059472048	Approved with shelf-life of two (02) years.
20.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [945-6L] D. No. 13957 dated 20-05-2025 Approved Sections:	Medi Plus Diabetic Socks Class: A Model: DS-2010 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 304572675623	Approved with shelf-life of two (02) years.

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
21.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [946-6L] D. No. 13958 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Paper Tape Class: A Code: PT-2015 Size: half inch, 1, 2, 3, 4 inch Shelf Life: 5 Years Fee: 6000 Fee Slip No. 400664894192	Deferred for confirmation of requisite manufacturing facility (section) and submission of sample label.
22.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [947-6L] D. No. 13959 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine	Medi Plus Face Mask KN-95 Class: A Code: KN-1230 (Premium Quality) KN-1235 (Standard Quality) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 71876461860	Approved with shelf-life of two (02) years.

	body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
23.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [948-7L] D. No. 13960 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Surgical Gloves (Powdered) Class: B Code: SG-1090 Size: 6.5, 7, 7.5, 8 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 2387985928	Approved with shelf-life of two years.
24.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [949-7L] D. No. 13961 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)	Medi Plus BP Apparatus (Aneroid) Class: B Model: AS-4030 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 5908092191	Deferred for confirmation of requisite manufacturing (section) facility, steps to be performed by manufacturer, and revision of application form and medical device class.

	v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
25.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [950-7L] D. No. 13962 dated 20-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Umbilical Cord Clamp Class: B Model: CC-1325 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 4814701599	Approved with shelf-life of two years.
26.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [951-7L] D. No. 13963 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only)	Medi Plus Reinforced Gown Class: B Code: RF-2018 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 002699231	Approved with shelf-life of two (02) years.

	ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
27.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [952-7L] D. No. 13964 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Non-Woven Fixation Dressing Roll Class: B Code: FDT-1325 Size: 2.5cm, 5cm, 7.5 cm, 10cm, 15cm Shelf Life: 5 Years Fee: 25000 Fee Slip No. 853044245	Deferred for clarification how the Non-woven fixation dressing roll differs from Non-woven tape and submission of Justification for classifying the applied product in 'Class B' with documentary evidence.
28.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [953-7L] D. No. 13965 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus BP Apparatus (Digital) Class: B AS-4031 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 39210554	Deferred for confirmation of requisite manufacturing facility (section) and steps of manufacturing to be performed by applicant and Justification for classifying the applied product in 'Class B' with documentary evidence.
29.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad	Medi Plus IV Cannula (Import, Packing & Sterilization) Class: B	Deferred for clarification of source of bulk cannula and type of cannula applied.

	<p>(ELM-0097) [954-7L] D. No. 13966 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Model: IV-P 2100 Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G IV-S 2100 Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G Shelf Life: 5 Years Fee: 25000 Fee Slip No. 0116605660</p>	
30.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [955-7L] D. No. 13967 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts)</p>	<p>Medi Plus Non-Woven Tape Class: B Code: NWT-1800 Sizes: 1, 2, 3 & 4 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 21469469</p>	<p>Deferred for clarification how the Non-woven fixation dressing roll differs from Non-woven tape and submission of Justification for classifying the applied product in 'Class B' with documentary evidence.</p>
31.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [956-7L] D. No. 13968 dated 20-05-2025 Approved Sections:</p>	<p>Medi Plus Anti-Embolism Stocking Class: B Codes: AES-K2786 (Knee High) AES-T2787 (Thigh-high) AES-W2788 (Waist High) Shelf Life: 5 Years</p>	<p>Approved in class A with shelf-life of two (02) years.</p>

