

**of Pakistan**  
**Ministry of National Health Services, Regulation & Coordination**  
**Drug Regulatory Authority of Pakistan**  
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**DECISIONS OF 93<sup>RD</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 16-07-2025**

93<sup>rd</sup> 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 16<sup>th</sup> July, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4	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
6	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
7	Mr Muzzamil Waheed, Director, DTL, Faisalabad.	Member
8	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
9	Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Agha Khan University Hospital, Karachi.	Member (attended meeting through videolink)
10	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
11	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. The Evaluators assisted the secretary in presenting the agenda of the meeting.

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

**FRESH CASES**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Remedix (Pvt) Ltd., Azam Medicine Market 2 <sup>nd</sup> Floor C#8 & C#9 Namak Mandi Peshawar. <b>Godown Address:</b> Shop # B12,B13, B14, 1 <sup>st</sup> Floor Azam Medicine Mariet, Namak Mandi, Peshawar.	Waseem Gohar Pharmacist Regn.No.9586-A/2025-PC  CNIC:16101-5230986-9	<b>Approved</b> for storage of room temperature medical devices, subject to submission of requisite fee for change of qualified person.
2.	M/s Medvision International Co, B/06 Malik Tower, Near Shama Cinema Pajaggi Road, Bacha Khan Chowk Peshawar. <b>Godown Address:</b> Shop No 08 ,Malik Tower Near Shama cinema,Pajaggi Road Bcha Khan Chowk Peshawar.	Shah Alija Baig Mughal, Pharmacist Registration No.1114-A/2008-PC CNIC:17301-4303071-3	<b>Approved</b> for storage of room temperature medical devices
3.	M/s Dental Bank, Shop #3 Ground Floor, Al-Khair Plaza Khyber Bazar, Peshawar City, Peshawar. <b>Godown Address:</b> Shop #37, First Floor, Al-Khair Plaza Khyber Bazar, Peshawar City.	Mr. Muhammad Arif, Pharmacist Registration No.3124-A/2015-PC CNIC:17301-4919531-9	<b>Approved</b> for storage of room temperature medical devices
4.	M/s Kwik Test Private Limited, 210-B, 3 <sup>rd</sup> Floor, Commercial Sector-C Corner, Bahria Town, Lahore.	Muhammad Usman, Pharm-D, Registration No.30575-A/23	<b>Approved</b> for storage of room temperature medical devices.  (The case processed for issuance of License on new MDMC Division L&R e-portal. Partial minutes of this case already approved by the Board. The license was issued during inauguration ceremony on 21.07.2025 by the Honorable Prime Minister of Pakistan.)
5.	M/s Shaikh Traders, Shop No.2, Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi	Shaikh Asadullah Tahir, BE (Bio-Medical Engineer) Registration No. BIOMEDICAL/ 003119 CNIC:422201-1341532-5	<b>Approved</b> for storage of room temperature medical devices

6.	M/s Pak Sterilization Solutions, Office No.9, Hussain Park Phase-2, Gulshan Canal View, Harbanspura, Lahore.	Ishmal Saeed Pharm-D Regn.No.33194-A/24	<b>Approved</b> for storage of room temperature medical devices
7.	M/s Multi Solutions, 6-S, Street No.10, Wapda Road, Shalimar Town, Lahore.	Hifza Saleem Pharm-D Regn.No/22052-A/19	<b>Approved</b> for storage of room temperature medical devices
8.	M/s Mansoor Chowhan Group, Suite No. 207, The Plaza, Khayaban-e-Iqbal, Block 09 Clifton, Karachi.	Preet Raza Pharm-D Regisn.No.14630 CNIC:45201-3377977-4	<b>Approved</b> for storage of room temperature medical devices

#### **DEFERRED CASES IMPORT MEDICAL DEVICES LICENSE**

S.#	Name of Establishment	Name of Qualified Technical	Decision of MDB in 89 <sup>th</sup> meeting.
1.	M/s MGM Traders, 3174C, Tulip, Park View City, Opposite DHA EME, Multan Road, Lahore.	Ms. Saba Ijaz (Pharm.D) Registration No. 21613-A/19	<b>Deferred</b> in 89 <sup>th</sup> meeting of MDB for the confirmation of Drug Sale Licence at the same premises by the Punjab Government.

Now the firm M/s MGM Traders, 3174C, Tulip, Park View City, Opposite DHA EME, Multan Road, Lahore has submitted a copy of Drug Sale License (DSL) issued by the Provincial Government at the same premises.

**Decision:** The Board after thorough deliberations, decided to re-inspect the establishment facility to ascertain suitability of site/storage facility by following panel:

1. **Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab (member MDB).**
2. **Mr. Muzzamil Waheed, Director DTL, Faisalabad (member MDB)**

#### **Item No. I(B): POST LICENSE VARIATION CASES.**

##### **A) Fresh Cases**

S.#	Name of Firm	Detail of existing office address and technical person	Detail of proposed office address and technical person	
1.	M/s Biorays Enterprises, 8 Karim Center 16-Moj Darya Road, Lahore.  ELI-01259	<b>Existing Technical Person</b>  Shabaht Qamar, House No.170-P1, Mohallah Valencia Town, Lahore	<b>Proposed Technical Person</b>  Saleha Shafi, Near Allied Hospital, House No.31,k Gali No.3, Mohallah Akbar Abad, Faisalabad, Tehsil Faisalabad,	<b>Approved.</b>

	<b>Change of Technical Person</b>	CNIC: 35202-1330066-4	District Faisalabad. CNIC:33100-2669561-0 Pharm-D	
2.	M/s Shahid Surgical, Basement Abdul Market, Shop No. 14, Namak Mandi Peshawar.  ELI-00492  <b>Change of Technical Person</b>	<b>Existing Technical Person</b>  Mr. Syed Muhammad Kashif, Narga, Post Office, Shabqadar Fort, Thesil, Shabqadar, Distt, Charsada  CNIC: 17103-0375258-8	<b>Proposed Technical Person</b>  Muhammad Shehzad CNIC:17301-3263615-0  Pharm-D	<b>Approved</b> , subject to submission of Appointment letter, Job acceptance letter and undertaking on stamp paper duly signed by the proposed technical person.
3.	M/s MR Medical Pakistan Pvt Ltd, Office No. 1101, 11 <sup>th</sup> Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  ELI-01008  <b>Change of Technical Person</b>	<b>Existing Technical Person</b>  Mr. Imran Ahmed Atta, House No. E-104, Phase 2, Sheraz Villas, Cavalry Ground, Lahore  CNIC: 35201-3192169-5	<b>Proposed Technical Person</b>  Mr. Zeeshzan, Korang Town. House No.3, Street No.47, Islamabad.  CNIC:34603-3342689-5  B.Sc Biomedical Engineering	<b>Approved</b> , subject to submission of Job acceptance letter of proposed technical person and declaration on stamp paper duly signed by Proprietor.
4.	M/s Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi  ELM-00109  <b>Change of Technical Person</b>	<b>Existing Technical Person</b>  Ms. Saman Shahzad D/o Muhammad Nadeem Shahzad, House No.8-H, CB/14, Wah Cantt, Taxila, Rawalpindi. CNIC:37406-6496159-8  Pharm-D	<b>Proposed Technical Person</b>  Ms. Wajiha Saleem W/o Muhammad Ehsan Ul Haq, House No.25-B, Street No.7, Gulshan Anwar Housing Society, Wah Cantt, RAwalpindi CNIC:37406-1176076-0  <b>Pharm-D</b>	<b>Approved</b> , subject to submission of appointment letter and job acceptance letter of proposed technical person as well as Undertaking on stamp paper duly signed by proprietor and proposed technical person.
5.	M/s Muaaz Medical Traders, Office No.401-402, 6th Floor, Saith Center 10-Syed Moj Darya Road, Lahore  ELI-00574  <b>Change of Technical Person</b>	<b>Existing Technical Person</b>  Ms. Misaal Fatima, 98-Madina Park, B-Block, Sabzazaar Scheme, Lahore  CNIC: 35202-8127304-6	<b>Proposed Technical Person</b>  Ms. Asma Sohail, House No.190-B, Mohallah Babar Road Near Post Office Mughalpora, Lahore Cantt, Lahore. CNIC:35202-6030105-2  Doctor of Medical Laboratory Sciences	<b>Approved</b> subject to submission of ELI copy, undertaking on stamp paper duly signed by proposed technical person and declaration on stamp paper duly signed by Proprietor.

6.	M/s. Ali Noor Industries, Office No. 1, 2nd Floor, Center Point Plaza, Gulberg III, Lahore  ELI-00816  <b>Change of Technical Person</b>	<b>Existing Technical Person.</b> Ms. Hafsa Riaz, Mughalpura House No.5, Mohallah Larex Colony, Usmanabad, Lahore Cantt, District Lahore. CNIC:35200-2066044-0 <b>Pharm-D</b>	<b>Proposed Technical Person</b> Ms. Tabinda, House No. 4, Street No. 3, Mohallah Hameed Park Jundiala Road, District Sheikhupura. CNIC: 35404-2984895-2  <b>(Pharm.D)</b>	<b>Approved,</b> subject to submission of Job acceptance letter of technical person.
7.	M/s Medi-Care Disposable Industries, 4.5 KM, Defence Road, Kahna Nau, Lahore ELM-0043  <b>Change of Production Incharge and Quality Control Incharge of Local manufacturer.</b>	<b>Existing Production Incharge.</b>  Ms. Sana Hanif (Pharm-D)  <b>Existing Quality Control Incharge.</b>  Mr. Umair Rafique (Pharm-D)	<b>Proposed Production Incharge</b> Mr. Muhammad Shafiq, House No,124, Street No.3, Mohallah Chaman Park Fateh Garh, Lahore Cantt, Lahore. CNIC:31304-1033528-3 <b>B-Pharmacy</b>  <b>Proposed Quality Control Incharge.</b>  Hafiz Muhammad Abid Rasool, P.O Khas, Chak No.39/12-L, Tehsil Chichawatni, District, Sahiwal. CNIC:36501-6003624-7 <b>Pharm-D</b>	<b>Approved,</b> subject to submission of additional Fee of Rs: 61,500/- as 02 post license variations (both new qualified persons) are applied by the firm.
8.	M/s NISA.SF (Pvt) Ltd., 10-KM Muridke - Sheikhupura Road, Muridke District, Sheikhupura.  ELM-0001, dated 03-08-2018  <b>Change of Production Incharge of Local Manufacturer</b>	<b>Existing Production Incharge</b>  Mr. Shoaib Saud Awan S/o Mr. Saud Ahmed Awan, House No.643, Block-F, Johar Town, Lahore. CNIC:34603-5792530-5  <b>Pharm-D</b>	<b>Proposed Production Incharge</b> Tanveer Ilyas, Post Office Khas, Ghazi Pur, Tehsil Sharqpur, District Sheikhupura. CNIC:35401-3040118-3  <b>Pharm-D</b>	<b>Approved.</b>
9.	M/s BQ Pharma & Medical Devices (OPvt) Ltd, Plot No.43-A, Industrial Estate, Hayatabad, Peshawar.  ELM-0066	<b>Existing Production Incharge</b>  Mr. Muhammad Tariq B-Pharmacy	<b>Proposed Production Incharge</b> Mr. Zia Ud Din Muhammad Atif, S/o Deedar Muhammad, Agricultural Training Institute Jamrood Road, House No.7/2, treet No.2, Peshawar.	Deferred for submission of prescribed application form (Form-1), Differential fee and job acceptance/joining

	<b>Change of Production Incharge (Local manufacture)</b>		CNIC: 17301-0825674-3 <b>Pharm-D</b>	letter.
10.	M/s Quality Medical Services, H-49, Gordon College Road, Rawalpindi. ELI-00123  <b>Change of Technical Person</b>	<b>Existing Technical Person.</b>	<b>Proposed Technical Person</b> Mr. Muhammad Farhan, House NJo.1708-L, Gali No.9/1, Block-D, Police Foundation, Loe Bhair, Tehsil & District, Islamabad.  CNIC:31201-1099329-5 <b>Pharm-D</b>	<b>Deferred</b> for submission of • Application form (Form-2), • Requisite fee of Rs: 12, 500/-. • ELI copy • Job Acceptance letter of proposed technical person. • Declaration and Undertakings on stamp paper duly signed by the Proprietor. • Details of existing technical person.
11.	M/s Roche Pakistan Ltd., 1 <sup>st</sup> Floor, 37-B, Block 6, PECHS, Karachi  ELI-00009	<b>Existing Office Address</b> 1 <sup>st</sup> Floor, 37-B, Block 6, PECHS, Karachi  <b>Existing Technical Persons</b>  Sheikh Muhammad Shahruxh, House No. L-390, Moh Gulshan Sir Syed Town, North Karachi Sector 11-L, Karachi. CNIC:42101-4301444-1 Pharm-D  Muhammad Owais Sulaiman, Sulaiman Plaza, Flat No.4-C, Block-10, Mohallah Gulshhan-e-Iqbal, Karachi. CNIC:42201-6059925-4 Pharm-D	<b>Proposed Office Address</b> Office No.1101-1104, 11 <sup>th</sup> Floor, Al-Tijarah Centre, Plot No.32-1-A, PECHS Block-6, Jamshed Town, Karachi East.  <b>Proposed Technical Persons</b>  Ms.Sadaf Aqeel, Saima Square -1 Tower, Flat No.F-804, Block 10-A, Mohallah Gulshan-e-Iqbal, Karaci East. CNIC:42301-1959355-0 <b>Pharm-D</b>  Mr.Hamas Kaparia, Crystal Homes, Plot No.63/3, Flat No.406, Mohallah BMCHS Bahadarabad, Karachi East. CNIC:42301-8290208-5 <b>Pharm-D</b>  <b>Proposed Management</b>  Ms. Hafsa Shamsie (Managing Director), House No.14-B, 11 <sup>th</sup> Centrl Street Phase 2, D.H.A, Karachi. CNIC:41301-2377433-4  M. Waqas Siquiqui, C-32/5-6,	<b>Approved.</b>

		<p><b>Existing Management</b></p> <p>Ms. Hafsa Shamsie (Managing Director), House No.14-B, 11<sup>th</sup> Centrl Street Phase 2, D.H.A, Karachi. CNIC:41301-2377433-4</p> <p>M. Waqas Siqqiqui, C-32/5-6, Malir Colony, Karachi CNIC:42501-4717400-9</p> <p><b>Farhan Bhatti, Sindh University Employees Society, House No. A-102, Kotri District Jamshoro. CNIC:41204-4185478-5</b></p> <p>Mr. Badaruddin F. Vellani, 12-Khayaban-e-Janbaz, Phase-V, DHA, Karachi. CNIC:42301-0918221-7</p> <p>Mr. Robert Ferraro, Eichenstrasse 41 4054 Basel, Switzerland. FO 672869</p>	<p>Malir Colony, Karachi CNIC:42501-4717400-9</p> <p><b>Mr. Muhammad Ashar Khan, House No.267, Blocj 15, Gulistan-e-Johar, Karachi. CNIC:41303-2719266-7</b></p> <p>Mr. Badaruddin F. Vellani, 12-Khayaban-e-Janbaz, Phase-V, DHA, Karachi. CNIC:42301-0918221-7</p> <p>Mr. Robert Ferraro, Eichenstrasse 41 4054 Basel, Switzerland. FO 672869</p>	
12.	<p>M/s Pakistan Marketing Services, Suit No. 312/A-2, Haji Abdul Razzaq Street, Lane No. 4-A, Peshawar Road, Rawalpindi.</p> <p>ELI-00198</p> <p><b>“Change of office &amp; Godown address”</b></p>	<p><b>Existing Office &amp; Godown Address.</b></p> <p>Suit No. 312/A-2, Haji Abdul Razzaq Street, Lane No. 4-A, Peshawar Road, Rawalpindi.</p>	<p><b>Proposed new office &amp; Godown Address.</b></p> <p>House No. 40, Near Fauji Foundation University, New Lalazar, Near Rose Lane No. 02, Jehlum road, Rawalpindi.</p>	<p>Approved for storage of room temperature medical devices.</p>
13.	<p>M/s Delta Plus Pvt. Ltd. 208, 2<sup>nd</sup> Floor Wall Street Plaza, G-15 Markaz, Sector G-15, Islamabad.</p> <p>ELI-00784</p>	<p><b>Existing Office &amp; Godown Address.</b></p> <p>208, 2<sup>nd</sup> Floor Wall Street Plaza, G-15 Markaz, Sector G-15, Islamabad.</p>	<p><b>Proposed new office &amp; Godown Address.</b></p> <p>Talha Plaza, Ramzan Colony, Budhana Road near Benazir Chowk, Tarnol, Islamabad.</p>	<p>Approved for storage of room temperature medical devices.</p>

**Case No. II. APPLICATION FOR ADDITION OF SCOPE OF MEDICAL DEVICES INTENDED TO BE MANUFACTURED AND ADDITION OF NEW SECTION UNDER MEDICAL DEVICES RULES, 2017 - INSPECTION THEREOF.**

M/s Lab Diagnostic System (Pvt) Limited, Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi has applied for grant/approval of addition of scope of medical devices and new Section to manufacture medical devices under Medical Devices Rules, 2017, detailed as: -

- (i) Vacutainer Section-II (New Section).
- (ii) Lateral Flow Assay (LFA) Membrane Coating & Sheet Production Unit –Addition of Scope in already approved section “Lateral Flow Immuno-Chromatographic Assay Kit (Rapid Testing).

**Decision: The Board approved the grant of following:**

1. Vacutainer Section-II
2. Lateral Flow Assay (LFA) Membrane Coating & Sheet Production Unit –Addition of Scope in already approved section “Lateral Flow Immuno-Chromatographic Assay Kit (Rapid Testing).