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Fee: 25000 Fee Slip No. 6662466923	
32.	Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate Sargodha Road Faisalabad (ELM-0019 valid till 06-04-2025) [960-6L] D. No. 15090 dated 27-05-2025 Approved Sections/Medical devices: 1. Gauze Section (Sterile/Non-Sterile) 2. Eye Pad Section (Sterile) 3. Tulle Section (Sterile) 4. Surgical Bandage Section 5. Sponge Section (Sterile) 6. Crepe Bandage Section	Sterimax-Ortho Orthopedic Padding Class: A Sizes: 7.5 cm × 2.7m 10cm × 2.7 m 15cm × 2.7 m Shelf Life: 5 Years Fee: 6000 Fee Slip No. 95798656	Deferred for following. • Submission of sample label
33.	Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate Sargodha Road, Faisalabad. (ELM-0019 valid till 06-04-2025) [961-6L] D. No. 15089 dated 27-05-2025 Approved Sections/Medical devices: 1. Gauze Section (Sterile/Non-Sterile) 2. Eye Pad Section (Sterile) 3. Tulle Section (Sterile) 4. Surgical Bandage Section 5. Sponge Section (Sterile) 6. Crepe Bandage Section	Sterimax-Absorbent Cotton Wool BPC Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 265186865359	Deferred for following. • Submission of sample label
34.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [1052-6L] Dy. No. 15039 dated 27-05-2025 Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings	Glim Semi-Automatic Biochemistry Analyzer BA-SA-100D Kinetic, End point, Two point, Absorbance Class: A Shelf Life: Not Mentioned Fee: Rs 6000/- Fee Slip No. 8036012385	Deferred for confirmation of requisite manufacturing facility (section), submission of application form complete in all respects, Manufacturing and quality control process, shelf life/service life,

	iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)		
35.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [962-6L] D. No. 15355 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Hernia Aid Abdominal Hernia Support Configuration code: HA-1130 Sizes: S, M, L, XL, XXL Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 72921584751	Approved with shelf-life of two (02) years.
36.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [963-7L] D. No. 15333 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only)	Medi Plus Surgical Dressing Configuration codes and size of dressing: SD-7552 (9cm X 10cm), SD-7553 (9cm X 15cm), SD-7554 (9cm X 20cm), SD-7555 (9cm X 25cm), SD-7556 (9cm X 30cm) Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 389235304	Deferred for confirmation of requisite manufacturing facility nad steps to be performed.

	ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
37.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [964-7L] D. No. 15335 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Posture Alignment Support Class: B Configuration code: PA-1140 (S, M, L, XL, XXL) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 61379228571	Approved with shelf life of 2 years.
38.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [965-7L] D. No. 15336 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Alcohol Swab (70 % v/v Isopropyl Alcohol Swabs) Class: B Model: AS-1295 Size: 3 cm × 6 cm Shelf Life: 5 Years Fee: 25000 Fee Slip No. 462497459	Approve in class A.

39.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [966-6L] D. No. 15326 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Infrared Forehead Thermometer</p> <p>Class: A Configuration Code: IT-500 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1153572490</p>	<p>Deferred for confirmation fo requisite manufacturing facility and steps to be performed.</p>
40.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [967-6L] D. No. 15328 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Air Mattress (Medical Pressure Relief Air Mattress)</p> <p>Class: A Code: AM-2510 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 33136855935</p>	<p>Deferred for confirmation of requisite manufacturing facility (section) and class of the applied product.</p>
41.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [968-6L]</p>	<p>Medi Plus P.E Tape</p> <p>Class: B Model: PET-2100 Sizes: 1, 2, 3, 4 inches</p>	<p>Deferred for confirmation of requisite manufacturing facility and clarification how the applied product Polyethyelene (P.E) differs</p>

	D. No. 15331 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Shelf Life: 5 Years Fee: 25000 Fee Slip No. 33283706297	from “Medi Plus Non-Woven Fixation Dressing Roll” and “Medi Plus Non-Woven Tape”, also applied for enlistment.
42.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [969-6L] D. No. 15321 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Heel Cover Heel protector Class: A HC-1355 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 207161885732	Approved.
43.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [970-6L] D. No. 15324 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section	Medi Plus Triangular Bandage Class: A Model: TB-3338 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 224952055	Approved with shelf-life of two (02) years.

	iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
44.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [971-6L] D. No. 15327 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Knee Immobilizer (Knee Orthosis) Class: A Configuration Code: KI-1150 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 706990748	Approved with shelf-life of two (02) years.
45.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [972-6L] D. No. 15329 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag	Medi Plus Cervical Collars Hard Class: A Configuration Code: CH-1170 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4757968228	Approved with shelf-life of two (02) years.

	<p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
46.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [973-6L]</p> <p>D. No. 15347 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Lace Pull (Lumbo Sacral Belt)</p> <p>Class: A</p> <p>Model Name: LP-3570</p> <p>Sizes: S, M, L, XL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 006662372</p>	Approved with shelf-life of two years.
47.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [974-6L]</p> <p>D. No. 15347 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p>	<p>Medi Plus Toe Finger Protector</p> <p>Class: A</p> <p>TFP-1210 (S, M, L)</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 3620530930</p>	Approved with shelf-life of two (02) years.

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
48.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [975-7L] D. No. 15347 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Nebulizer Mask Kit Class: B Sizes: Mini, Adult Shelf Life: 5 Years Fee: 25000 Fee Slip No. 8999463682	Approved with shelf-life of two (02) years.
49.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [976-7L] D. No. 15347 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only)	Medi Plus Mesh Nebulizer (Vibrating Mesh Nebulizer) Class: B Configuration Code: MNB-1540 Capacity: Small Capacity (2-5ml) Medium Capacity (6-10 ml) Large Capacity (>10ml) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 26041804121	Deferred for confirmation of requisite manufacturing facility (section).

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
50.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [977-7L] D. No. 15347 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Corn Plaster</p> <p>Class: B</p> <p>Configuration Code: CP-1540</p> <p>Sizes: S, M, L</p> <p>Shelf Life: 5 Years</p> <p>Fee: 25000</p> <p>Fee Slip No. 578755782492</p>	<p>Deferred for</p> <ul style="list-style-type: none"> • Confirmation of version (whether medicated or non-medicated) required as Keratolytic agent (Salicylic acid) mentioned in application form, however, in brand name the version not specified /mentioned. • For requisite manufacturing facility (Section) in which applied product to be manufactured. • Based upon declared versions, the medical device class will be classified accordingly.
51.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [978-6L] D. No. 15330 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Hallus Valgus Splint (Toe Orthosis)</p> <p>Class: A</p> <p>HVS-4050</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 428201637</p>	<p>Approved with shelf-life of two (02) years.</p>
52.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad</p>	<p>Medi Plus Ultrasound Gel (Ultrasound Coupling Gel)</p> <p>Configuration codes:</p>	<p>Approved with shelf-life of two (02) years.</p>

	<p>(ELM-0097) [979-6L] D. No. 15331 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>UTG-2410 UTG-2425 UTG-2450 UTG-24100 Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 86054101838</p>	
53.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [980-7L] D. No. 15341 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Skin Traction Kit Configuration code: ST-1285 Sizes: Adult, Child, Infant Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 175996150588</p>	<p>Deferred as clarification required for classifying the applied product in Class B with documentary evidence or else submit application Form (Form 6) for Class A medical device.</p>
54.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [981-6L] D. No. 15342 dated 29-05-2025 Approved Sections:</p>	<p>Medi Plus Tubi Grip Support Class: A Configuration code: TG-1125 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years</p>	<p>Approved with shelf-life of two (02) years.</p>

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Fee: 6000 Fee Slip No. 871675455759	
55.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [982-7L] D. No. 15338 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Drainage Bottle Class: B Configuration Code: DB-2335 Capacity: 400ml, 500ml, 1000ml, 2000ml Shelf Life: 5 Years Fee: 25000 Fee Slip No. 575674893	Approve. Firm shall submit clarification whether sterile or non-sterile.
56.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [983-6L] D. No. 15354 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine	Medi Plus Inhaler Spacer (Aerosol Holding Chamber) Class: A Sizes: Small, Medium, Large Shelf Life: 5 Years Fee: 6000 Fee Slip No. 599636956917	Deferred for confirmation of the particular class in which the applied product falls along with evidence.