**Case No. III. GRANT OF ADDITIONAL SECTION/FACILITY TO MANUFACTURE MEDICAL DEVICES - INSPECTION THEREOF.**

M/s Medsenso (Private) Limited, Office No.1, 4<sup>th</sup> Floor, 13-A, Kohistan Road, F-8 Markaz, Islamabad (Site address: Medical Diagnostic Devices Center (MDDC)-NUST, H-12, Islamabad) has applied for grant/approval of New Section/manufacturing facility to manufacture medical devices under Medical Devices Rules, 2017, detailed as: -

1. Rapid Diagnostic Test (RDT) Kits (Assembling, Labelling, Sealing & Packing) for following products:
  - (i) HIV 1/2 Rapid Test Kit
  - (ii) HCV Rapid Test Kit
  - (iii) hCG Pregnancy Rapid Test Kit
  - (iv) Malaria Pf/Py Rapid Test Kit
  - (v) Dengue NS1 Antigen Rapid Test Kit
  - (vi) Syphilis (TP) Rapid Test Kit
  - (vii) HBsAg Rapid Test Kit

**Decision: Dr. Aleem, member of inspection panel and member of Board apprised the Board that the firm possess the de-humidifiers and Air Conditioner for control of humidity conditions and temperature. Hence the requirement of humidity and temperature control is already fulfilled. However, condition of HVAC was recommended/suggested by the panel for control of humidity/temperature in a more validated manner. Keeping in view the above and**



recommendations by panel of inspectors, the Board approved the additional section of Rapid Diagnostic Test (RDT) Kits (Assembling, Labelling, Sealing and Packing).

**B) Deferred Cases/Approved subject to cases:**

**Case No.01. Change of Technical Person.**

S.#	Name of Firm	Detail of existing office address and technical person	Detail of proposed office address and technical person	Decision of MDB
1.	M/s Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-D Gulshan-e-Iqbal Karachi ELI-002867, dated 22-10-2018  <b>Change of Technical Person</b>	<b>Existing Technical Person.</b> Mr. Muhammad Abdul Basit, Goth Malik Khan Zaman, PO Bandhi, Daulat Pur, Tehsil Qaziahmed, District Shaheed Benazirabad.  CNIC:42501-8066353-3	<b>Proposed Technical Person</b> Mr. Meer Ahmed, Classic View, Flat No.322-D, Block-19, Gulistan—Johar, Karachi East  CNIC:43102-5315548-1  Pharm-D	<b>Deferred</b> in M-69 for provision of following documents: -  (i) Required Fee (ii) Copy of Appointment letter & Job acceptance letter of proposed technical person (iii) Attested Copy of Degree of proposed technical person.

The decision of MDB was communicated to the firm for provision of above mentioned documents.

In response, the firm has appointed new qualified technical person instead of provision of above mentioned documents as per requirement of Medical Devices Rules, 2017. The detail of new qualified technical person is tabulated below: -

Name of Firm	Detail of existing office address and technical person	Detail of proposed office address and technical person	decision
M/s Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-D Gulshan-e-Iqbal Karachi ELI-00286, dated 22-10-2018  <b>Change of Technical Person</b>	<b>Existing Technical Person.</b> Mr. Muhammad Abdul Basit, Goth Malik Khan Zaman, PO Bandhi, Daulat Pur, Tehsil Qaziahmed, District Shaheed Benazirabad.  CNIC:42501-8066353-3	<b>Proposed Technical Person</b> Ms. Shanza Shabbir, House No. A/17, Street Qaim Khani Thana Road, Jhaddo, District Mir Pur Khas.  CNIC: 44101-2874285-0  <b>B.E (Bachelors of Biomedical Engineering)</b>	<b>Approved.</b>

**Case No.02. Change of Quality Control Incharge (Local Manufacturer)**

S.#	Name of Establishment	Existing Details of ELI	Proposed Details for ELI	Decision of 72 <sup>nd</sup> MDB Meeting
1.	M/s BQ Pharma & Medical Devices (OPvt) Ltd, Plot No.43-A, Industrial Estate, Hayatabad, Peshawar.  ELM-0066  <b>Change of Quality Control Incharge (Local manufacture)</b>	<b>Existing QC Incharge</b> Dr. Muhammad Sohrab Pharm-D	<b>Proposed QC Incharge</b> Muhammad Sadiq, Miana Shakh No.6, Post Office Shakh NO.6, Charsaddah.  CNIC: 17101-9496297-5  M.Sc Chemistry	<b>Approved in 72<sup>nd</sup> Meeting of MDB subject</b> to submission of application on Form-2 duly signed by Proprietor/Chief Executive/Managing Director or an authorized officer.

The decision of MDB was communicated to the firm for provision of above-mentioned documents.

In response, the firm has appointed new Quality Control Incharge instead of provision of above mentioned documents as per requirement of Medical Devices Rules, 2017. The detail of new qualified technical person is tabulated below: -

Name of Firm	Detail of existing office address and technical person	Detail of proposed office address and technical person	Decision
M/s BQ Pharma & Medical Devices (OPvt) Ltd, Plot No.43-A, Industrial Estate, Hayatabad, Peshawar.  ELM-0066  <b>Change of Quality Control Incharge (Local manufacture)</b>	<b>Existing QC Incharge</b> Dr. Muhammad Sohrab  Pharm-D	<b>Proposed QC Incharge</b> Muhammad Sadiq, Miana Shakh No.6, Post Office Shakh NO.6, Charsaddah.  CNIC: 17101-9496297-5  M.Sc Chemistry	<b>The board deferred</b> for submission of Form-1 and requisite differential fee for change of QC incharge.

**Item No. V: REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.****New cases**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19303 dated 30.06.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling)	Medsenso Blood Glucose Test Strips Models/Variants: G-427BS, G-425-2S Class B Shelf Life: 24 months Rs: 25000/- Fee Slip No. 3205370213	Approved as Class C medical device.

	2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)		
2.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19305 dated 30.06.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso Blood Glucose Monitoring System with Bluetooth Class B Model: G-427B Fee Rs: 100000/- (6935154570)	Approved assembling in Class C medical device.
3.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19908 dated 04.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso Blood Glucose Monitoring System, Non-Bluetooth Class B Model: G-425-2 Fee Rs: 100000/- (615215885103)	Approved assembling and as Class C medical device.
4.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19832 dated 03.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso Laboratory Glass Slides (Microscope glass slides) Variants: Plain slides, Frosted Slides, Color Frosted Slides, Adhesive Slides Class A Shelf-life 05 years Fee Rs: 6000/- (13384531632)	Approved.
5.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19304 dated 30.06.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso Blood Pressure Monitor with Bluetooth (Sphygmomanometer- Electronic/Automatic) Models: 2006-2B Class: B Service-life: 3-5 years Fee Rs: 25000/- (Slip No. 67546120)	Approved assembling of the Medsenso Blood Pressure Monitor with Bluetooth
6.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19909 dated 04.07.2025	Medsenso Blood Pressure Monitor Non- Bluetooth (Sphygmomanometer- Electronic/Automatic)	Approved assembling of the Medsenso Blood Pressure Monitor Non-

	<b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Model: 2006-2 Service Life: 5 years Class: B Fee Rs: 25000/- (Challan No. 715961761)	Bluetooth
7.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19907 dated 04.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso HBsAg (Hepatitis B surface antigen) RDT (Rapid Diagnostic Kit) Code: RDT-HBSAG Shelf Life: 18-24 months Class: D  Fee Rs: 25000/- (Slip No. 111360383)	The Board deferred the application for consideration in the forthcoming meeting of MDB.
8.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19912 dated 04.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso HCV RDT (Rapid Diagnostic Kit) Code: RDT-HCV Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 32694675387)	The Board deferred the application for consideration in the forthcoming meeting of MDB.
9.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19910 dated 04.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso hCG Pregnancy RDT (Rapid Diagnostic Kit) Code: RDT-hCG Shelf Life: 18-24 months Class: B Fee Rs: 25000/- (Slip No. 1177730929)	The Board deferred the application for consideration in the forthcoming meeting of MDB.
10.	Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R & I :19911 dated 04.07.2025 <b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2. Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)	Medsenso Dengue NS1 Antigen Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-Dengue-NS1 Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 6012706155)	The Board deferred the application for consideration in the forthcoming meeting of MDB.

11.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R &amp; I :19913 dated 04.07.2025</p> <p><b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso TP Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-SYP Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 333439176887)</p>	<p>The Board deferred the application for consideration in the forthcoming meeting of MDB.</p>
12.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R &amp; I :19914 dated 04.07.2025</p> <p><b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso Malaria Pf/Pv Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-MAL Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 946737563502)</p>	<p>The Board deferred the application for consideration in the forthcoming meeting of MDB.</p>
13.	<p>Medsenso Pvt. Ltd. H-12, NUST, Islamabad. (ELM-0099) R &amp; I :19915 dated 04.07.2025</p> <p><b>Approved Sections:</b> 1. Glucometer and Gluco Test Strips (Assembling) 2.Sphygmomanometer (Assembling) 3. Laboratory Glass Slides (Production)</p>	<p>Medsenso HIV ½ Rapid Test Kit (Rapid Diagnostic Kit) Code: RDT-HIV Shelf Life: 18-24 months Class: C Fee Rs: 25000/- (Slip No. 7476247817)</p>	<p>The Board deferred the application for consideration in the forthcoming meeting of MDB.</p>

**Item No. VI: DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.**

S.No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision
1.	<p>NISA.SF Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura ELM-0001</p>	<p>BM 100 Unit Disposable Insulin Syringe Disposable insulin syringe Class:B Shelf-life:5Years Sizes:100 units' syringe Needle sizes: 29G x 5/16" (0.33mm x 8mm) 30G x 5/16" (0.30mm x 8mm) 31G x 5/16" (0.25mm x 8mm)</p>	<p>Approved.</p>

		32G x 5/16" (0.23mm x 8mm) Fee of 20,000 vide Challan No. 38422505497	
2.	<b>NISA.SF</b> Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura <b>ELM-0001</b>	<b>BM Disposable Heparin Cap</b> (Heparin Cap) <b>Class: B</b> <b>Shelf-life: 5 Years</b> <b>Sizes:</b> <b>Connector:</b> Male Luer Lock Connector <b>Color:</b> Yellow and transparent <b>Length:</b> 18mm 19.32mm 22mm Fee of 20,000 vide Challan No. 07486207625	The Board decided for confirmation of manufacturing and testing facilities by panel for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
3.	<b>NISA.SF</b> Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura <b>ELM-0001</b>	<b>Dosiflow Plus</b> Disposable flow regulator Extension Line <b>Class: B</b> <b>Shelf-life: 3 Years</b> <b>Sizes:</b> <b>30 cm</b> <b>Types:</b> <b>1. Dosiflow Plus</b>  (with Y-port injection site). <b>2. Dosiflow Plus</b>  (with Needle free valve, and side clamp). <b>3. Dosiflow Plus</b>  (with Needle free Valve, side Clamp, and precision filter) <b>Fee of 20,000 vide Challan No.</b> 48643085	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
4.	<b>NISA.SF</b> Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura <b>ELM-0001</b>	<b>HP Disposable Stopcock with Extension Tube</b> Stopcock Extension Tube (1 Way, 2 Way, 3 Way & 4 Way) <b>Class: B</b> <b>Shelf-life: 5 Years</b> <b>Length:</b> 10cm, 15cm, 20cm 25cm, 50cm, 100cm <b>Fee of 20,000 vide Challan No.</b> 51757256	The Board decided for confirmation of manufacturing and testing facilities by panel for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
5.	<b>NISA.SF</b> Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura	<b>Super Stopper Disposable Stopcock with Extension Tube</b> Stopcock Extension Tube <b>Class: B</b>	The Board decided to inspect by the panel for confirmation of manufacturing and

	<b>ELM-0001</b>	<b>Shelf-life:</b> 5Years <b>Length:</b> (1 Way, 2 Way, 3 Way & 4 Way) 10cm 15cm 20cm 25cm 50cm 100cm <b>Fee of 20,000</b> vide Challan No. 11296827	testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
6.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [708-7L] Feb-2025	BM Disposable Breathing Bag Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 92330370662	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
7.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [709-7L] Feb-2025 The firm has following approved sections as per record. 1. Auto Disable Syringes 2. Disposable Syringe 3. I.V. Cannula 4. I.V Products	BM Disposable Anesthetic Circuit Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 9611402310	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
8.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [710-7L] Feb-2025 The firm has following approved sections as per record. 1. Auto Disable Syringes 2. Disposable Syringe 3. I.V. Cannula 4. I.V Products	BM Disposable Oxygen Mask Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 823610502	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.

9.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [711-7L] Feb-2025	BM Disposable Urine Bag Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 5078076597	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
10.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [712-7L] Feb-2025	BM Disposable Anesthetic Mask Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 89224587	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
11.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [713-7L] Feb-2025	BM Disposable Breathing Circuit Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 933019586	The Board decided to inspect by the panel of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
12.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM-0001) [714-7L] Feb-2025	BM Disposable Enteral Feeding Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 65267853330	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
13.	M/S Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore	MB-Tulle (Chlorhexidine Acetate B.P....0.5%) Class-D Shelf-life: 3 years	Approved for Export Purpose Only.



	[ELM No. 0051] Approved Section: Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section Arsotulle/Arsotin Section (Sterile) Medi-Swab Section Crepe Bandage	Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m Fee Challan No 0205725540 Rs. 20000/- Date 02-05-2024	
14.	M/S Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051] Approved Section: Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section Arsotulle/Arsotin Section (Sterile) Medi-Swab Section Crepe Bandage	<b>Sofray Tulle</b> (Export Purpose) Framycetin Sulphate....1% <b>B.P....1%</b> Class-D Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m Fee Challan No 0242175113 Rs. 5000/- Slip No 1457006022 Rs 15000	Approved for export purpose only.
15.	M/S Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051] Approved Section: Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section Arsotulle/Arsotin Section (Sterile) Medi-Swab Section Crepe Bandage	<b>Arso-Tulle</b> <b>(Chlorhexidine Acetate B.P....0.5%)</b> Sterile Gauze Tulle Dressing Class-D Form-7 See rule 14(2) (b),16(1) and 17(2) Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m Fee Challan No 67811730 Rs. 5000/- Slip No 24333001059 Rs 15000	Approved.
16.	<b>ArsoTin</b> <b>(Sofra-Tulle)</b> <b>Framycetin Sulphate</b> <b>B.P....1%</b> <b>Class-D</b> <b>Shelf-life: 3 years</b> <b>Sizes:</b> <b>10cm x 10cm</b> <b>15cm x 20cm</b>	ArsoTin (Sofra-Tulle) (Framycitin Sulphate B.P....1%) Dressing uses Lacerations, Abrasions, Grazes Bite (animal and insect) cuts puncture wounds, crush injuries, surgical wound & incisions, traumatic ulcer.	Approved.

	<b>15cm x 1.50m</b> <b>Fee Challan No</b> <b>86249589030</b> <b>Rs. 5000/-</b> <b>Slip No</b> <b>8785333264</b> <b>Rs 15000</b>		
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**Item No. III: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.**

S#	Importer Name	Manufacturer Details	Name of Medical Device/ Class / Shelf life / Codes / etc	Decision
1.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373  Date of R&I 22-04-2025  <b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 1550770078 7195-P	<b><u>Legal Manufacturer:</u></b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b><u>Manufacturing Site:</u></b> Global Care Medical Technology Co., Ltd. 7th Building, 39 Middle Industrial Mian Road, European Industrial Zone, Xiaolan Town, 528415 Guangdong Zhongshan City, Province, PEOPLE/S REPUBLIC OF CHINA  LOA Validity: 31-12-2025  FSC: Germany Issue date: 23-01-2025  ISO Validity: 29-11-2026  EC Certificate Validity: 26-05-2024	Beurer Nebulizer  Class-B  Shelf life: 7 years  Models/specifications: IH-58	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany.
2.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373	<b><u>Legal Manufacturer:</u></b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b><u>Manufacturing Site:</u></b> Technology (Shenzhen) Grandway Limited No.5, the Second Industrial zone, zhukeng Community,	Beurer Blood Pressure Monitor  Class-B  Shelf life: 7 years  Models/specifications:	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will

	<p>Date of R&amp;I 22-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 8993835111 7198-P</p>	<p>Longtian street, Pingshan District, 518118 Shenzhen, Guangdong, PEOPLE/S REPUBLIC OF CHINA</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>EC Certificate Validity: 26-05-2024</p>	BM-54	be issued as per FSC of Germany.
3.	<p><b>Applicant Name:</b> Muslim Medical Services, 1<sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore</p> <p>ELI-00373</p> <p>Date of R&amp;I 22-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 032198892713 7159-P</p>	<p><b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany.</p> <p><b>Manufacturing Site:</b> Contec Medical Systems Co., Ltd. No. 112 Qinhuang West Street, Economic &amp; Technical Development Zone, Qinhuangdao, Hebei Province, P.R. China.</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>EC Certificate Validity: 26-05-2024</p>	<p>Beurer Pulse Oximeter Class-B</p> <p>Shelf life: 7 years</p> <p>Models/specifications: PO-13</p>	<p>Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany.</p>
4.	<p><b>Applicant Name:</b> Muslim Medical Services, 1<sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore</p> <p>ELI-00373</p> <p>Date of R&amp;I 22-04-2025</p>	<p><b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany.</p> <p><b>Manufacturing Site:</b> Contec Medical Systems Co., Ltd. No. 112 Qinhuang West Street, Economic &amp; Technical Development Zone, Qinhuangdao, Hebei Province, P.R. China.</p> <p>LOA Validity:</p>	<p>Beurer Pulse Oximeter Class-B</p> <p>Shelf life: 7 years</p> <p>Models/specifications: PO-60</p>	<p>Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany. Shelf life or service life studies.</p>

	<b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 770249041440 7158-P	31-12-2025  FSC: Germany Issue date: 23-01-2025  ISO Validity: 29-11-2026  EC Certificate Validity: 26-05-2024		
5.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373  Date of R&I 22-04-2025  <b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 547053147 7160-P	<b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b>Manufacturing Site:</b> HIVOX Biotec Inc. also trading as HIVOX electronics Co., Ltd. 5F., No.123, Xingde Rd., Sanchong Dist., New Taipei City 241, Taiwan  LOA Validity: 31-12-2025  FSC: Germany Issue date: 23-01-2025  ISO Validity: 29-11-2026  EC Certificate Validity: 26-05-2024	Beurer TENS/EMS Device  Class-B  Shelf life: 7 years  Models/specifications: EM98	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany. Shelf life or service life studies.
6.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373  Date of R&I 22-04-2025  <b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 24269505294 7199-P	<b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b>Manufacturing Site:</b> Shenzhen AOJ Medical Technology Co. Ltd. Room no 301&4F, Block A, Jingfa Intelligent Manufacturing Park, Xiawei yuan, Gushu Community, Xixiang street, Bao'an District, Shenzhen, 518126 REPUBLIC OF CHINA  LOA Validity: 31-12-2025  FSC: Germany Issue date: 23-01-2025	Beurer Blood Pressure Monitor  Class-B  Shelf life: 7 years  Models/specifications: BM-59	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany.