	<p>Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
57.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [984-7L]</p> <p>D. No. 15363 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Ear Syringe (Ear Irrigation Syringe)</p> <p>Class: B</p> <p>Configuration Code: ES-1020</p> <p>Sizes: 60ml, 90ml</p> <p>Shelf Life: 5 Years</p> <p>Fee: 25000</p> <p>Fee Slip No. 6736115842</p>	<ul style="list-style-type: none"> Deferred for Confirmation of the type of Ear Syringe (whether Bulb-type ear syringe or Piston-type ear syringe) as both types mention in the attached annexures/details to the Application form, but the brand name/title and sample label of the applied product do not specify it. Confirmation of the requisite manufacturing facility.
58.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [985-7L]</p> <p>D. No. 15364 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p>	<p>Medi Plus Vacuum Drainage Bottle</p> <p>Class: B</p> <p>VDB-2335</p> <p>Capacity: 400ml, 500ml, 1000ml, 2000ml</p> <p>Shelf Life: 5 Years</p> <p>Fee: 25000</p> <p>Fee Slip No. 562937206</p>	<p>Approved with shelf-life of two (02) years.</p>

	v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
59.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [986-7L] D. No. 15368 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Gauze Swab Packing & Sterilization only. Class: B Model: GS-1800 Ply count: 8 Ply Size: 10cm × 10cm Shelf Life: 5 Years Fee: 25000 Fee Slip No. 5443685242	Approved in class A.
60.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [987-6L] D. No. 15308 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section	Medi Plus Toe Splint (Toe Immobilizer) Class: A Configuration code: AS-1180 Sizes: Infant, Child, Adult Shelf Life: 5 Years Fee: 6000 Fee Slip No. 10773440	Approved with shelf life of 2 years.

	viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
61.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [988-6L] D. No. 15307 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Band Aid (Adhesive bandage) Class: A Model: BS-2150 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 409699344	Deferred for confirmation of the requisite manufacturing facility (section) and steps of manufacturing to be performed.
62.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [989-6L] D. No. 15320 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only)	Medi Plus Heel Pad (Pressure-Relieving Heel Pad) Class: A Configuration code: HP-1350 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 6094704365	Approved with shelf life of 2 years.

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
63.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [990-6L] D. No. 15317 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Fever Cooling Patch</p> <p>Class: A</p> <p>Configuration code: FP-1136</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 4665440038</p>	Deferred for confirmation of the requisite manufacturing facility (section).
64.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [991-6L] D. No. 15316 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Cervical Collars with Chin Rest</p> <p>Class: A</p> <p>Configuration code: CC-1125</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 42317403</p>	Approved.
65.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad	<p>Medi Plus Cervical Collars Soft</p> <p>Class: A</p>	Approved with shelf-life of two (02) years.

	(ELM-0097) [992-6L] D. No. 15315 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Configuration code: CS-1170 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 562828480	
66.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [993-6L] D. No. 15315 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Finger Frog Splints Class: A Configuration code: FS-1530 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 191494272	Deferred for clarification of the intended use as description showed uses for fingers or toes. While a separate application also submitted for "Medi Plus Toe Splint".
67.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [994-6L] D. No. 15339 dated 29-05-2025 Approved Sections:	Medi Plus Breast Pump Class: B Configuration code: BP-1540 (Breast Pump Silicon) BP-1541 (Breast Pump) Sizes: S, M, L Shelf Life: 5 Years	Approved with shelf-life of two (02) years.

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Fee: 25000 Fee Slip No. 4357033650	
68.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [995-6L] D. No. 15345 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Hot Cold Pack (Hot and Cold Compress Pack) Class: A Configuration Code: HS-1326 Size: 12cm × 24 cm Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1882083741	Deferred for confirmation of the requisite manufacturing facility (section).
69.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [996-7L] D. No. 15340 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)	Medi Plus Steamer Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 6258360159	Approved with shelf-life of two (02) years.

	iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)		
70.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [997-6L] D. No. 15356 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Wrist Brace (Wrist Orthosis) Class: A Configuration code: WS-1131 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 568025084517	Approved with shelf-life of two years.
71.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [998-7L] D. No. 15337 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp	Medi Plus Surgical Drape Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 55020505131	Deferred for clarification since a separate application submitted for "Medi Plus Drape Sheet" with almost same description and intended used. Moreover, separate applications required for the various configurations of Medi Plus Surgical Drape intended to be registered.

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
72.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [999-6L] D. No. 15390 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Sole Pad Class: A Configuration code: SP-1250 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 6780981279	Deferred for confirmation of the requisite manufacturing facility (section) and justification for categorizing the applied product as medical device with documentary evidence.
73.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1000-7L] D. No. 15350 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Nebulizer Machine Class: B Configurations Code: NM-9026 (Nebulizer machine) NM-9025 (Mini Nebulizer Machine) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 337851399241	Deferred for confirmation of the requisite manufacturing facility (section) as firm has approval for the nebulizer machine body. Clarification of manufacturing steps to be performed by applicant

74.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1001-6L] D. No. 15383 dated 29-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders) 	<p>Medi Plus Dental Bib</p> <p>Class: A Configuration Code: DB-1150 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 6065163886</p>	Approved.
75.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1002-6L] D. No. 15385 dated 29-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders) 	<p>Medi Plus Pelvic Binder</p> <p>Class: A Configuration code: PB-6040 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 39020653577</p>	Approved with shelf-life of two (02) years.

Decisions of the additional agenda

APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

S.#	Name of Establishment	Name of Qualified person	Decision
1	M/s Biocare Systems, B143, Block-13, Gulistan-e-Jouhar, Karachi East Gulshan Town, Karachi.	Mr. Muhammad Irtiza Sajjad Qualification: BS Biomedical CNIC No. 42000-6632535-9	Approved for storage of room temperature medical devices.
2	M/s Healthtronics (Pvt) Limited, Ground Floor No.C-259, Block-14, Gulistan-e-Jauhar, Karachi East, Gulshan Town, Karachi.	Mr. Sameer Qualification: BS Biomedical CNIC No. 42501-2652133-7	Approved for storage of room temperature medical devices.
3	M/s Ali International, Momin Flats, Near Grand Hotel Street, University Road Peshawar. Godown Address: Ground Floor, Momin Flats, Grand Hotel Street, University Road, Peshawar.	Mr. Fazli Azim (Pharm.D) CNIC No. 15401-2980717-7	Approved for storage of room temperature medical devices.
4	M/s Diamond Eye Trading (SMC-Private) Limited, Ward No.02, Golarchi, Tehsil Shaheed Fazal Rahu, District, Karachi.		Rejected due to reason that inspection of M/s Diamond Eye (SMS-Private) Ltd, could not be conducted as the address of said facility i.e Ward No.02, Golarchi, Tehsil Shaheed Fazal Rahu, District, Karachi is not correct.

REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURING.

1.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1003-6L] D. No. 15380 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag	Medi Plus Tourniquet Class: A Configuration code: TQ-1395 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 36706216	Approved with shelf life of 2 years.
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	<p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
2.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad.</p> <p>(ELM-0097)</p> <p>[1004-6L]</p> <p>D. No. 15378 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine</p> <p>Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer</p> <p>tourniquet urine bag</p> <p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Heel Gel Socks</p> <p>Class: A</p> <p>Model: HGS-1210</p> <p>Sizes: S, M, L</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 38881049071</p>	<p>Approved with shelf life of 2 years.</p>
3.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad.</p> <p>(ELM-0097)</p> <p>[1005-6L]</p> <p>D. No. 15386 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine</p> <p>Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer</p> <p>tourniquet urine bag</p> <p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p>	<p>Medi Plus Chest Binder</p> <p>Class: A</p> <p>Configuration code: CB-1160</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 8345354039</p>	<p>Deferred for justification/clarification for categorizing the applied product as medical device with documentary evidence.</p>

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
4.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1006-6L] D. No. 15377 dated 29-05-2025</p> <p>Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus P.E Gloves (Polyethylene Gloves)</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 7665922774</p>	<p>Deferred for justification/clarification for categorizing the applied product as medical device with documentary evidence.</p>
5.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1007-6L] D. No. 15376 dated 29-05-2025</p> <p>Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Dignity Sheet</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0569879768</p>	<p>Deferred for confirmation of requisite manufacturing facility (section).</p>
6.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1008-6L] D. No. 15387 dated 29-05-2025</p> <p>Approved Sections:</p>	<p>Medi Plus Elbow Support Configuration Code: ES-1125 Sizes: S, M, L, XL, XXL Class: A</p>	<p>Approved with shelf life of 2 years.</p>