		ISO Validity: 29-11-2026  EC Certificate Validity: 26-05-2024		
7.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373  Date of R&I 22-04-2025  <b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 510058526773 7196-P	<b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b>Manufacturing Site:</b> Beurer-Hungaria Kft Parna utca 1, 8200 Veszprem, Hungary.  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: 7 years  Models/specifications: BM-53	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany.
8.	<b>Applicant Name:</b>  Muslim Medical Services, 1 <sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore  ELI-00373  Date of R&I 22-04-2025  <b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 225271596696 7200-P	<b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany. <b>Manufacturing Site:</b> Global Care Qingdao Future Medical Technology Co.,Ltd. South B1 Building E, No.621 Jiushui Rd Laoshan District, Qingdao City, Shandong province, P.R. China.  LOA Validity: 31-12-2025  FSC: Germany Issue date: 23-01-2025  ISO Validity: 29-11-2026  EC Certificate Validity: 26-05-2024	Beurer Nebulizer  Class-B  Shelf life: 7 years  Models/specifications: IH-57	Approved. The firm will submit legalized FSC and notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany. Shelf life or service life studies.
9.	<b>Applicant Name:</b>  Muslim Medical	<b>Legal Manufacturer:</b> Beurer GmbH, SoeflingerStrasse 218, 89077	Beurer Blood Pressure Monitor	Approved. The firm will submit legalized FSC and

	<p>Services, 1<sup>st</sup> Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore</p> <p>ELI-00373</p> <p>Date of R&amp;I 22-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 31,000/-</b> Fee Challan No: 267811849400 7197-P</p>	<p>Ulm Germany. <b><u>Manufacturing Site:</u></b> Beurer-Hungaria Kft Parna utca 1, 8200 Veszprem, Hungary.</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>EC Certificate Validity: 26-05-2024</p>	<p>Class-B</p> <p>Shelf life: 7 years</p> <p>Models/specifications: BM-96</p>	<p>notarized LOA and ISO 13485 before issuance of Registration letter. Furthermore, registration letter will be issued as per FSC of Germany.</p>
10.	<p>M/s Vertex Medical Pvt. Ltd.</p> <p>Address: 401-402, Block – F, Johar Town, Lahore</p> <p>ELI-00150</p> <p>Application Submitted in R&amp;I 25-april-2025 Fee Rs. 50,000/ through slip no. 25901127271</p>	<p><b><u>Legal Manufacturer:</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA <b><u>(Manufacturing site)</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA.</p> <p>LOA Valid till: 30-09-2025</p> <p>FSC: Country of Origin Germany Issuance 17-07-2024</p> <p>EU MDR Certificate Valid till: 15-02-2028</p> <p>ISO 13485 Certificate: Valid till: 31-10-2027</p>	<p>ACUSON NX3 Ultrasound Imaging System</p> <p>Service Life: 10 Years</p> <p>Class B</p> <p>Codes: ACUSON NX3 Series - 11235612</p>	<p>approved</p>
11.	<p>M/s Vertex Medical Pvt. Ltd.</p> <p>Address: 401-402, Block – F, Johar Town, Lahore</p> <p>ELI-00150</p> <p>Application Submitted in R&amp;I</p>	<p><b><u>Legal Manufacturer:</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA <b><u>(Manufacturing site)</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA.</p>	<p>ACUSON Sequoia Select Ultrasound Imaging System</p> <p>Service Life: 10 Years</p> <p>Class B</p> <p>Codes: ACUSON Sequoia Select -</p>	<p>Approved</p>

	25-april-2025 Fee Rs. 50,000/ through slip no. 0558711965	LOA Valid till: 30-09-2025  FSC: Country of Origin Germany Issuance 17-07-2024  EU MDR Certificate Valid till: 15-02-2028  ISO 13485 Certificate: Valid till: 31-10-2027	11658635	
12.	M/s Vertex Medical Pvt. Ltd.  Address: 401-402, Block – F, Johar Town, Lahore  ELI-00150  Application Submitted in R&I 25-april-2025 Fee Rs. 50,000/ through slip no. 24987558956	<b><u>Legal Manufacturer:</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA <b><u>(Manufacturing site)</u></b> SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA. LOA Valid till: 30-09-2025  FSC: Country of Origin Germany Issuance 17-07-2024  EU MDR Certificate Valid till: 15-02-2028  ISO 13485 Certificate: Valid till: 31-10-2027	ACUSON Maple Select Ultrasound Imaging System  Service Life: 10 Years  Class B  Codes: ACUSON Maple Select - 11711779, 11268679, 11711446, 10136143, 11319682, 11711157, 11575443,	Deferred for following:  ACUSON Maple Select was subject to a Class II recall by USFDA initiated by Seimens on August 15, 2024. This recall was due to changes from factory default Mm/sec Mm/mint; then system will perform incorrect unit conversion of liters to milliliters using multiplier 100 instead of 1000, resulting values 10x smaller than actual, which could contribute misdiagnosis or negatively influence patient management.  <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=209873">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=209873</a>  Therefore, provide following details: Has this product been cleared for use post- recall in its country of origin? If yes, please provide the evidence.
13.	M/s Vertex Medical Pvt. Ltd.	<b><u>Legal Manufacturer:</u></b>	ACUSON Juniper Select	Deferred for following:

	<p>Address: 401-402, Block – F, Johar Town, Lahore</p> <p>ELI-00150</p> <p>Application Submitted in R&amp;I 25-april-2025</p> <p>Fee Rs. 50,000/ through slip no. 124853251779</p>	<p>SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA <b>(Manufacturing site)</b></p> <p>SIEMENS MEDICAL SOLUTIONS USA, Inc. 22010 S.E. 51st STREET ISSAQUAH, WA 98029, USA.</p> <p>LOA Valid till: 30-09-2025</p> <p>FSC: Country of Origin Germany Issuance 17-07-2024</p> <p>EU MDR Certificate Valid till: 15-02-2028</p> <p>ISO 13485 Certificate: Valid till: 31-10-2027</p>	<p>Ultrasound Imaging System</p> <p>Service Life: 10 Years</p> <p>Class B</p> <p>Codes: ACUSON Juniper Select - 11653093</p>	<p>ACUSON Juniper Select</p> <p>was subject to a Class II recall by USFDA initiated by Seimens on August 15, 2024. This recall was due to changes from factory default Mm/sec Mm/mint; then system will perform incorrect unit conversion of liters to milliliters using multiplier 100 instead of 1000, resulting values 10x smaller than actual, which could contribute misdiagnosis or negatively influence patient management.</p> <p><a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=209828">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=209828</a></p> <p>Therefore, provide following details: Has this product been cleared for use post-recall in its country of origin? If yes, please provide the evidence</p>
14.	<p>M/s Martin Dow Specialties (Pvt) Limited</p> <p>7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>ELI-00160</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 302954325948</p>	<p><b><u>Legal Manufacturer:</u></b></p> <p>Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b></p> <p>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: 07-02-2025</p>	<p>sthemO AT L</p> <ul style="list-style-type: none"> <li>• 4 x 6-mL Vials of Thrombin</li> <li>• 4 x 6-mL Vials of Substrate</li> <li>• 4 x 6-mL Vials of Solvent</li> </ul> <p>Models/ Specification (as per Free sale certificate ) (01303)</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Approved</p>



	Dated: 07-04-2025	ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A		
15.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 46807511233 Dated: 07-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> 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: 07-02-2025</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>sthemO dRVV screen M sthemO dRVV screen L sthemO dRVV confirm • sthemO dRVV screen M: 12 x 2 mL Vials • sthemO dRVV screen L: 12 x 5 mL Vials • sthemO dRVV confirm: 12 x 2 mL Vials</p> <p>Models/ Specification (as per Free sale certificate): sthemO dRVV screen M: 01237 sthemO dRVV screen L: 01238 sthemO dRVV confirm: 01239</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Approved kit sthemO dRVV screen M: 01237 sthemO dRVV screen L: 01238</p>
16.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 17048180 Dated: 07-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> 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: 07-02-2025</p> <p>ISO 13485 certificate validity:</p>	<p>sthemO Fib M 12 x 4-ml Vials of sthemO Fib M</p> <p>Models/ Specification (as per Free sale certificate): 01224</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Approved</p>

		23-05-2028 CE Mark validity: N/A		
17.	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 23-04-2025  Fee: PKR 31,000/- Slip # 19071643 Dated: 07-04-2025	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> 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: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	sthemO II 6 x 1-ml Vials  Models/ Specification (as per Free sale certificate): 01229  Class-B  Shelf life: 24 Months	Approved
18.	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 23-04-2025  Fee: PKR 31,000/- Slip # 4251972986 Dated: 07-04-2025	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> 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: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	sthemO IX 6 x 1-ml Vials  Models/ Specification (as per Free sale certificate): 01226  Class-B  Shelf life: 24 Months	Approved
19.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France	sthemO LA QC 1&2  • Reagent 1: 3 x 1-mL Vials of Level 1	Approved

	Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160  Date of R& I 23-04-2025  Fee: PKR 31,000/- Slip # 783404978 Dated: 07-04-2025	<b><u>Manufacturing Site:</u></b> 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: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	• Reagent 2: 3 x 1-mL Vials of Level 2  Models/ Specification (as per Free sale certificate): 01251  Class-B  Shelf life: 24 Months	
20.	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 23-04-2025  Fee: PKR 31,000/- Slip # 66972961281 Dated: 07-04-2025	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> 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: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	sthemO PC chrom  • Reagent 1: 6 x 3-mL vials of Activator • Reagent 2: 6 x 6-mL vials of substrate  Models/ Specification (as per Free sale certificate): 01240  Class-B  Shelf life: 24 Months	Approved
21.	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	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny.	sthemO Pool Norm  • 12 x 1 ml vials  Models/ Specification (as per Free sale certificate): 01304  Class-B  Shelf life: 24 Months	Approved

	23-04-2025  Fee: PKR 31,000/- Slip # 992668229563 Dated: 07-04-2025	LOA validity: 31-Dec-2025  FSC country of origin validity: Date of Issue: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A		
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 23-04-2025  Fee: PKR 31,000/- Slip # 107118972 Dated: 07-04-2025	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> 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: 07-02-2025  ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	sthemO PS Free L  • Reagent 1: 6 x 5-mL vials • Reagent 2: 6 x 6-mL vials  Models/ Specification (as per Free sale certificate): 01243  Class-B  Shelf life: 15 Months	Approved
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 23-04-2025  Fee: PKR 31,000/- Slip # 4006022723 Dated: 07-04-2025	<b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  <b><u>Manufacturing Site:</u></b> 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: 07-02-2025 ISO 13485 certificate validity: 23-05-2028  CE Mark validity: N/A	sthemO PS VWF QC 1&2  • 12 x 1ml Vials of Level 1 (Reagent 1) • 12 x 1ml Vials of Level 2 (Reagent 2)  Models/ Specification (as per Free sale certificate): 01252  Class-B  Shelf life: 24 Months	Approved

24.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 066084557559 Dated: 07-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> 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: 07-02-2025</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>sthemO Unical 6 x 1ml vials</p> <p>Models/ Specification (as per Free sale certificate): 01254 Class-B</p> <p>Shelf life: 24 Months</p>	Approved
25.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 30530590384 Dated: 07-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> 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: 07-02-2025</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>sthemO V 6 x 1ml vials</p> <p>Models/ Specification (as per Free sale certificate): 01230</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	Approved
26.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> DIAGNOSTICA STAGO S.A.S. 23-29 Rue Constantin</p>	<p>sthemO VIII 6 x 1ml vials</p> <p>Models/ Specification (as per Free sale certificate): 01225</p> <p>Class-B</p>	Approved

	<p>ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 49762715 Dated: 07-04-2025</p>	<p>Pecqueur ZAC "Les Châtaigners" 95150 Taverny.</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: Date of Issue: 07-02-2025</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>Shelf life: 24 Months</p>	
27.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44- A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 31,000/- Slip # 7455322052 Dated: 07-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p><b><u>Manufacturing Site:</u></b> 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: 07-02-2025</p> <p>ISO 13485 certificate validity: 23-05-2028</p> <p>CE Mark validity: N/A</p>	<p>sthemO X 6 x 1ml vials</p> <p>Models/ Specification (as per Free sale certificate): 01232</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Approved</p>
28.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G- 11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7248-P 31,000/-</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p><b>Telephone number:</b> 82-43- 266-2315</p> <p><b>Official website:</b> www.diadent.co.kr</p> <p><b>Email:</b> www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p>	<p>DiaEtch Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes: 5gm tubes + Applicator tips</p> <p>5x5gm tube + Applicator tips</p>	<p>Deferred for the provision of following:</p> <p>Revised application on the prescribed Form for Class-B devices.</p> <p>Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.</p> <p>Generic name of the applied product.</p> <p>Clarification since the</p>

		LOA Validity: 01.12.2029  ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification		applied sizes are not mentioned in FSC.
29.	M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza, main service golra road opp G-11/1. Islamabad  ELI-00982 Issue Date: 21.10.2022 7252-P 31,000/-	<b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA Validity: 01.12.2029  ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification	DiaFill Flow  Class-B  Shelf Life: 2 Years  Sizes 2gm tube + Applicator tips	Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Generic name of the applied product.  Clarification since the applied sizes are not mentioned in FSC.
30.	M/s. Future Technologies Office no 2, First Floor Malik Sarwar plaza, main service Golra road Opp G-11/1. Islamabad  ELI-00982 Issue Date: 21.10.2022 7253-P 31,000/-	<b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA	Diadent DiaFill  Class-B  Shelf Life: 2 Years  Sizes 4gm tubes	Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Clarification of Brand name and Generic name of the device is required.

		<p>Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>		<p>Clarification since the applied sizes are not mentioned in FSC.</p>
31.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7254-P 31,000/-</p>	<p><b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent Diapex Plus Regular Kit Type-A</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes 2gm tube + Applicator tips</p>	<p>Deferred for the provision of following:</p> <p>Revised application on the prescribed Form for Class-B devices.</p> <p>Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.</p> <p>Clarification of Brand name and Generic name of the device is required.</p> <p>Clarification since the applied sizes are not mentioned in FSC.</p>
32.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7249-P 31,000/-</p>	<p><b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p>	<p>Diadent DiaPaste Plus Regular Kit Type-A</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes 2gm tube + Applicator tips</p>	<p>Deferred for the provision of following:</p> <p>Revised application on the prescribed Form for Class-B devices.</p> <p>Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.</p> <p>Clarification of Brand name and Generic name of the device is required.</p> <p>Clarification since the</p>



		ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification		applied sizes are not mentioned in FSC.
33.	M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad  ELI-00982 Issue Date: 21.10.2022 7255-P 31,000/-	<b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA Validity: 01.12.2029  ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification	Diadent DiaPlus  Class-B  Shelf Life: 2 Years  Sizes 5ml Bottle	Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Clarification of Brand name and Generic name of the device is required.
34.	M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad  ELI-00982 Issue Date: 21.10.2022 7250-P 31,000/-	<b>Legal Manufacturer:</b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA Validity: 01.12.2029	Diadent DiaPrep Pro  Class-B  Shelf Life: 2 Years  Sizes 6gmx2 tubes + Applicator tips	Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Clarification of Brand name and Generic name of the device is required.

		ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification		
35.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7251-P 31,000/-</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA Validity: 01.12.2029  ISO 13485 validity 01-06-2027  CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent Dia Proseal  Class-B  Shelf Life: 2 Years  Sizes 8gmx2 tubes + Applicator tips 2gmx2 tubes + Applicator</p>	<p>Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Clarification of Brand name and Generic name of the device is required.</p>
36.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7256-P 31,000/-</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea <b>Telephone number:</b> 82-43-266-2315 <b>Official website:</b> www.diadent.co.kr <b>Email:</b> www.diadent@diadent.co.kr  FSC: Korea Issued on: 18.03.2025  LOA Validity: 01.12.2029  ISO 13485 validity 01-06-2027</p>	<p>Diadent E-Temp  Class-B  Shelf Life: 2 Years  Sizes 30gm jar</p>	<p>Deferred for the provision of following:  Revised application on the prescribed Form for Class-B devices.  Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.  Clarification of Brand name and Generic name of the device is required.</p>

		CE certificate validity 26-05-2024 with extension notification		
37.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7257-P 31,000/-</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p><b>Telephone number:</b> 82-43-266-2315</p> <p><b>Official website:</b> www.diadent.co.kr</p> <p><b>Email:</b> www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent Gutta Percha</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Pkt of 120 &amp; Pkt of 60</p>	<p>Deferred for the provision of following:</p> <p>Revised application on the prescribed Form for Class-B devices.</p> <p>Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.</p> <p>Clarification of Brand name and Generic name of the device is required.</p> <p>Clarification since the applied sizes are not mentioned in FSC.</p>
38.	<p>M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7247-P 31,000/-</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p><b>Telephone number:</b> 82-43-266-2315</p> <p><b>Official website:</b> www.diadent.co.kr</p> <p><b>Email:</b> www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p>	<p>Diadent Paper Points</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Pkt of 120 &amp; Pkt of 200</p>	<p>Deferred for the provision of following:</p> <p>Revised application on the prescribed Form for Class-B devices.</p> <p>Original, valid and legalized documents including Credentials, LOA, FSC, ISO 13485 and CE certificates.</p> <p>Clarification of Brand name and Generic name of the device is required.</p> <p>Clarification since the applied sizes are not mentioned in FSC.</p>

		CE certificate validity 26-05-2024 with extension notification		
39.	<p>M/s Tech Zone, Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore</p> <p>ELI- 00040</p> <p>R&amp;I 28-04-2025</p> <p>Fee: PKR 31000/- Slip: 164375843165 Dated: 24-04-2025</p>	<p><b><u>Legal Manufacturer</u></b> M/s Zhejiang Haisheng Medical Device Co.,Ltd, No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China</p> <p>LOA validity: 21-01-2028</p> <p>FSC validity: 11-05-2026</p> <p>ISO 13485 validity 30-11-2026</p> <p>CE certificate: 26-05-2024 with extension notification</p>	<p>HISNER Disposable Pressure Transducer</p> <p>Shelf Life: 05 Years</p> <p>Class B</p> <p>Model: DBPT-0103, DBPT-0130, DBPT-0203, DBPT-0230, DBPT-0303, DBPT-0330, DBPT-0403, DBPT-0430, DBPT-0503C3, DBPT-0503C5, DBPT-0503C10, DBPT-0530C3, DBPT-0530C5, DBPT-0530C10, DBPT-0603C3, DBPT-0603C5, DBPT-0603C10, DBPT-0630C3, DBPT-0630C5, DBPT-0630C10, DBPT-0703C3, DBPT-0703C5, DBPT-0703C10, DBPT-0730C3, DBPT-0730C5, DBPT-0730C10, DBPT-0803C3, DBPT-0803C5, DBPT-0803C10, DBPT-0830C3, DBPT-</p>	<p>Approved subject to submission of revised Form along with fee for Class-C medical device since the applied product falls in Class-C. also submit the fee as per revised SRO for Family.</p>

			0830C5、DBPT-0830C10、 DBPT-0903、 DBPT-0930	
40.	<p>M/s Tech Zone, Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore</p> <p>ELI- 00040</p> <p>R&amp;I 28-04-2025</p> <p>Fee: PKR 31000/- Slip: 939909009173 Dated: 24-04-2025</p>	<p><b><u>Legal Manufacturer</u></b> M/s Zhejiang Haisheng Medical Device Co.,Ltd, No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China</p> <p>LOA validity: 21-01-2028</p> <p>FSC validity: 11-05-2026</p> <p>ISO 13485 validity 30-11-2026</p> <p>CE certificate: 26-05-2024 with extension notification</p>	<p>HISNER Disposable Electrosurgical Pencil</p> <p>Shelf Life: 05 Years</p> <p>Class B</p> <p>Model: HEP4、 HEP7、 HEP8、 HEP10、 HEP12、 HEP14、 HEP16</p>	<p>Approved subject to submission of revised Form along with fee for Class-C medical device since the applied product falls in Class-C. also submit the fee as per revised SRO for Family.</p>
41.	<p>M/s Tech Zone, Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore</p> <p>ELI- 00040</p> <p>R&amp;I 28-04-2025</p> <p>Fee: PKR 31000/- Slip: 5586528103 Dated: 24-04-2025</p>	<p><b><u>Legal Manufacturer</u></b> M/s Zhejiang Haisheng Medical Device Co.,Ltd, No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China</p> <p>LOA validity: 21-01-2028</p> <p>FSC validity: 11-05-2026</p> <p>ISO 13485 validity 30-11-2026</p> <p>CE certificate: 26-05-2024 with extension notification</p>	<p>HISNER Disposable Anesthesia Mask</p> <p>Shelf Life: 05 Years</p> <p>Class B</p> <p>Model: Inflatable、 Non-inflatable</p> <p>Size: Newborn, Infant, Child, Adult (S) Adult (M) Adult (L)</p>	<p>Approved Inflatable subject to submission of fee as per revised SRO for Family including sizes Newborn, Infant, Child, Adult (S) Adult (M) Adult (L).</p>
42.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p>	<p><b><u>Legal Manufacturer</u></b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany</p> <p><b>LOA Validity:</b></p>	<p>Transferrin (Transferrin) FS</p> <p><b>Class: B</b></p> <p><b>Codes/Sizes:</b> 172529910921</p>	<p>Approved</p>

	<b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 35275591607 <b>Dated:</b> 14/04/2025	15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	(4x100 Test) 172529910930 (4x20mL/2x8mL) 172529910935 (2x20mL/1x8mL) 172529910964 (600 Test)  <b>Shelf life:</b> 172529910921 – <b>24 months</b> 172529910930 – <b>24 months</b> 172529910935 – <b>24 months</b> 172529910964 – <b>24 months</b>	
43.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 31000</b> <b>Slip:</b> 8739226148 <b>Dated:</b> 14/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	NEFA Standard FS (Non-esterified fatty acids Standard)  <b>Class: B</b>  <b>Codes/Sizes:</b> 157809910065 (3x3mL)  <b>Shelf life:</b> 157809910065 – 12 months	Approved
44.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 31000</b> <b>Slip:</b> 508701282295 <b>Dated:</b> 17/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	TruCal Cystatin C (Cystatin C calibrator)  <b>Class: B</b>  <b>Codes/Sizes:</b> 171509910059 (5x1mL)  <b>Shelf life:</b> 171509910059 - 12 weeks	Approved
45.	M/s. Nextek	<b>Legal Manufacturer</b>	TRUCAL G6PDH 2	Approved

	Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 31000</b> <b>Slip:</b> 11217734657 <b>Dated:</b> 11/04/2025	DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	levels (Glucose-6-phosphate dehydrogenase calibrator) <b>Class: B</b> <b>Codes/Sizes:</b> 179009910040 (2 x 0.5 mL) <b>Shelf life:</b> 179009910040 – 36 months	
46.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 31000</b> <b>Slip:</b> 346601817 <b>Dated:</b> 11/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	TruCal CK-MB (Creatine kinase-MB calibrator) <b>Class: B</b> <b>Codes/Sizes:</b> 594509910074 (6x1 mL) <b>Shelf life:</b> 594509910074 – 24 months	Approved
47.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 4155683895 <b>Dated:</b> 11/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	TruLab L Level 1 (Lipid control) <b>Class: B</b> <b>Codes/Sizes:</b> 590209910065 (3x3mL) 590309910065 (3x3mL) <b>Shelf life:</b> 590209910065 – 36 months 590309910065 – 36 months	Approved
48.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9,	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH.	TruLab Urine Level 1 (Urine Control)	Approved

	Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 84811947 <b>Dated:</b> 11/04/2025	Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	TruLab Urine Level 2 (Urine Control) <b>Class: B</b> <b>Codes/Sizes:</b> 591709910061 (6x5mL) 591709910062 (20x5mL) 591809910061 (6x5mL) 591809910062 (20x5mL) <b>Shelf life:</b> 591709910061 – 24 months 591709910062 – 24 months 591809910061 – 24 months 591809910062 – 24 months	
49.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 707459662087 <b>Dated:</b> 11/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	TruLab N (Control) <b>Class: B</b> <b>Codes/Sizes:</b> 590009910061 (6x5mL) 590009910062 (20x5mL) <b>Shelf life:</b> 590009910061 – <b>36 months</b> 590009910062 – <b>36 months</b>	Approved
50.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 840370388	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022	TruLab P (Control) <b>Class: B</b> <b>Codes/Sizes:</b> 590509910061 (6x5mL) 590509910062 (20x5mL) <b>Shelf life:</b>	Approved



	<b>Dated:</b> 11/04/2025	<b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	590509910061 – 36 months 590509910062 – 36 months	
51.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 38961134338 <b>Dated:</b> 11/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	TruLab Protein Level 1 (Protein control)  TruLab Protein Level 2 (Protein control)  <b>Class: B</b>  <b>Codes/Sizes:</b> 595009910046 (3x1mL) 595109910046 (3x1mL)  <b>Shelf life:</b> 595009910046 – 36 months 595109910046 – 36 months	Approved
52.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 005798270061 <b>Dated:</b> 17/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	TruLab Bicarbonate (Bicarbonate control)  <b>Class: B</b>  <b>Codes/Sizes:</b> 597009910065 (3x3mL)  <b>Shelf life:</b> 597009910065 – 15 months	Approved
53.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 118154381	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022	TruLab PCT Level 1 (Procalcitonin control)  TruLab PCT Level 2 (Procalcitonin control)  <b>Class: B</b>  <b>Codes/Sizes:</b> 599709910046 (3x1mL) 599809910046	Approved

	<b>Dated:</b> 10/04/2025	<b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	(3x1mL) <b>Shelf life:</b> 599709910046 – 12 months 599809910046 – 12 months	
<b>54.</b>	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 5521715429 <b>Dated:</b> 10/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	CK-NAC FS (Creatine kinase NAC)  <b>Class: B</b>  <b>Codes/Sizes:</b> 116019910021 (5x20mL/1x25mL) 116019910023 (1x800mL/1x200mL) 116019910026 (5x80mL/1x100mL) 116019910704 (8x50mL/8x12.5mL) 116019910921 (4x120 Test) 116019910930 (4x20mL/2x10mL) 116019910962 (1890 Test)  <b>Shelf life:</b> 116019910021 – 18 months 116019910023 – 18 months 116019910026 – 18 months 116019910704 – 18 months 116019910921 – 18 months 116019910930 – 18 months 116019910962 – 18 months	Approved
<b>55.</b>	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b>	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany  <b>LOA Validity:</b> 15-02-2028  <b>FSC issue date:</b>	Procalcitonin FS (Procalcitonin)  <b>Class: B</b>  <b>Codes/Sizes:</b> 173189910930 (2x18mL/2x6mL)  <b>Shelf life:</b>	Approved

	<b>Slip:</b> 10700642087 <b>Dated:</b> 10/04/2025	18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	173189910930 – 18 months	
56.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 971534357424 <b>Dated:</b> 17/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	G6PDH (Glucose 6 phosphate dehydrogenase) <b>Class: B</b> <b>Codes/Sizes:</b> 179009910026 (1x20mL+4x5mL+1x40) <b>Shelf life:</b> 179009910026– 12 months	Approved
57.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b> 23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 2695301283 <b>Dated:</b> 14/04/2025	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028 <b>FSC issue date:</b> 18-08-2022 <b>ISO 13485 Validity:</b> 21-11-2025 <b>DOC</b> Issue date : 27-07-2022	NEFA FS (Non-esterified fatty acids) <b>Class: B</b> <b>Codes/Sizes:</b> 157819910921 (4x120 Test) 157819910935 (2x20mL/1x10mL) 157819910964 (540 Test) <b>Shelf life:</b> 157819910921 – 12 months 157819910935 – 12 months 157819910964 – 12 months	Approved
58.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. <b>(ELI- 00619)</b> <b>R&amp;I detail</b>	<b>Legal Manufacturer</b> DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany <b>LOA Validity:</b> 15-02-2028	Phospholipids FS (Phospholipids) <b>Class: B</b> <b>Codes/Sizes:</b> <b>157419910921</b> (4x120 Test)	Approved

	23/04/2025 <b>Fee: 50000</b> <b>Slip:</b> 05590236746 <b>Dated:</b> 14/04/2025	<b>FSC issue date:</b> 18-08-2022  <b>ISO 13485 Validity:</b> 21-11-2025  <b>DOC</b> Issue date : 27-07-2022	<b>157419910930</b> (4x20mL/2x10mL) <b>157419910964</b> (420 Test)  <b>Shelf life:</b> <b>157419910921 –</b> <b>12 months</b> <b>157419910930 –</b> <b>12 months</b> <b>157419910964 –</b> <b>12 months</b>	
<b>59.</b>	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: 21-04-2025 DRAP Fees: Rs: 31,000/- Challan No. 9335397324 Dated: 19-04-2025	<b><u>Legal Manufacturer:</u></b> Tianchang Hengsheng Medical Devices Co.,Ltd.  Address: Qinlan Industrial Park, 239341, Tianchang City, Anhui Province, People's Republic of China. Tel: 0086-550-7811946 Fax: 0086-550-7816946  Free Sale Certificate Date of Issue: 22-11-2025  LOA Expiry: Jan-2029  CE Certificate Expiry: 2024-05-26  ISO Certificate Expiry: 2026-04-11	X-MED Disposable Sterile Latex Surgical Gloves  Class: B  Shelf Life: 5 Years  Sizes Code: 6,6.5,7,7.5,8.0, 8.5 & 9.0	Deferred for the provision of following:  Valid and notarized CE certificate along with extension notification letter if applicable.  Clarification of Brand name of applied device since Brand name on application form is X-Med whereas in LOA the mentioned Brand name is Monarch.
<b>60.</b>	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: 21-04-2025 DRAP Fees: Rs: 31,000/- Challan No. 1003442015 Dated: 19-04-2025	<b><u>Legal Manufacturer:</u></b> Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd. China Address: Floor 2, Building 102, NO.198East Wuzhou Road, Development Zone, Yangzhou, CHINA Tel: +86 0514 85165235 Fax: +86 0514 85165135  Free Sale Certificate Date of Issue: 2025-09-02  LOA Expiry: Dec-2027  CE Certificate Expiry: 2026-05-24 ISO Certificate	X-MED Disposable Thoracic Chest Drainage Catheter  Class: B  Shelf Life: 5 Years  Codes: ZI - 7Fr - 250 21 - 8.5Fr - 250 ZI-10Fr-250 ZI-12Fr-250 ZI-16Fr-280 ZI-20Fr-280 ZI-24Fr-280 ZI- 28Fr - 280 ZII - 16Fr - 350 ZII-20Fr-350	Deferred for the provision of following:  Notarized Credentials.  Original, valid and notarized LOA.  Original, valid and attested FSC of China.  Notarized and valid ISO 13485 and CE certificate.  Clarification of grouping the applied models in Single

		Expiry: 2025-10-20	ZII - 24Pr - 350 ZII- 28Fr - 350 ZIII - 16Fr - 300 ZIII - 16Fr - 300 ZIII - 20Fr - 300 ZIII - 24Fr - 300 ZIII- 28Fr - 300	application.
61.	<p>Applicant Name: A&amp;E Medical 323- ATA TURK BLOCK NEW GARDEN TOWN LAHORE (ELI-00023)</p> <p>Date of R&amp;I 17-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 16568829 Dated: 10-04-2025</p>	<p><b><u>Name of Manufacturer:</u></b> Sunny Medical Device (Shenzhen) Co, Ltd located at 1F and 401, Zhongtianxin Building, Longgang District, 518000, Shenzhen, Peoples Republic of China</p> <p>LOA Validity: 04-09-2027</p> <p>FSC: Spain Issuance 03-11-2023</p> <p>ISO Validity: 18.10.2027</p> <p>EU QA Certificate Validity: 26-04-2028</p>	<p>SUNMED Inflation Device Kit</p> <p>Class-B</p> <p>Shelf life: 03 years</p> <p>Models/ Specification 1-SM-ID-S3030HC14- TB 2-SM-ID-S3030HP14- TB 3-SM-ID-S3030HS14- TB 4-SM-ID-S3030HC42- TB</p>	<p>Deferred for the clarification since the same Brand name, of the subject device, from the same manufacturer is also addressed in M-59 for Health Care International, First Floor, 210/J-2, Johar Town, Lahore.</p> <p>Fee is not as per the revised SRO for Family.</p>
62.	<p>KASBN International, 42-A1 Gulberg III Lahore</p> <p>ELI-00434</p> <p>Date of R&amp;I 18-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 54219932159</p>	<p><b><u>Legal Manufacturer:</u></b> Nouvag AG, St. Gallerstrasse 25, CH-9403 Goldach, Switzerland</p> <p>LOA Validity: 31-12-2027</p> <p>FSC: Switzerland Validity: 21-01-2025</p> <p>ISO Validity: 26-01-2028</p> <p>EU QA Certificate Validity: 26-05-2024 with extension notification</p>	<p>Dermatome</p> <p>Class-B</p> <p>Shelf life: N/A</p> <p>Models/ Specification; 100mm 75mm 50mm 25mm E-Fitting for free skin grafting (without blade)</p>	<p>Deferred for the provision of following:</p> <p>Notarized Credentials.</p> <p>Original, valid and notarized LOA.</p> <p>Original, valid and attested FSC</p> <p>Notarized and valid ISO 13485 and CE certificate.</p> <p>Description of the product.</p> <p>Brand name.</p> <p>Shelf life and shelf life studies.</p>
63.	<p>KASBN International, 42-A1 Gulberg III Lahore</p>	<p><b><u>Legal Manufacturer:</u></b> Nouvag AG, St. Gallerstrasse 25, CH-9403 Goldach,</p>	<p>ENT/Neuro Drill System</p>	<p>Deferred for the provision of following:</p>