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders	Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1793557560	
7.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1009-6L] R & I. 15372 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders	Medi Plus Oxygen Mask Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 283821115742	Approved with shelf life of 2 years.
8.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1010-7L] R & I. 15369 dated 29-05-2025 Approved Sections: Personal Protective Equipment (PPE) Section Ultrasound Gel Section Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)	Medi Plus Nasal Aspirator Class: B Code: NA-2501 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 0770729498	Deferred for confirmation of the requisite manufacturing (section) facility and confirmation of the particular medical device class.

	EO (Ethylene Oxide) Sterilization Section Blistering / packing Section of IV Cannula / Cord Clamp Surgical Drapes Section Surgical Swab Section (Packing & Sterilization only) Surgical Gloves Section (Packing & Sterilization only) Orthopedic Soft Wears Section (soft braces belts slings and binders)		
9.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1011-6L] R & I. 15388 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Suspensory Bandage Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 586269374	Deferred for confirmation of the requisite manufacturing (section) facility
10.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1012-6L] R & I. 15389 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Wrist Support Class: A Configuration code: WS-1125 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 93473488752	Approved with shelf life of 2 years.

11.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1013-6L] R & I. 15373 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders</p>	<p>Medi Plus Adult Pant</p> <p>Class: A Model: AP-1710 Sizes: S, M, L, XL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 99548243105</p>	<p>Deferred for confirmation of the requisite manufacturing (section) facility</p>
12.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1014-6L] R & I. 15371 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders</p>	<p>Medi Plus Knee Support Padded Patella and Spring Support (Knee Othosis with Lateral Stays and Patella Padding)</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4201776700</p>	<p>Approved with shelf life of 2 years.</p>
13.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1015-7L] R & I. 15370 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section</p>	<p>Medi Plus Dropper</p> <p>Variant code: D-0.5, D-1.0, D-2.0, D-3.0, D-5.0 with capacities as 0.5ml, 1.0ml, 2.0ml, 3.0ml & 5.0ml. Class: B</p>	<p>Deferred for confirmation of the requisite manufacturing facility, clarification regarding five variants being</p>

	iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Shelf Life: 5 Years Fee: 25000 Fee Slip No. 5993301355	applied as a single medical device and justification for assigning same medical device class to all variants.
14.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1016-7L] R & I. 15384 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Medi Plus Gauze Sponge Model Code: GSP-1524 Size: 30 cm× 30 cm Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 38048088	Deferred for justification of classifying the applied product as Class B medical device with documentary evidence.
15.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1017-6L] R & I. 15332 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section	Medi Plus Crepe Bandage Class: A Configuration Code: CP-2867 Sizes: 3 inch, 4 inch, 6 inch Shelf Life: 5 Years Fee: 6000 Fee Slip No. 03670170000	Deferred for confirmation of the requisite manufacturing facility,

	vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
16.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1018-6L] R & I. 15358 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Thumb Splint Class: A Configuration code: TS-1125 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 062065787991	Approved with shelf life of 2 years
17.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1019-6L] R & I. 15359 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Knee Supports Class: A Configuration code: KS-1125 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 239373453979	Approved with shelf life of 2 years
18.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad.	Medi Plus Apron	Deferred for confirmation/justi

	(ELM-0097) [1020-6L] R & I. 15379 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Class: A APR-3035 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 43897568	fication of categorizing the applied product as medical device with documentary evidence And requisite manufacturing facility (section)
19.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1021-6L] R & I. 15323 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Test Tube Class: A Configurations code: TST-2102 (5ml) TST-2103 (10ml) TST-2104 (15ml) TST-2105 (20 ml) TST-2106 (25ml) TST-2107 (30ml) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 9634158179	Deferred for confirmation/justi fication of categorizing the applied product as medical device with documentary evidence And requisite manufacturing facility (section)
20.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1022-6L] R & I. 15325 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine	Medi Plus Dental Floss Class: A Configurations code: DF-3536 Sizes: 10m, 25m, 50m, 100m Shelf Life: 5 Years Fee: 6000 Fee Slip No. 236553760441	Deferred for confirmation of the requisite manufacturing facility (section).