	<p>ELI-00434</p> <p>Date of R&amp;I 18-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 091421443</p>	<p>Switzerland</p> <p>LOA Validity: 31-12-2024</p> <p>FSC: Switzerland Validity: 21-01-2025</p> <p>ISO Validity: 26-01-2028</p> <p>EU QA Certificate Validity: 26-05-2024</p>	<p>Class-B</p> <p>Shelf life: N/A</p> <p>Models/ Specification; Control unit HighSurg30 100V; 115V; 230V (3360) Control unit TCM 3000ib (3280)</p>	<p>Notarized Credentials.</p> <p>Original, valid and notarized LOA.</p> <p>Original, valid and attested FSC</p> <p>Notarized and valid ISO 13485 and CE certificate.</p> <p>Description of the product.</p> <p>Brand name.</p> <p>Shelf life and shelf life studies.</p> <p>Two different product applied as System, clarification is required regarding the applied Brand name.</p>
64.	<p>Bio Links International, 243, Ground Floor Rewaz Garden Lahore</p> <p>ELI-00933</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 67634191582 Dated: 23-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Suzhou Coming Changye Medical Technology Co., Ltd., No. 258 Huajin Road, High &amp; New Tech Zone, Suzhou, China</p> <p>LOA Validity: 20-03-2030</p> <p>FSC: China: Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p>	<p>Eaglenos Blood Gas Control Solution</p> <p>Class-B</p> <p>Shelf life: 06 Months</p> <p>Models/ Specification EG-c1,EG-c2, EG-c3</p>	<p>Deferred for the provision of following:</p> <p>Valid and legalized FSC of reference country/ notarized and valid CE marked document.</p> <p>The applied Brand name is not mentioned in LOA and FSC, clarification is required.</p> <p>Fee needs to be revised for Cluster.</p> <p>Original Fee challan.</p>
65.	<p>Bio Links International, 243, Ground Floor Rewaz Garden Lahore</p> <p>ELI-00933</p>	<p><b><u>Legal Manufacturer:</u></b> Suzhou Coming Changye Medical Technology Co., Ltd., No. 258 Huajin Road, High &amp; New Tech Zone, Suzhou, China</p>	<p>Eaglenos Blood Gas Test Cartridge</p> <p>Class-B</p>	<p>Deferred for the provision of following:</p> <p>Valid and legalized FSC of reference</p>

	<p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 83374126 Dated: 23-04-2025</p>	<p>LOA Validity: 20-03-2030</p> <p>FSC: China: Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p>	<p>Shelf life: 12 Months</p> <p>Applied as System</p> <p>Models/ Specification EG10+, EG4+, EL4+, EG9+, EG8+, EG7-Ca, EG6+, EG+ EG3+ EC7+ EC6+, EC5+, EC4+</p>	<p>country/ notarized and valid CE marked document.</p> <p>The applied Brand name is not mentioned in LOA and FSC, clarification is required.</p> <p>Fee needs to be revised for Cluster.</p> <p>Original Fee challan.</p>
66.	<p>Bio Links International, 243, Ground Floor Rewaz Garden Lahore</p> <p>ELI-00933</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 25000/- Fee Challan No: 6891675674 Dated: 18-11-2022</p>	<p><b><u>Legal Manufacturer:</u></b> Suzhou Coming Changye Medical Technology Co., Ltd., No. 258 Huajin Road, High &amp; New Tech Zone, Suzhou, China</p> <p>LOA Validity: 20-03-2030</p> <p>FSC: China: Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p>	<p>Lyser for Hematology Analyser IVD Reagent for Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 2 Years</p> <p>Models/ Specification 300ml Pack 400ml Pack 500ml Pack 1 Liter Pack 5 Liter Pack</p>	<p>Deferred for the provision of following:</p> <p>Valid and legalized FSC of reference country/ notarized and valid CE marked document.</p> <p>Brand name and also specify the type of subject reagent</p> <p>Fee needs to be revised for Family.</p> <p>Original Fee challan.</p>
67.	<p>Bio Links International, 243, Ground Floor Rewaz Garden Lahore</p> <p>ELI-00933</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 25000/- Fee Challan No: 80468803862 Dated: 18-11-2022</p>	<p><b><u>Legal Manufacturer:</u></b> Suzhou Coming Changye Medical Technology Co., Ltd., No. 258 Huajin Road, High &amp; New Tech Zone, Suzhou, China</p> <p>LOA Validity: 20-03-2030</p> <p>FSC: China: Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p>	<p>Cleaner for Hematology Analyser IVD Reagent for Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 2 Years</p> <p>Models/ Specification 1 Liter 5 Liter 1.5 Liter 10 Liter 20 Liter</p>	<p>Deferred for the provision of following:</p> <p>Valid and legalized FSC of reference country/ notarized and valid CE marked document.</p> <p>Brand name and also specify the type of subject reagent</p> <p>Fee needs to be revised for Family.</p> <p>Original Fee challan.</p>
68.	<p>Bio Links International, 243, Ground Floor Rewaz</p>	<p><b><u>Legal Manufacturer:</u></b> Suzhou Coming Changye Medical Technology Co., Ltd.,</p>	<p>Diluent for Hematology Analyser</p>	<p>Deferred for the provision of following:</p>

	<p>Garden Lahore</p> <p>ELI-00933</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 25000/- Fee Challan No: 572036824 Dated: 18-11-2022</p>	<p>No. 258 Huajin Road, High &amp; New Tech Zone, Suzhou, China</p> <p>LOA Validity: 20-03-2030</p> <p>FSC: China: Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p>	<p>IVD Reagent for Hematology Analyzer</p> <p>Class-B</p> <p>Shelf life: 2 Years</p> <p>Models/ Specification 20 Liter</p>	<p>Valid and legalized FSC of reference country/ notarized and valid CE marked document.</p> <p>Brand name.</p> <p>Original Fee challan.</p>
69.	<p>Roys and Roys International, 1<sup>st</sup> Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore</p> <p>ELI-00708</p> <p>Date of R&amp;I 11-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 35421187109</p>	<p><b><u>Legal Manufacturer:</u></b> Changsha Sinocare Inc. 265 Guyuan Roas, Hi-Tech Zone, Changsha, Hunan Province, 410205, People's Republic of China.</p> <p>Original FSC: China Date of Validity: 14-03-2026. LOA validity 07-02-2027 ISO 13485 validity 31-01-2028</p> <p>CE certificate validity 26-05-2024</p>	<p>Sinocare AQ max I Blood Glucose Test Strip</p> <p>Class-B</p> <p>Shelf life: 24 Months</p> <p>Models/ Specification; 50 pcs and 100 pcs</p>	<p>Approved subject to submission of valid and notarized CE certificate along with extension notification letter.</p>
70.	<p>Merlin International, Office No. 341, 3rd Floor, Land Mark Plaza, Jail Road, Lahore</p> <p>ELI: 00569 5953-P Fee 31,000/- slip no. 962491027856</p>	<p><b><u>Legal Manufacturer:</u></b> Chifeng Tianbo Medical Device Co., Ltd Zhongjing Industrial Park Economic Development Area, Ninhcheng District, Chifeng 024200, Inner Mongolia, P.R China.</p> <p>LOA validity: Not clear</p> <p>FSC validity 14-04-2025</p> <p>ISP 13485 validity 17-02-2025</p> <p>Production QA certificate validity 17-02-2027</p>	<p>Well-Flow Infusion Set with Y-Port</p> <p>Class-B</p> <p>Shelf life: Not mentioned</p> <p>Codes/Specifications: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Original and legalized documents including: Notarized and valid LOA, attested/apostilled FSC, notarized &amp; valid ISO 13485 and Production QA certificates.</p> <p>The model mentioned on DoC is not available in FSC of China, clarification is required.</p> <p>Shelf life along with studies.</p>



71.	<p>Madina Pharma Links, Office No. 4, 2<sup>nd</sup> Floor, 447/448, Akbar Plaza, G-I, Muhammad Ali Johar Town, Lahore</p> <p>ELI-00556</p> <p>Date of R&amp;I 24-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 466742335414</p>	<p><b><u>Legal Manufacturer:</u></b> Shandong Ruyue Medical Technology Co. Ltd., North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City, 256600 Shandong, China</p> <p>LOA Validity: 22-12-2028</p> <p>FSC: China Validity: 25-3-2027</p> <p>FSC: Germany Issuance 15-06-2023</p> <p>ISO Validity: 29-12-2026</p> <p>EU QA Certificate Issue date: 16-05-2024 with extension notification letter.</p>	<p>Infusion Care IV Burette Type Set with Y Injection Port with Needle</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Models/ Specification; As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of Germany is attested from Pakistani Embassy located at China.</p> <p>FSC of China is issued from China Chamber of Commerce.</p> <p>The applied product is not mentioned in FSC of China and Germany.</p>
72.	<p>Madina Pharma Links, Office No. 4, 2<sup>nd</sup> Floor, 447/448, Akbar Plaza, G-I, Muhammad Ali Johar Town, Lahore</p> <p>ELI-00556</p> <p>Date of R&amp;I 24-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 7985041863</p>	<p><b><u>Legal Manufacturer:</u></b> Shandong Ruyue Medical Technology Co. Ltd., North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City, 256600 Shandong, China</p> <p>LOA Validity: 22-12-2028</p> <p>FSC: China Validity: 25-3-2027</p> <p>FSC: Germany Issuance 15-06-2023</p> <p>ISO Validity: 29-12-2026</p> <p>EU QA Certificate Issue date: 16-05-2024</p>	<p>Infusion Care IV Set with Needle</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Models/ Specification; As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of Germany is attested from Pakistani Embassy located at China.</p> <p>FSC of China is issued from China Chamber of Commerce.</p>
73.	<p>Madina Pharma Links, Office No. 4, 2<sup>nd</sup> Floor, 447/448, Akbar Plaza, G-I, Muhammad Ali Johar Town, Lahore</p> <p>ELI-00556</p> <p>Date of R&amp;I 24-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Shandong Ruyue Medical Technology Co. Ltd., North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City, 256600 Shandong, China</p> <p>LOA Validity: 22-12-2028</p> <p>FSC: China Validity: 25-3-2027</p>	<p>Infusion Care IV Set with Y Injection Port with Needle</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Models/ Specification; As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of Germany is attested from Pakistani Embassy located at China.</p> <p>FSC of China is issued from China Chamber of Commerce.</p>

	<p>Fee Details: Paid Fee: 31000/- Fee Challan No: 167493056840</p>	<p>FSC: Germany Issuance15-06-2023</p> <p>ISO Validity: 29-12-2026</p> <p>EU QA Certificate Issue date: 16-05-2024 with extension notification letter.</p>		<p>The applied product is not mentioned in FSC of China and Germany.</p>
74.	<p>Shams Scientific Traders, 22-Y-J Madina Town Faisalabad</p> <p>ELI-00459</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 93156241018</p>	<p><b><u>Legal Manufacturer:</u></b> Rapid Labs Ltd., Unit 2, Hall Farm Church Road, Little Bentley Colchester, Essex, CO7 8SD, United Kingdom</p> <p>LOA Validity: 13-03-2030</p> <p>FSC: UK Validity: 27-05-2026</p> <p>ISO Validity: 15-10-2027</p> <p>EU QA Certificate Validity: 27-05-2025</p>	<p>Rapid Biotec RA (RF) Latex Kit</p> <p>Class-B</p> <p>Shelf life: 30 months</p> <p>Models/ Specification; RL-RA100 (with accessories) RL-RA100NA (without accessories) RL-RA50 RL-RA50NA</p>	<p>Approved RA (RF) Latex Kit with accessories in Class-C subject to submission of revised Form and differential fee.</p>
75.	<p>Shams Scientific Traders, 22-Y-J Madina Town Faisalabad</p> <p>ELI-00459</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 752954897247</p>	<p><b><u>Legal Manufacturer:</u></b> Rapid Labs Ltd., Unit 2, Hall Farm Church Road, Little Bentley Colchester, Essex, CO7 8SD, United Kingdom</p> <p>LOA Validity: 13-03-2030</p> <p>FSC: UK Validity: 27-05-2026</p> <p>ISO Validity: 15-10-2027</p> <p>EU QA Certificate Validity: 27-05-2025</p>	<p>Rapid Biotec ASO Latex Kit</p> <p>Class-B</p> <p>Shelf life:30 months</p> <p>Models/ Specification; RL-ASO100 (with accessories) RL-ASO100NA (without accessories) RL- ASO50 RL- ASO50NA</p>	<p>Approved ASO Latex Kit with accessories in Class-C subject to submission of revised Form and differential fee.</p>
76.	<p>Shams Scientific Traders, 22-Y-J Madina Town Faisalabad</p> <p>ELI-00459</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 752954897247</p>	<p><b><u>Legal Manufacturer:</u></b> Rapid Labs Ltd., Unit 2, Hall Farm Church Road, Little Bentley Colchester, Essex, CO7 8SD, United Kingdom</p> <p>LOA Validity: 13-03-2030</p> <p>FSC: UK Validity: 27-05-2026</p> <p>ISO Validity: 15-10-2027</p> <p>EU QA Certificate</p>	<p>Rapid Biotec CRP Latex Kit</p> <p>Class-B</p> <p>Shelf life:30 months</p> <p>Models/ Specification; RL-CRP100 (with accessories) RL-CRP100NA (without accessories) RL- CRP50</p>	<p>Approved CRP Latex Kit with accessories in Class-C subject to submission of revised Form and differential fee.</p>

		Validity: 27-05-2025	RL- CRP50NA	
77.	Orbit Diagnostics, 403, Plaza 55, Civic Centre, Bahria Town, Islamabad  ELI-00630  Date of R&I 18-04-2025  Fee Details: Paid Fee: 31000/- Fee Challan No: 596577365775	<b><u>Legal Manufacturer:</u></b> AEHEALTH Limited, Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen, P.R. China  LOA Validity: 12-03-2030  FSC: China Validity: 03-12-2026  FSC: Germany Issue date: 25-07-2023  ISO Validity: 26-02-2026	AEHEALTH Cardiac Marker – Immunofluorescence Assays  Class-B  Shelf life: 2 years  Applied as Cluster  Models/ Specification;	Deferred since all the applied products are kits. Also inform for which product instant application to be considered for along with correct class and differential fee. The firm will submit all the kits separately according to their Class of medical device with revised application Form and fee, codes etc.
78.	Orbit Diagnostics, 403, Plaza 55, Civic Centre, Bahria Town, Islamabad  ELI-00630  Date of R&I 18-04-2025  Fee Details: Paid Fee: 31000/- Fee Challan No: 841910119280	<b><u>Legal Manufacturer:</u></b> AEHEALTH Limited, Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen, P.R. China  LOA Validity: 12-03-2030  FSC: China Validity: 03-12-2026  FSC: Germany Issue date: 25-07-2023  ISO Validity: 26-02-2026	AEHEALTH Inflammation Marker – Immunofluorescence Assays  Class-B  Shelf life:2 years  Applied as Cluster  Models/ Specification;	Deferred since all the applied products are kits. Also inform for which product instant application to be considered for along with correct class and differential fee. The firm will submit all the kits separately according to their Class of medical device with revised application Form and fee., codes etc
79.	Orbit Diagnostics, 403, Plaza 55, Civic Centre, Bahria Town, Islamabad  ELI-00630  Date of R&I 18-04-2025  Fee Details: Paid Fee: 31000/- Fee Challan No: 49967772263	<b><u>Legal Manufacturer:</u></b> AEHEALTH Limited, Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen, P.R. China  LOA Validity: 12-03-2030  FSC: China Validity: 03-12-2026  FSC: Germany Issue date: 25-07-2023  ISO Validity: 26-02-2026	AEHEALTH Hormone – Immunofluorescence Assays  Class-B  Shelf life:2 years  Applied as Cluster  Models/ Specification;	Deferred for the provision of revised application form and fee as per the grouping the products in Cluster. Also inform for which product instant application to be considered for along with differential fee, codes etc.

80.	<p>Opti-Med, 37A Main Gulberg Lahore</p> <p>ELI-00501</p> <p>Date of R&amp;I 24-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 235995157578 5400612479 79438925</p>	<p><b><u>Legal Manufacturer:</u></b> Shenzhen Certainn Technology Co., Ltd., L302, Bldg 2, Skyworth Innovation Valley, No. 8 Tangtou 1<sup>st</sup> Road, Tangtou Community, Shiyan Subdistrict, Bao'an District, 518108, Shenzhen, People's Republic of China</p> <p>LOA Validity: 07-11-2027</p> <p>FSC: China Validity: 22-03-2025</p> <p>ISO Validity: 25-03-2026</p> <p>EU QA Certificate Validity: 26-05-2024 with extension notification.</p>	<p>OCT/OCTA (Model: Mocean)</p> <p>Brand Name: Optical Biometer (Model: Colombo IOL I &amp; Colombo IOL II)</p> <p>Brand Name: Smart Ref (Auto Ref-Keratometer)</p> <p>Class-B</p> <p>Shelf life:8 years</p> <p>Model for OCT/OCTA is Mocean 4000</p>	<p>Approved OCT/OCTA is Mocean 4000.</p> <p>The firm is required to submit the FSC for other two products including Optical Biometer (Model: Colombo IOL I &amp; Colombo IOL II) And Smart Ref (Auto Ref-Keratometer). Separately apply for Colombo IOL II</p>
81.	<p>Uniplan Trade Intl, 132/1 Quaid-e-Azam Industrial Estate Kot Lakh Pat, Lahore</p> <p>ELI-00132</p> <p>Date of R&amp;I 21-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 441754218</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 557925231</p>	<p><b><u>Legal Manufacturer:</u></b> Fresenius Kabi AG Else-Kroner-str.1 61352 Bad homburg Germany</p> <p><b><u>Other Site:</u></b> Fenwal international Inc. Carretera Sanchez km 18.5, Parque International Itabo.zona, Franca ind. De s.c Halna, Dominican Republic</p> <p>LOA Validity: 31-12-2026</p> <p>FSC: Germany Issue date: 30-10-2024</p> <p>ISO Validity: 31-03-2025</p> <p>EU QA Certificate Validity: 17-10-2026</p>	<p>Blood Component Filter Set with Vented Spike and Luer Adapter X7C2170 Amicus Ancillary Set</p> <p>Waste Transfer Set X7C2172 Amicus Ancillary Set</p> <p>Class-B</p> <p>Shelf life: 24 months Blood Component Filter Set with Vented Spike and Luer Adapter X7C2170 Shelf life: 24 months Waste Transfer Set X7C2172</p>	<p>Approved both Blood Component Filter Set with Vented Spike and Luer Adapter X7C2170 Amicus Ancillary Set and Waste Transfer Set X7C2172 Amicus Ancillary Set</p>
82.	<p>Claris Medical, Flat No. 001, Ground Floor, Rayyan Heights, Gangal East Service Road, Islamabad Expressway, Islamabad</p> <p>ELI-00269</p>	<p><b><u>Legal Manufacturer:</u></b> De Soutter Medical Limited, Halton Brook Business Park, Weston Road, Aston Clinton, Bucks, HP22 5WF United Kingdom</p> <p>LOA Validity: 08-04-2027</p> <p>FSC: UK</p>	<p>De Soutter Medical SternuDrive Sternum Saw</p> <p>Class-B</p> <p>Shelf life:5 years</p> <p>Models/ Specification;</p>	<p>Deferred for clarification since the same device already applied by G med and addressed in M-78 meeting of MDB.</p>

	<p>Date of R&amp;I 25-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 2779821195</p>	<p>Validity: 30-06-2029</p> <p>ISO Validity: 11-08-2026</p> <p>EU QA Certificate Validity: 10-05-2028</p>	As per FSC	
83.	<p>Aqib Trading Company (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak District Nowshera, KPK</p> <p>ELI-0628</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 31475910396</p>	<p><b><u>Legal Manufacturer:</u></b> Jiangxi Hongda Medical Equipment Group Ltd., 39 South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China</p> <p>LOA Validity: 03-09-2029</p> <p>FSC: China Validity: 01-09-2026</p> <p>ISO Validity: 30-06-2025</p> <p>EU QA Certificate Validity: 26-05-2024 with extension notification</p>	<p>AT-CAN IV Cannula Pen Type for Single Use</p> <p>Class-B</p> <p>Shelf life:5 years</p> <p>Models/ Specification; Iv Cannula Pen Type. Size: 0.6 * 16mm (266 * 0.63IN) 0. 6x19mm (266 * 0.75IN) , 7 * 19mm (24Gx0. 75IN) 0.9 * 19mm (22G * 0.75IN) 0.9 * 25mm (22G * 1IN) 1. 0 * 32mm ( 20G * 1 . 25IN), 1. 1 * 25mm ( 20G * 1 00IN), 1. 1 * 30mm ( 20G * 1 16IN), 1. 1x48mm (20G * 1.88IN) 1. 3 * 30mm ( 18G * 1 16IN), 1. 3 * 48mm (18G * 1.881N) 1. 6 * 55mm ( 166 * 2 17IN), 2. 0 * 55m ( 14G * 2 17IN).</p>	Approved subject to submission of attested free sale certificate from concerned regulatory authority.
84.	<p>Aqib Trading Company (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak District Nowshera, KPK</p> <p>ELI-0628</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 31000/-</p>	<p><b><u>Legal Manufacturer:</u></b> Jiangxi Hongda Medical Equipment Group Ltd., 39 South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China</p> <p>LOA Validity: 03-09-2029</p> <p>FSC: China Validity: 01-09-2026</p> <p>ISO Validity: 30-06-2025</p>	<p>AT-Vein Scalp Vein Set for Single Use</p> <p>Class-B</p> <p>Shelf life:5 years</p> <p>Models/ Specification; 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.2mm</p>	Approved subject to submission of attested free sale certificate from concerned regulatory authority.

	Fee Challan No: 78965268680	EU QA Certificate Validity: 26-05-2024 with extension notification		
85.	<p>Alsons Technology (Pvt) Ltd., Plot No. 8- C, Old Sunset Boulevard Commercial Street, Phase 2 DHA Karachi</p> <p>ELI-01322</p> <p>Date of R&amp;I 25-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 406941327574</p>	<p><b><u>Legal Manufacturer:</u></b> GE Medical Systems (China) Co. Ltd., No. 19 Changjiang Road, Wuxi National Hi-Tech Dev. Zone 214028, Jiangsu China</p> <p>LOA Issue date: 24-09-2024</p> <p>FSC: France Issue: 27-01-2025</p> <p>FSC: China Validity: 25-08-2025</p> <p>ISO Validity: 07-05-2026</p> <p>EU QA Certificate Validity: 07-05-2026</p>	<p>Versana Active General Purpose Ultrasound imaging system</p> <p>Class-B</p> <p>Shelf life: N/A</p> <p>Models/ Specification; N/A</p>	deffered submission of fee as per the revised SRO for System and original and legalized documents and model
86.	<p>Alsons Technology (Pvt) Ltd., Plot No. 8- C, Old Sunset Boulevard Commercial Street, Phase 2 DHA Karachi</p> <p>ELI-01322</p> <p>Date of R&amp;I 25-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 3303836016</p>	<p><b><u>Legal Manufacturer:</u></b> GE Medical Systems (China) Co. Ltd., No. 19 Changjiang Road, Wuxi National Hi-Tech Dev. Zone 214028, Jiangsu China</p> <p>LOA Issue date: 24-09-2024</p> <p>FSC: France Issue: 27-01-2025</p> <p>FSC: China Validity: 25-08-2025</p> <p>ISO Validity: 07-05-2026</p> <p>EU QA Certificate Validity: 07-05-2026</p>	<p>Vivid T8 Cardiovascular Ultrasound Imaging System</p> <p>Class-B</p> <p>Shelf life: N/A</p> <p>Models/ Specification; N/A</p>	Deferred for clarification since the same brand already applied by M/s Shiraz Trading addressed in M-40 from the same manufacturer with different Model i.e Vivid Iq
87.	<p>Alsons Technology (Pvt) Ltd., Plot No. 8- C, Old Sunset Boulevard Commercial Street, Phase 2 DHA Karachi</p> <p>ELI-01322</p>	<p><b><u>Legal Manufacturer:</u></b> GE Medical Systems (China) Co. Ltd., No. 19 Changjiang Road, Wuxi National Hi-Tech Dev. Zone 214028, Jiangsu China</p> <p>LOA Issue date: 24-09-2024</p> <p>FSC: France</p>	<p>Vivid T9 Cardiovascular Ultrasound Imaging System</p> <p>Class-B</p> <p>Shelf life: N/A</p>	Deferred for clarification since the same brand already applied by M/s Shiraz Trading addressed in M-40 from the same manufacturer with different Model i.e Vivid Iq

	<p>Date of R&amp;I 25-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 01670860890</p>	<p>Issue: 27-01-2025</p> <p>FSC: China Validity: 25-08-2025</p> <p>ISO Validity: 07-05-2026</p> <p>EU QA Certificate Validity: 07-05-2026</p>	<p>Models/ Specification; N/A</p>	
88.	<p>Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1 Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi</p> <p>ELI-00232</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 50000/- Fee Challan No: 634604953905 230174351120</p>	<p><b><u>Legal Manufacturer:</u></b> Wenzhou Bokang Instruments Co., Ltd., No. 1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province China</p> <p>LOA Validity: 16-03-2028</p> <p>FSC: Germany Issue date: 26-05-2021</p> <p>FSC: China Validity: 16-12-2026</p> <p>ISO Validity: 01-04-2026</p> <p>EU QA Certificate (MDR) Validity: 01-07-2028</p>	<p>Bokang Digital Blood Pressure Monitor</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification; BKDC01T1, BKDC01T2 BKDC02T1, BKDC02T2 BKDC03T1, BKDC03T2 BKDC04T1, BKDC04T2 BKDC05T1, BKDC05T2 BKDC06T1, BKDC06T2 BKDC07T1, BKDC07T2 BKDC08T1, BKDC08T2 BKDC09T1, BKDC09T2 BKDC10T1, BKDC10T2 BKDC11T1, BKDC11T2</p>	<p>Approved BKDC01T1.</p> <p>The firm shall apply separately for rest of models</p>
89.	<p>Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1 Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi</p>	<p><b><u>Legal Manufacturer:</u></b> Wenzhou Bokang Instruments Co., Ltd., No. 1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province China</p>	<p>Bokang Mercury Free Sphygmomanometer</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification;</p>	<p>Approved BK1016.</p> <p>The firm shall apply separately for rest of models</p>

	<p>ELI-00232</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 50000/- Fee Challan No: 861580921 42784978598</p>	<p>LOA Validity: 16-03-2028</p> <p>FSC: Germany Issue date: 26-05-2021</p> <p>FSC: China Validity: 16-12-2026</p> <p>ISO Validity: 01-04-2026</p> <p>EU QA Certificate (MDR) Validity: 01-07-2028</p>	<p>BK1016, BK1018, BK1016B, BK1016T, BK1016L</p>	
90.	<p>Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1 Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e- Faisal, Karachi</p> <p>ELI-00232</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 3107663559</p>	<p><b><u>Legal Manufacturer:</u></b> Wenzhou Bokang Instruments Co., Ltd., No. 1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province China</p> <p>LOA Validity: 16-03-2028</p> <p>FSC: Germany Issue date: 26-05-2021</p> <p>FSC: China Validity: 16-12-2026</p> <p>ISO Validity: 01-04-2026</p> <p>EU QA Certificate (MDR) Validity: 01-07-2028</p>	<p>bokang Infrared Forehead Thermometer</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification; BK8005</p>	Approved
91.	<p>Royal Medical, Office No. 26<sup>th</sup>, 3<sup>rd</sup> United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi</p> <p>ELI-00691</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 086749938764</p>	<p><b><u>Legal Manufacturer:</u></b> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China</p> <p>Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan</p> <p>LOA Validity: 16-02-2030</p> <p>FSC: China Validity: 26-10-2025</p> <p>ISO Validity: 30-10-2026</p> <p>EU QA Certificate Validity: 05-02-2029</p>	<p>Antmed Inflation Device</p> <p>Class-B</p> <p>Shelf life: 5 Years</p> <p>Models/ Specification; ID-1000 ID-1001 ID-3000 ID-3001</p>	<p>Deferred for the clarification since the same Brand name is already applied by Ahmad care International from the same manufacturer and addressed in M-65.</p> <p>The provided CE certificate missing the subject device.</p>



92.	<p>Royal Medical, Office No. 26<sup>th</sup>, 3<sup>rd</sup> United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi</p> <p>ELI-00691</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 501445524411</p>	<p><b><u>Legal Manufacturer:</u></b> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China</p> <p>Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan</p> <p>LOA Validity: 16-02-2030</p> <p>FSC: China Validity: 26-10-2025</p> <p>ISO Validity: 30-10-2026</p> <p>EU QA Certificate Validity: 05-02-2029</p>	<p>Antmed Maniflod</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification; MD-M-1 MD-M-2 MD-M-3 MD-M-4 MD-L-1 MD-L-2</p>	<p>Deferred for the clarification since the same Brand name is already applied by Ahmad care International from the same manufacturer and addressed in M-65.</p> <p>The provided CE certificate missing the subject device.</p>
93.	<p>IMCO Technologist Plot No. 155, Sector 31/C1 Korangi Industrial Area Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 843418483927</p>	<p><b><u>Legal Manufacturer:</u></b> Yangzhou Medline Industry Co. Ltd., No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu China</p> <p>LOA Validity: 25-10-2026</p> <p>FSC: China Validity: 13-08-2024</p> <p>FSC: Germany Issue date: 18-02-2022</p> <p>ISO Validity: 11-10-2024</p> <p>CE Certificate with extension notification</p>	<p>GD Vacunator Safety Vacuum Blood Collection needles (Pen Type without Holder)</p> <p>Class-B</p> <p>Shelf life: 60 months</p> <p>Models/ Specification; 21G, 22G, 23G</p>	<p>Deferred for the clarification of applied Brand name since the applied brand name is not mentioned in LOA and/or FSC. Also provide the original and legalized documents.</p>
94.	<p>IMCO Technologist Plot No. 155, Sector 31/C1 Korangi Industrial Area Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/-</p>	<p><b><u>Legal Manufacturer:</u></b> Yangzhou Medline Industry Co. Ltd., No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu China</p> <p>LOA Validity: 25-10-2026</p> <p>FSC: China Validity: 13-08-2024</p> <p>FSC: Germany</p>	<p>GD Vacunator Safety Vacuum Blood Collection needles (Butterfly Type without Holder)</p> <p>Class-B</p> <p>Shelf life: 60 months</p> <p>Models/ Specification;</p>	<p>Deferred for the clarification of applied Brand name since the applied brand name is not mentioned in LOA and/or FSC. Also provide the original and legalized/notrized documents.</p>

	Fee Challan No: 9633610751	Issue date: 18-02-2022  ISO Validity: 11-10-2024  CE Certificate with extension notification	19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	
95.	Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi  ELI-0000471  Date of R&I 28-04-2025  Fee Details: Paid Fee: 31000/- Fee Challan No: 0535848999	<b><u>Legal Manufacturer:</u></b> Jiangsu Kanghua Medical Equipment Co. Ltd., Sanhekou Changzhou Jiangsu 213115, China  LOA Validity: 18-03-2030  FSC: China Validity: 21-12-2025  ISO Validity: 30-04-2026  EU QA Certificate Validity: 26-05-2024 with extension notification letter	Tirzi Disposable Syringe  Class-B  Shelf life: 5 Years  Models/ Specification; Syringe specification: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100 ml, with Hypodermic needle specification: Hypodermic needle specification 0.30×9RW LB, 0.30×13RW LB, 0.33×9RW LB, 0.33×13RW LB, 0.36×9RW LB, 0.36×13RW LB, 0.4×13RW LB, 0.4×16RW LB, 0.45×13RW LB, 0.45×16RW LB, 0.5×16RW LB, 0.5×25RW LB, 0.55×16RW LB, 0.55×25RW LB, 0.6×25TW LB, 0.6×32TW LB, 0.6×38TW	Deferred for the provision of following: Original and legalized/ notarized documents including LOA, ISO 13485 and CE certificates and legalized FSC of China,  The attached DoC is of Insulin syringe whereas in LOA the product mentioned is disposable syringe. Clarification is required.  Original Fee Challan.
96.	M/s BATLA IMPEX. SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI. <b>ELI-00170</b> <b>R&amp;I Details:</b> 18/04/2025 <b>Fee Challan No.</b>	<b><u>Legal Manufacture</u></b> M/s ZHUHAI LINTE MEDICAL Co. Ltd. CHINA.  <b>Address:</b> JINLIANG ROAD HONGQI TOWNJINWAN DIST ZHUHAI GUANGDONG PEOPLE'S REPUBLIC OF CHINA	B Care Blood Pressure Monitor  Class B  Shelf life: 05Years  Models: LT-P30, LT-P31	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates. Also mention which model

	891783755 Date 18/04/25. Fee: 31000	LOA: Validity: 03-12-2034  FSC: Country of Origin Validity: 28-12-2027  EC Certificate: Validity: 28-12-2027  ISO 13485: Validity: 27-12-2026		for ibstant application.
97.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI  <b>ELI-00170</b>  <b>R&amp;I Details</b> 18/04/2025  <b>Fee Challan No.</b> 01077120722 Date 16/04/25. Fee: 31000.	<b><u>Legal Manufacture</u></b> M/s ZHUHAI LINTE MEDICAL Co. Ltd. CHINA.  <b>Address:</b> JINLIANG ROAD HONGQI TOWNJINWAN DIST ZHUHAI GUANGDONG PEOPLE'S REPUBLIC OF CHINA  LOA: Validity: 03-12-2034  FSC: Country of Origin Validity: 28-12-2027  EC QMS Certificate MDR: Validity: 28-12-2027  ISO 13485: Validity: 27-12-2026	B Care Nebulizer  Class B  Shelf life: 05Years  Models: LT-N400, LT-N100, LT-N200,	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates. Also mention which model for ibstant application.
98.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 21/04/2025 Fee Challan No 4621150966 Date 17/04/25 Fee: 31000.	<b><u>Legal Manufacture</u></b> M/s ZIBO EASTMED HEALTHCARE PRODUCTS Co. Ltd. CHINA. Address: NO.118 HUAGUANG ROAD ZHANGDIAN DISTRICT ZIBO 255000 SHANDONG CHINA  LOA: Validity: 25-10-2029  FSC: Country of Origin Validity: 27-09-2029	New Golden Spinal Needle  Class B  Shelf life: 05Years  Codes/Sizes: 16G,17G, ,18G,19G, 20G,21G,22G,23G,24G , 25G26G,27G,28G,29G.	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.