	<p>Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
21.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097)</p> <p>[1023-6L]</p> <p>R & I. 15360 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine)</p> <p>Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Shoulder Support (Orthopedic Shoulder Orthosis)</p> <p>Class: A</p> <p>Configuration code: SS-1175</p> <p>Sizes; S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 84726105644</p>	<p>Approved with shelf life of 2 years</p>
22.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097)</p> <p>[1024-6L]</p> <p>R & I. 15322 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine)</p> <p>Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p>	<p>Medi Plus Finger Cot Splint</p> <p>Class: A</p> <p>Configuration code: FS-1320</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 58930567</p>	<p>Deferred for Clarification as to how the applied product that is 'Medi Plus Finger Cot Splint' differs from "Medi Plus Finger Frog Splints", also applied for enlistment, both products have almost identical composition and intended uses/purposes.</p>

	ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
23.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1025-6L] R & I. 15314 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Palm Support Class: A Configuration code: PS-1125 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0125226491	Approved with shelf life of 2 years
24.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1026-7L] R & I. 15353 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Petri Dishes Class: B Configurations code: PTS-2335 PTS-2360 PTS-2390 PTS-2310 PTS-2315 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 3594557839	Deferred for confirmation/justification of categorizing the applied product as medical device with documentary evidence, confirmation of requisite manufacturing facility (section) and classifying the applied product as Class B medical device.
25.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1027-6L] R & I. 15333 dated 29-05-2025	Medi Plus BP Cuff Class: A Configuration code: CB-5021 (BP Cuff)	Deferred for confirmation of the requisite manufacturing facility and

	Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	CB-5020 (BP Cuff with Bladder) Sizes: S, M, L. Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3533197159	applying two variants (BP Cuff and BP Cuff with bladder) as single medical device.
26.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1028-6L] R & I. 15312 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Baseball Finger Splint Class: A Configurations code: FS-1520 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0373698307	Approved with shelf life of 2 years
27.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1029-6L] R & I. 15313 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag	Medi Plus BP Bulb Class: A Configuration code: BB-5020 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5846127042	Deferred for Confirmation of the requisite manufacturing facility (Section) in which applied product will be manufactured.

	<p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
28.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1030-7L] R & I. 15362 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Airways</p> <p>Configurations: Nasopharyngeal Airway, Oropharyngeal Airway</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 61868096</p>	<p>Approved with shelf life of 2 years</p>
29.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1031-7L] R & I. 15365 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p>	<p>Medi Plus Disposable Surgical Gown</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 82480053</p>	<p>Approved with shelf life of 2 years</p>

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
30.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1032-7L] R & I. 15366 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Hydrocolloid Wound Dressing</p> <p>Class: B Model Code: HCR-2045 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 25000 Fee Slip No. 458748782</p>	<p>Deferred for Confirmation of the requisite manufacturing facility (Section) in which applied product will be manufactured.</p>
31.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1033-6L] R & I. 15348 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Knee Support Lace Up</p> <p>Class: B Configuration code: KSL-3035 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 990566442</p>	<p>Approved with shelf life of 2 years</p>
32.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1034-6L] R & I. 15348 dated 29-05-2025</p> <p>Approved Sections:</p>	<p>Medi Plus Examination Gloves (Family) i. Medi Plus Vinyl Examination Gloves</p>	<p>Deferred for submission of separate application form for each type of examination glove</p>

	i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	ii. Medi Plus Nitrile Examination Gloves iii. Medi Plus TPE Examination Gloves, iv. Medi Plus Latex Examination Gloves Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4099952129	and also clarify for which type instant application be considered..
33.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1035-6L] R & I. 15382 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Lumbo Corset Class: A Configuration code: LC-1275 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3326155720	Approved with shelf life of 2 years
34.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1036-6L] R & I. 15381 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)	Medi Plus Spinal Jacket Class: A Configurations code: SJ-1075 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 296562089210	Deferred for confirmation of the particular medical device class of the applied product.

	v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
35.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1037-6L] R & I. 15374 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Arch Pad (Orthotic Arch Support Pad) Class: A Configuration code: AP-2230 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 07831866	Approved with shelf life of 2 years
36.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1038-6L] R & I. 15346 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Pulse Oximeter Class: A Configurations code: POX-4022 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 306222466598	Deferred for Confirmation of the requisite manufacturing facility (Section) and manufacturing steps to be performed by applicant.