		ISO 13485: Validity: 31-12-2028  CE extension notification is provided		
99.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 22/04/2025  Fee Challan No. 69003930471 Date 18/04/25. Fee: 31000	<b><u>Legal Manufacture</u></b> M/s SUPER HEALTH MEDICAL (QINDAO) Co. Ltd. CHINA. Address: NO.236 HEYUAN ROAD HIGH-TECH ZONE QINGDAO CHINA  LOA: Validity:17-02-2030  FSC: Country of Origin Validity: 27-04-2026  EC Certificate: Validity: 27-04-2026  ISO 13485: Validity: 29-03-2026	B Care Infusion Set  Class B  Shelf life: 05Years  Codes/Sizes: Not mentioned	Deferred for the provision of following:  original documents including credentials, notarized LOA, legalized FSC of China, notarized ISO 13485 and CE extension notification.  Codes/models as per FSC.
100.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI  ELI-00170  R&I Details 22/04/2025  Fee Challan No. 645987711583 Date 18/04/25. Fee: 31000	<b><u>Legal Manufacture</u></b> M/s SUPER HEALTH MEDICAL (QINDAO) Co. Ltd. CHINA. Address: NO.236 HEYUAN ROAD HIGH-TECH ZONE QINGDAO CHINA  LOA: Validity:17-02-2030  FSC: Country of Origin Validity: 27-04-2026  EC Certificate: Validity: 27-04-2026  ISO 13485: Validity: 29-03-2026	B Care Three Way Stopcock  Class B  Shelf life: 05Years  Codes/Sizes: Not mentioned	Deferred for the provision of following:  original documents including credentials, notarized LOA, legalized FSC of China, notarized ISO 13485 and CE extension notification.  Codes/models as per FSC.
101.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET	<b><u>Legal Manufacture</u></b> M/s SUPER HEALTH MEDICAL (QINDAO) Co. Ltd. CHINA. Address: NO.236 HEYUAN	B Care HEPARIN CAP  Class B  Shelf life: 05Years	Deferred for the provision of following:  original documents

	<p>KARACHI ELI-00170 R&amp;I Details 22/04/2025</p> <p>Fee Challan No. 92578327457 Date 18/04/25. Fee: 31000</p>	<p>ROAD HIGH-TECH ZONE QINGDAO CHINA</p> <p>LOA:Validity:17-02-2030</p> <p>EC Certificate: Validity: 27-04-2026</p> <p>ISO 13485: Validity: 29-03-2026</p>	<p>Codes/Sizes: Not mentioned</p>	<p>including credentials, notarized LOA, legalized FSC of China, notarized ISO 13485 and CE extension notification.</p> <p>Codes/models as per FSC.</p>
102.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 24/04/2025</p> <p>Fee Challan No. 460234315 Date 19/04/25. Fee: 31000</p>	<p><b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA</p> <p>Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA</p> <p>LOA:Validity:29/11/2034</p> <p>FSC: Country of Origin Validity: 05/07/2026</p> <p>EC Certificate: Validity: 05/07/2026</p> <p>ISO 13485: Validity:30/06/2026</p>	<p>B Care Disposable Syringe with Needle Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 1ML, 10ML, 20ML, 30ML, 50ML, 60ML,</p>	<p>Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.</p>
103.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 24/04/2025</p> <p>Fee Challan No. 104675722593 Date 19/04/25 Fee: 31000</p>	<p><b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA</p> <p>Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA</p> <p>LOA:Validity:29/11/2034</p> <p>FSC: Country of Origin Validity: 05/07/2026</p> <p>EC Certificate: Validity: 05/07/2026</p>	<p>B Care Disposable Hypodermic Needle Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 16G,17G,18G,19G,20G , 21G,22G,23G,24G,25G , 26G,27G,</p>	<p>Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates..</p>

		ISO 13485: Validity:30/06/2026		
104.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 24/04/2025  Fee Challan No. 4701394598 Date 19/04/25 Fee: 31000	<b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA  Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA  LOA:Validity:29/11/2034  FSC: Country of Origin Validity: 05/07/2026  EC Certificate: Validity: 05/07/2026  ISO 13485: Validity:30/06/2026	B Care Auto Disable Syringes with Needle  Class B  Shelf life: 05Years  Codes/Sizes 2ML, 3ML, 5ML,	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.
105.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 24/04/2025  Fee Challan No. 09996171 Date 19/04/25 Fee: 31000	<b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA  Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA  LOA:Validity:29/11/2034  FSC: Country of Origin Validity: 05/07/2026  EC Certificate: Validity: 05/07/2026  ISO 13485: Validity:30/06/2026	B Care Disposable Insulin Syringe with Needle  Class B  Shelf life: 05Years  Codes/Sizes U-100	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.
106.	M/s BATLA IMPEX SHOP NO.40	<b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT	B Care Blood Collecting Tube	Deferred for the provision of following:

	<p>NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 24/04/2025</p> <p>Fee Challan No. 296186874702 Date 19/04/25 Fee: 31000</p>	<p>Co. Ltd. CHINA</p> <p>Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA</p> <p>LOA: Validity: 29/11/2034</p> <p>FSC: Country of Origin Validity: 05/07/2026</p> <p>EC Certificate: Validity: 05/07/2026</p> <p>ISO 13485: Validity: 30/06/2026</p>	<p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes/Sizes EDTA.K2 TUBE , EDTA.K3 TUBE, SODIUM CITRATE TUBE, ESR TUBE, SODIUM FLUORIDE/EDTA.K2</p>	<p>Revised application and form since the device falls in Class-A also separate application and fee for all tubes depending upon the composition or type of tube.</p> <p>Original and legalized documents including credentials, LOA, FSC of China, ISO 13485 and CE certificates.</p>
107.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 24/04/2025</p> <p>Fee Challan No. 22012874997 Date 19/04/25 Fee: 31000</p>	<p><b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA</p> <p>Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA</p> <p>LOA: Validity: 29/11/2034</p> <p>FSC: Country of Origin Validity: 05/07/2026</p> <p>ISO 13485: Validity: 30/06/2026</p>	<p>B Care Scalp Vein Set</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes/Sizes 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G</p>	<p>Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.</p>
108.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 24/04/2025</p> <p>Fee Challan No. 48354181 Date 19/04/25</p>	<p><b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA</p> <p>Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA</p> <p>LOA: Validity: 29/11/2034</p>	<p>B Care Blood Transfusion Set</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes/Sizes: Not mentioned</p>	<p>Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates. Also mention which model for instant application. .</p>

	Fee: 31000	FSC: Country of Origin Validity: 05/07/2026  ISO 13485: Validity:30/06/2026		
109.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI  <b>ELI-00170</b>  R&I Details 24/04/2025  <b>Fee Challan No.</b> 83309259115 Date 19/04/25 Fee: 31000	<b><u>Legal Manufacture</u></b> M/s JIANGSU KANGYU MEDICAL INSTRUMENT Co. Ltd. CHINA  Address: TANGZHUANG, YAOTANG TOWN, JINTAN CITY, JIANGSU PROVINCE CHINA  LOA:Validity:29/11/2034  FSC: Country of Origin Validity: 05/07/2026  ISO 13485: Validity:30/06/2026	Crystal Disposable Infusion Set  Class B  Shelf life: 05Years  Codes/Sizes: Not mentioned	Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates. Also mention which model for instant application.
110.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 28/04/2025  Fee Challan No. 134997370 Date 23/04/25 Fee: 31000	<b><u>Legal Manufacture</u></b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE & TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHONG PROVINCE, CHINA  LOA:Validity:18/02/2030  FSC: Country of Origin Validity: 19/04/2026  ISO 13485: Validity: 19/04/2026	DOCTOR + Non-Absorbable Surgical Suture with Needle Poly Propylene  Class B  Shelf life: 05Years  Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m,	Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.  The subject device falls in Class-C, so the firm is required to submit the revised application along with relevant documents for Class-C products.
111.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE	<b><u>Legal Manufacture</u></b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA	DOCTOR + Non-Absorbable Surgical Suture with Needle Polyester	Deferred for the provision of following: Original and legalized



	<p>CAMBELL STREET KARACHI</p> <p><b>ELI-00170</b></p> <p>R&amp;I Details 28/04/2025</p> <p><b>Fee Challan No.</b> 16206267 Date 22/04/25 Fee: 31000</p>	<p><b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p> <p>LOA: Validity: 18/02/2030</p> <p>FSC: Country of Origin Validity: 19/04/2026</p> <p>EC Certificate: Validity: 19/01/2027</p> <p>ISO 13485: Validity: 19/04/2026</p>	<p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m,</p>	<p>Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-C, so the firm is required to submit the revised application along with relevant documents for Class-C products.</p>
112.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI</p> <p><b>ELI-00170</b></p> <p>R&amp;I Details 28/04/2025</p> <p><b>Fee Challan No.</b> 62744631178 Date 23/04/25 Fee: 31000</p>	<p><b>Legal Manufacture</b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p> <p>LOA: Validity: 18/02/2030</p> <p>FSC: Country of Origin Validity: 19/04/2026</p> <p>ISO 13485: Validity: 19/04/2026</p>	<p>DOCTOR + Non-Absorbable Surgical Suture with Needle Silk</p> <p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m,</p>	<p>Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-C, so the firm is required to submit the revised application along with relevant documents for Class-C products.</p>
113.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI</p> <p><b>ELI-00170</b></p> <p>R&amp;I Details 28/04/2025</p>	<p><b>Legal Manufacture</b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p>	<p>DOCTOR + Non-Absorbable Surgical Suture with Needle Nylon</p> <p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2</p>	<p>Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-C, so the</p>

	<b>Fee Challan No.</b> 4090189576 Date 23/04/25 Fee: 31000	LOA: Validity: 18/02/2030  FSC: Country of Origin Validity: 19/04/2026  EC Certificate: Validity: 19/01/2027  ISO 13485: Validity: 19/04/2026	m, 2.5m, 3m, 3.5m, 4m, 4.5m , 5m , 5.5m,	firm is required to submit the revised application along with relevant documents for Class-C products.
114.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI  <b>ELI-00170</b>  R&I Details 28/04/2025  <b>Fee Challan No.</b> .075479709940 Date 22/04/25 Fee: 31000	<b>Legal Manufacture</b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE & TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA  LOA: Validity: 18/02/2030  FSC: Country of Origin Validity: 19/04/2026  EC Certificate: Validity: 19/01/2027  ISO 13485: Validity: 19/04/2026	DOCTOR + Absorbable Surgical Suture with Needle PDO  Class B  Shelf life: 05Years  <b>Codes/Sizes</b> 45cm, 50cm, 60cm, 75cm, 90cm, 1m, 1.5m, 2m, 2.5m, 3m, 3.5m, 4m, 4.5m , 5m , 5.5m	Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.  The subject device falls in Class-D, so the firm is required to submit the revised application along with relevant documents for Class-C products.
115.	M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI  <b>ELI-00170</b>  R&I Details 28/04/2025  <b>Fee Challan No.</b> 919497114423 Date 22/04/25 Fee: 31000	<b>Legal Manufacture</b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE & TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA  LOA: Validity: 18/02/2030  FSC: Country of Origin	DOCTOR + Absorbable Surgical Suture with Needle PGA (Polyglycolic Acid)  Class B Shelf life: 05Years  <b>Codes/Sizes</b> 45cm, 50cm, 60cm, 75cm, 90cm, 1m, 1.5m, 2m, 2.5m, 3m, 3.5m, 4m, 4.5m , 5m , 5.5m	Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.  The subject device falls in Class-D, so the firm is required to submit the revised application along with relevant documents for

		<p>Validity: 19/04/2026</p> <p>EC Certificate: Validity: 19/01/2027</p> <p>ISO 13485: Validity: 19/04/2026</p>		Class-C products.
116.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 28/04/2025</p> <p>Fee Challan No. 7232320691 Date 22/04/25 Fee: 31000</p>	<p><b><u>Legal Manufacture</u></b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p> <p>LOA:Validity:18/02/2030</p> <p>FSC: Country of Origin Validity: 19/04/2026</p> <p>EC Certificate: Validity: 19/01/2027</p> <p>ISO 13485: Validity: 19/04/2026</p>	<p>DOCTOR + Absorbable Surgical Suture with Needle, PGCL</p> <p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m</p>	<p>Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-D, so the firm is required to submit the revised application along with relevant documents for Class-C products.</p>
117.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI</p> <p>ELI-00170 R&amp;I Details 28/04/2025 Fee Challan No. 556004835403 Date 22/04/25 Fee: 31000.</p>	<p><b><u>Legal Manufacture</u></b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p> <p>LOA:Validity:18/02/2030</p> <p>FSC: Country of Origin Validity: 19/04/2026</p> <p>ISO 13485: Validity: 19/04/2026</p>	<p>DOCTOR + Absorbable Surgical Suture with Needle Chromic Catgut</p> <p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m</p>	<p>Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-D, so the firm is required to submit the revised application along with relevant documents for Class-C products.</p>

118.	<p>M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&amp;I Details 28/04/2025</p> <p>Fee Challan No. 9158454141 Date 22/04/25 Fee: 31000</p>	<p><b><u>Legal Manufacture</u></b> M/s SHANGDONG HAIDIKE MEDICAL PRODUCT Co. Ltd. CHINA <b>Address:</b> PLANT NO .01 SCIENCE &amp; TECHNOLOGY ENTERPRICES INCUBATOR PARK SHAN COUNTY HEZE CITY, SHAHDONG PROVINCE, CHINA</p> <p>LOA: Validity: 18/02/2030</p> <p>FSC: Country of Origin Validity: 19/04/2026</p> <p>ISO 13485: Validity: 19/04/2026</p>	<p>Doctor + Absorbable Surgical Suture with Needle (Polyglactin)</p> <p>Class B</p> <p>Shelf life: 05Years</p> <p>Codes/Sizes 45cm,50cm,60cm, 75cm,90cm,1m,1.5m,2 m, 2.5m,3m,3.5m,4m,4.5m , 5m ,5.5m</p>	<p>Deferred for the provision of following: Original and legalized Documents including LOA, FSC of China, FSC of ref country or CE marked and ISO 13485.</p> <p>The subject device falls in Class-D, so the firm is required to submit the revised application along with relevant documents for Class-C products.</p>
119.	<p>M/s. BIOMADICS, Karachi Address: Gate #1, 211/B Sindhi Muslim, Block B Corporation Housing Society, Karachi</p> <p>ELI:00432</p> <p>Date of R&amp; I 17 April 2025</p> <p>Fee: 25000/ Slip: 185059769006 Dated 17.10.2023</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Diagon Solutions Address: No.H-1047 Budapest, Baross u, Street 48- 52, Hungary</p> <p>ISO 13485 Validity: 17/01/2027</p> <p>FSC (Hungary): Validity: 30/07/2026</p> <p>LOA Validity: 30/07/2026</p> <p>DOC: 24/ 08 / 2023</p>	<p>Diagon Coagulation Analyzer Reagents. Dia-TT Dia-AT III (FIIa) Dia-F II (Deficient Plasma) Dia-F V (Deficient Plasma) Dia-F VII (Deficient Plasma) Dia-F VIII (Deficient Plasma) Dia-F IX (Deficient Plasma) Dia-F X (Deficient Plasma) Dia-F XI (Deficient Plasma) Dia-F XII (Deficient Plasma) Dia-Protein C (Chromogenic)</p> <p>Class B</p> <p>Shelf Life: Not Specified</p>	<p>Deferred for the provision of following: Original valid and legalized FSC of ref country or CE marked document.</p> <p>Original and notarized LOA, attested FSC of Hungary and valid and notarized ISO 13485.</p> <p>The firm applied the product as Cluster, clarification is required since the products are kits.</p> <p>Shelf life and shelf life studies.</p>
120.	<p>MSB Medical, F2 1<sup>st</sup> Floor 51-1/C, PECHS</p>	<p><b><u>Legal Manufacturer:</u></b> Super Health Medical (Qingdao) No. 236, Heyuan</p>	<p>Flow One I.V Cannula with Small Wings</p>	<p>Deferred for clarification since the products mentioned in</p>

	<p>Block 6 75400, Karachi</p> <p>ELI-00035</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 0229869798</p>	<p>Road, High-Tech Zone, Qingdao, 266510 Shandong P.R. China</p> <p>LOA Validity: 08-02-2030</p> <p>FSC: China Validity: 27-04-2025</p> <p>FSC: UK Issue date: 31-12-2029</p> <p>ISO Validity: 29-03-2029 CE Certificate with extension notification letter.</p>	<p>Class-B</p> <p>Shelf life: 3 years</p> <p>Models/ Specification; 16, 18G, 20G, 22G, 24G</p>	<p>FSC of MHRA are mentioned as type IA, type IB and Type IC and authorization is granted only for straight type in LOA, clarification is required.</p>
121.	<p>MSB Medical, F2 1<sup>st</sup> Floor 51-1/C, PECHS Block 6 75400, Karachi</p> <p>ELI-00035</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 23014783812</p>	<p><b><u>Legal Manufacturer:</u></b> Super Health Medical (Qingdao) No. 236, Heyuan Road, High-Tech Zone, Qingdao, 266510 Shandong P.R. China</p> <p>LOA Validity: 08-02-2030</p> <p>FSC: China Validity: 27-04-2025</p> <p>FSC: UK Issue date: 31-12-2029</p> <p>ISO Validity: 29-03-2029</p> <p>CE Certificate with extension notification letter.</p>	<p>Flow One I.V Cannula with Small Wings and injection Port</p> <p>Class-B</p> <p>Shelf life: 3 years</p> <p>Models/ Specification; 16, 18G, 20G, 22G, 24G</p>	<p>Deferred for clarification since the products mentioned in FSC of MHRA are mentioned as type IA, type IB and Type IC and authorization is granted only for straight type in LOA, clarification is required.</p>
122.	<p>MSB Medical, F2 1<sup>st</sup> Floor 51-1/C, PECHS Block 6 75400, Karachi</p> <p>ELI-00035</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 60047640</p>	<p><b><u>Legal Manufacturer:</u></b> Super Health Medical (Qingdao) No. 236, Heyuan Road, High-Tech Zone, Qingdao, 266510 Shandong P.R. China</p> <p>LOA Validity: 08-02-2030</p> <p>FSC: China Validity: 27-04-2025</p> <p>FSC: UK Issue date: 31-12-2029</p> <p>ISO Validity: 29-03-2029</p>	<p>Flow One I.V Cannula Pen Type</p> <p>Class-B</p> <p>Shelf life: 3 years</p> <p>Models/ Specification; 16, 18G, 20G, 22G, 24G</p>	<p>Deferred for clarification since the products mentioned in FSC of MHRA are mentioned as type IA, type IB and Type IC and authorization is granted only for straight type in LOA, clarification is required.</p>