37.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1039-6L] R & I. 15357 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders</p>	<p>Medi Plus Clavicle Support</p> <p>Class: A Configuration code: CS-3050 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0524721559</p>	<p>Approved with shelf life of 2 years</p>
38.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1040-6L] R & I. 15305 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders</p>	<p>Medi Plus Arm Sling (Arm sling with valve)</p> <p>Class: A Configurations code: AS-1180 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 8577339219</p>	<p>Approved with shelf life of 2 years</p>
39.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1041-6L] R & I. 15306 dated 29-05-2025</p> <p>Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section</p>	<p>Medi Plus Manual Apparatus Dial (Aneroid Dial Gauge)</p> <p>Class: A Configuration code: MDA-3051 Shelf Life: 5 Years</p>	<p>Deferred for Confirmation of the requisite manufacturing facility (Section) and steps to be performed by applicant</p>

	iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Fee: 6000 Fee Slip No. 2888136686	
40.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1042-6L] R & I. 15310 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Medi Plus Urine Container Class: A Configurations code: URC-2202 URC-2203 URC-2204 URC-2205 Sizes: 60ml, 100ml, 120ml, 150ml Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0689696438	Approved with shelf life of 2 years
41.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1043-6L] R & I. 15318 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp	Medi Plus Adult Diaper Class: A Model: AD-1700 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 070006597	Deferred for Confirmation of the requisite manufacturing facility (Section)

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
42.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1044-7L] R & I. 15343 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Hot Shaper Belt Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 49659126	Deferred for confirmation of categorizing the applied product as medical device with documentary evidence.
43.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1045-7L] R & I. 15361 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Breast Pump Electric Class: B Configurations code: BPE-5121 (Single Electric Breast Pump) BPED-5120 (Double Electric Breast Pump) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 96820077998	Deffered for clarification regarding manufacturing facility of applied product.
44.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)	Medi Plus Urine Bag Class: B	Approved.

	<p>[1046-7L] R & I. 15367 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Capacity/sizes: 500ml, 1000ml, 2000ml, 3000ml</p> <p>Shelf Life: 5 Years</p> <p>Fee: 25000</p> <p>Fee Slip No. 560826418076</p>	
45.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)</p> <p>[1047-6L] R & I. 15391 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Pregnancy Belt</p> <p>Class: A</p> <p>Configuration code: PB-1215</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 14889168800</p>	Deferred for Confirmation of the requisite manufacturing facility (Section).
46.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)</p> <p>[1048-6L] R & I. 15375 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p>	<p>Medi Plus Hot and Cold Therapy for Breast Pumping</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 52026373802</p>	Deferred for Confirmation of the requisite manufacturing facility (Section) in which applied product will be manufactured.

	iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders		
47.	Intra Health Sciences Pvt Ltd FD-21-A7, Korangi Creek Industrial Park, Korangi Karachi. (ELM-0078) [1049-6L] R & I. 15888 dated 30.05.2025.	Comfeel Plus (Latex Examination Gloves) Latex Examination Gloves Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 84426574159	Approved with shelf life of 2 years
48.	Global Health Care Pvt Ltd., Plot # 3A, N4 RCC Industrial Area Rawat, Islamabad (ELM-0091) [1051-7L] R & I. 15300 dated 29.05.2025. Approved Sections: 1. Assembling, Filling, Packaging, Labelling & Testing of Reagent kits. 2. Cutting, Assembling, Packaging, Labelling & Testing of Rapid Test Kits.	Ichroma Progesterone, Ichroma FSH, Ichroma LH, Ichroma PRL, Ichroma BHG, Ichroma Testosterone Class: B Shelf Life: 20 months Fee: 25000 Fee Slip No. 54929461241	Approved Ichroma™ Progesterone. The rest of products needs separate application.

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