		CE Certificate with extension notification letter.		
<b>123.</b>	<p>AJ &amp; Sons, Plot-MRI/20, Marriot Road, 12 Makkah Market, Kathchi Gali 1, Karachi South Saddar Town,</p> <p>ELI-0000471</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 269338132039</p>	<p><b><u>Legal Manufacturer:</u></b> Jiangyin Medical Devices Co., Ltd., No. 698, Zhencheng Road, Xiangang Town, 214442 Jiangyin City P.R. China</p> <p>LOA Validity: 31-12-2028</p> <p>FSC: China Validity: 26-02-2027</p> <p>ISO Validity: 20-01-2028</p> <p>EU QMS Certificate MDR Validity: 11-12-2029</p>	<p>National Plus+ (Scalp Vein set for single use only)</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification; 0.4×15、0.45×15、 0.5×20、0.55×20、 0.6×25、07×25、 0.8×28、0.9×28、 1.1×32, 1.2x32 (mm)</p>	<p>Approved subject to submission of stability studies for the claimed shelf life before the issuance of registration letter.</p>
<b>124.</b>	<p>Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 31000/- Fee Challan No: 7681066025</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.) NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>LOA: Valid till: 03-12-2029</p> <p>FSC: Validity Date: 03-08-2025</p> <p>Reference Country FSC (Germany) Issue Date: 30-01-2025</p> <p>ISO - Validity Date: 31-12-2025 (Copy)</p> <p>EU QMS Certificate MDR Valid till: 14-12-2025 (Copy)</p>	<p>MAGLUMI Vitamin B12 (CLIA) and Vitamin B12(CLIA) controls</p> <p>Class-B</p> <p>Shelf Life: 18 months</p> <p>Code/sizes: Vitamin B12 (CLIA): 100 tests/kit, 50 Tests/kit, 30 Test/kit</p> <p>Vitamin B12(CLIA) Controls Control 1: 1x1.5ml Control 2: 1x1.5ml</p>	<p>Deferred for the provision of following: Original and legalized/ notarized documents including Credentials, LOA, FSC of China, ISO 13485 and CE certificates.</p>
<b>125.</b>	<p>Shirazi Trading Comoany Pvt Ktd, 114 -C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi 75500</p> <p>Godown: 2nd Floor, Nadir House, I.I.</p>	<p><b><u>Legal Manufacturer:</u></b> Nihon Kohden Corporation, 1-31-4 Nishiochiai, Shinjuku-Ku 161-8560 Tokyo, Japan</p> <p>LOA: Sole Agency Agreement Validity date: 31-03-2026</p>	<p>ECG-1200K Electroencephalograph</p> <p>Class B</p> <p>Service Life: 06 years</p> <p>Model: EEG-1200K</p>	<p>Approved subject to submission of differential fee as per revised SRO for System before the issuance of registration letter.</p>

	<p>Chandrigar Road, Karachi Pakistan</p> <p>(ELI-00263)</p> <p><b>Fees:</b> Rs 50000 Challan # 09599088538</p> <p><b>Date of R&amp; I</b> 10-04-2025</p>	<p>FSC: Japan Issue date: 07-11-2023</p> <p>EC Certificate with extension notification</p> <p>ISO: Valid till: 05-04-2027</p>		
126.	<p>Medco Health Care, 155, C.P. Barar Society, Alamgir Road, Karachi</p> <p>(ELI-00072)</p> <p>Fees: Rs 31000 Challan # 6564455741</p> <p>Date of R&amp; I 18-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> CerenUretimPlastikUrunleri San. Ve Tic A.sS. ZaferMah. 143. SK. No: 8 D8a-8/3 Esenyurt-Istanbul</p> <p>LOA: Sole Agency Agreement Validity date: 31-12-2027 (Original Notarized)</p> <p>FSC: Turkey Validity: 22-01-2028</p> <p>EC Certificate with extension notification letter:</p> <p>ISO: Valid till: 22-09-2025 (Copy Notarized)</p>	<p>Ceren Sterile Thorax Drainage Set</p> <p>Class B</p> <p>Shelf Life: 05 years</p> <p>Codes/Sizes: S2014-305</p>	Approved
127.	<p>Macter International Limited, F-216, SITE, Karachi</p> <p>(ELI-01403)</p> <p><b>Fees:</b> Rs 31000 Challan # 1242862809</p> <p><b>Date of R&amp; I</b> 23-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Promisemed Hangzhou Meditech Co., Ltd., No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhoucity, 311121 Zhejiang P.R. China</p> <p>FSC: CHINA Validity: 30-06-2026</p> <p>EC Certificate valid until:</p> <p>ISO: Valid till: 22-10-2027</p>	<p>Arofine Hypodermic Needle for Luer Lock Syringe</p> <p>Class B</p> <p>Shelf Life: 06 years</p> <p>Codes/Sizes: Not specified</p>	<p>Deferred for the provision of following: The application form is not filled as per the requirements.</p> <p>Notarized Credentials.</p> <p>Original, valid and notarized LOA mentioning the Brand and generic or list of authorized products.</p> <p>Original, valid and embassy attested FSC mentioning the subject device.</p>

				Original, valid and embassy attested FSC of ref country or notarized CE marked document.
128.	<p>S. Ejazuddin &amp; Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi  (ELI-00078)</p> <p>Fees: Rs 31000 Challan # 8702663186</p> <p>Date of R&amp; I 21-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan</p> <p><b><u>Manufacturing Sites:</u></b> 1. Sysmex Corporation, i-Square 262-11 Mizuashi, Noguchicho, Kakogawa, Hyogo 675-0019 Japan, Kakogawa Factory 314-2 Kitano, Noguchi-Cho, Kakogawa, Hyogo 675-0011 Japan. 2. Sysmex RA CO., Ltd., Main Plant 1850-3 Hirooka-Nomura, Shiojiri, Nagano 399-0702 Japan</p> <p>LOA: Sole Agency Agreement Issue date: 14-03-2023</p> <p>FSC: Japan Issue date: 14-12-2023</p> <p>ISO: Valid till: 31-07-2024</p>	<p>Sysmex BN168792 - Automated Tube Sorter TS-10 AN735871 - BT-50 Transportation Unit AT903180 - TA-01 Automated Tube Archiver AU291973 - TS-01 Automated Tube Sorter CG723992 - CDR_ASSY No. 532 BH111948 - XN Blood Bank Mode</p> <p>Class B</p> <p>Shelf Life: Not Applicable</p>	<p>Deferred for following reasons:</p> <p>The FSC is issued by OMETA (Overseas Medical Equipment Technical assistants) a non-profit organization.</p> <p>In certificate it is mentioned as “The product is not applicable as medical devices which are defined under the Medical devices and Other Therapeutic Products Act of Japan. Therefore, it is not necessary to be produced under the supervision of The Ministry of Health, Labour and Welfare in Japan as stipulated in the Pharmaceuticals, Medical Therapeutic Products Act of Japan, and it is sold domestically and in foreign countries freely.</p> <p>Justification for applying as medical device.</p>
129.	<p>S. Ejazuddin &amp; Co., 237/B Block II, P.E.C.H.S., Shahrah-e-Qaideen, Karachi  (ELI-00078)</p> <p><b>Fees:</b> Rs 31000</p>	<p><b><u>Legal Manufacturer:</u></b> Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan</p> <p>LOA: Sole Agency Agreement Issue date:</p>	<p>Sysmex CN464998 - Platelet Check L1 CC118360-Platelet Check L2 ZPPAV021787 - Lysercell WDF</p> <p>Class B</p>	<p>Deferred for provision of clarification/ justification is required from the firm for applying the subject device as Family and revised the Fee as per the grouping either Family</p>



	Challan # 924428364  <b>Date of R&amp; I</b> 21-04-2025	19-02-2024  FSC: Singapore Issue date: 12-09-2022  FSC: USA Valid till: 07-06-2025  EC Certificate valid until: 31-07-2024  ISO: Valid till: 28-11-2025	Shelf Life: 12 Months for Lysercell WDF 85 days for Platelet Check L1 & L2	or Cluster.
<b>130.</b>	Kamran Bashir and Brothers, Flat No. E/2, First Floor, Angola Flats, 24 Jail Road, Lahore  (ELI-00831)  Fees: Rs 25000 Challan # 4172344315  Date of R& I 08-11-2023	<b><u>Legal Manufacturer:</u></b> AJL Ophthalmic S.A. Parque Tecnologico de Alava Ferdinand Zeppelin, 1 01510 Minano, Alava – Spain.  LOA: Sole Agency Agreement Issue date: 27-03-2023  FSC: Spain Issue date: 20-01-2022  EC Certificate valid until: 20-08-2027  ISO: Valid till: 20-08-2027	AJL Blue 0.6% Dye Ophthalmic Solutions  Class B  Shelf Life: 3 Years  Codes/model: N/A	Approved subject to submission of notarized Credentials.
<b>131.</b>	Kamran Bashir and Brothers, Flat No. E/2, First Floor, Angola Flats, 24 Jail Road, Lahore  (ELI-00831)  Fees: Rs 25000 Challan # 625967100830  Date of R& I 22-02-2023	<b><u>Legal Manufacturer:</u></b> Surgical Specialties Mexico (Corza Medical Company), Corredor Tijuana-Rosario 2000 # 24702-B, Ejido Francisco Villa Tijuana, B.C. C.P. 22235, Mexico 1.352.226.4674  LOA: Sole Agency Agreement Validity: 31-12-2025  FSC: USA Validity: 08-11-2025  EC Certificate valid until: 24-05-2024  ISO: Valid till: 08-11-2025	ShapePoint Surgical Knives  Class B  Shelf Life: 5 Years  Codes/Sizes: 71-2001, 71-2301, 72-1501, 72-2561, 72-2761, 72-3261, 74-1010, 76-5161, 76-5561	Approved subject to submission of notarized Credentials.

132.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 097852390988</p> <p><b>Date of R&amp; I</b> 18-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China</p> <p>LOA: Sole Agency Agreement Validity: 18-02-2028</p> <p>FSC: China Validity: 19-02-2027</p> <p>ISO: Valid till: 28-11-2025</p>	<p>Inst Answer Dengue NS1 Rapid Test</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 27 months</p> <p>Codes/Sizes: DEN NS1-W23, DEN NS1-W11</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and legalized documents including LOA, FSC, FSC of reference country or CE marked document and ISO 13485.</p> <p>Revised application form and differential fee since the subject device falls in Class- C.</p> <p>FSC of China to be issued from Regulatory authority of China.</p>
133.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 36835444110</p> <p><b>Date of R&amp; I</b> 18-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China</p> <p>LOA: Sole Agency Agreement Validity: 18-02-2028</p> <p>FSC: China Validity: 19-02-2027</p> <p>ISO: Valid till: 28-11-2025</p>	<p>Inst Answer Salmonella Typhi/ Paratyphi Antigen Rapid Test</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 27 months</p> <p>Codes/Sizes: TYP-F23, TYP-F11</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and legalized documents including LOA, FSC, FSC of reference country or CE marked document and ISO 13485.</p> <p>Revised application form and differential fee since the subject device falls in Class- C.</p> <p>FSC of China to be issued from Regulatory authority of China.</p>
134.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000</p>	<p><b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China</p> <p>LOA:</p>	<p>Inst Answer Typhoid Rapid Test</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 27 months</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and legalized documents including LOA, FSC, FSC of reference country or CE marked</p>

	Challan # 4450615743  <b>Date of R&amp; I</b> 18-04-2025	Sole Agency Agreement Validity: 18-02-2028  FSC: China Validity: 19-02-2027  ISO: Valid till: 28-11-2025	Codes/Sizes: TYP-W23, TYP-P23, TYP-P11, TYP-W11	document and ISO 13485.  Revised application form and differential fee since the subject device falls in Class- C.  FSC of China to be issued from Regulatory authority of China.
135.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 88412880553  <b>Date of R&amp; I</b> 18-04-2025	<b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China  LOA: Sole Agency Agreement Validity: 18-02-2028  FSC: China Validity: 19-02-2027  ISO: Valid till: 28-11-2025	Inst Answer H. pylori Antigens Rapid Test  Class B  Applied as: Kit  Shelf Life: 27 months  Codes/Sizes: HP-F23, HP-F11	Deferred for the provision of following:  Original, valid and legalized documents including LOA, FSC, FSC of reference country or CE marked document and ISO 13485.  FSC of China to be issued from Regulatory authority of China.
136.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 994691948  <b>Date of R&amp; I</b> 18-04-2025	<b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China  LOA: Sole Agency Agreement Validity: 18-02-2028  FSC: China Validity: 19-02-2027  ISO: Valid till: 28-11-2025	Inst Answer HCG Pregnancy Rapid Test Strip  Class B  Applied as: Kit  Shelf Life: 27 months  Codes/Sizes: HCG-U23, HCG-U23- 10, HCG-U23-20, HCG-U11-25, HCG- C11	Deferred for the provision of following:  Original, valid and legalized documents including LOA, FSC, FSC of reference country or CE marked document and ISO 13485.  FSC of China to be issued from Regulatory authority of China.
137.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)	<b><u>Legal Manufacturer:</u></b> Assure Tech (Hangzhou) Co., Ltd., Building 4, NO. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China	Inst Answer H. Pylori Antibodies Rapid Test  Class B  Applied as: Kit	Deferred for the provision of following:  Original, valid and legalized documents

	<b>Fees:</b> Rs 31000 Challan # 15806937384  <b>Date of R&amp; I</b> 18-04-2025	<b>LOA:</b> Sole Agency Agreement Validity: 18-02-2028  <b>FSC:</b> China Validity: 19-02-2027  <b>ISO:</b> Valid till: 28-11-2025	Shelf Life: 27 months  <b>Codes/Sizes:</b> HP-W23, HP-W11, HP-P23 HP-P11	including LOA, FSC, FSC of reference country or CE marked document and ISO 13485.  FSC of China to be issued from Regulatory authority of China.
138.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 6883947415  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  <b>LOA:</b> Sole Agency Agreement Validity: 31-12-2027  <b>FSC:</b> Spain Issue Date: 27-08-2024  <b>ISO:</b> Valid till: 25-07-2026	Getein Progesterone Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved
139.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 1476398675  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  <b>LOA:</b> Sole Agency Agreement Validity: 31-12-2027  <b>FSC:</b> Spain Issue Date: 27-08-2024  <b>ISO:</b> Valid till: 25-07-2026	Getein FT4 Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved
140.	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 878263800738	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  <b>LOA:</b> Sole Agency Agreement Validity: 31-12-2027  <b>FSC:</b> Spain	Getein Anti-TP Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C

	<b>Date of R&amp; I</b> 28-04-2025	Issue Date: 27-08-2024 ISO:Valid till: 25-07-2026		
<b>141.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 21305766240  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein RF Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C
<b>142.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 8950254366  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein Ferritin Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved
<b>143.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 50970417  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein Hs-Tnl Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C
<b>144.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505	Getein FT3 Fast Test Kit  Class B	Approved

	<p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 116783385</p> <p><b>Date of R&amp; I</b> 28-04-2025</p>	<p>China</p> <p>LOA: Sole Agency Agreement Validity: 31-12-2027</p> <p>FSC: Spain Issue Date: 27-08-2024</p> <p>ISO: Valid till: 25-07-2026</p>	<p>Applied as: Kit</p> <p>Shelf Life: 24 months</p>	
145.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 721083044</p> <p><b>Date of R&amp; I</b> 28-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China</p> <p>LOA: Sole Agency Agreement Validity: 31-12-2027</p> <p>FSC: Spain Issue Date: 27-08-2024</p> <p>ISO: Valid till: 25-07-2026</p>	<p>Getein ASO Fast Test Kit</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 24 months</p>	<p>Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C</p>
146.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 33692024907</p> <p><b>Date of R&amp; I</b> 28-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China</p> <p>LOA: Sole Agency Agreement Validity: 31-12-2027</p> <p>FSC: Spain Issue Date: 27-08-2024</p> <p>ISO: Valid till: 25-07-2026</p>	<p>Getein Estradiol Fast Test Kit</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 24 months</p>	<p>Approved</p>
147.	<p>Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad</p> <p>(ELI-00442)</p> <p><b>Fees:</b> Rs 31000 Challan # 845416186</p>	<p><b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China</p> <p>LOA: Sole Agency Agreement Validity: 31-12-2027</p> <p>FSC: Spain</p>	<p>Getein Anti-CCP Fast Test Kit</p> <p>Class B</p> <p>Applied as: Kit</p> <p>Shelf Life: 24 months</p>	<p>Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C</p>

	<b>Date of R&amp; I</b> 28-04-2025	Issue Date: 27-08-2024 ISO:Valid till: 25-07-2026		
<b>148.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 299048903718  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein Dengue NS1 Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved subject to submission of revised Form and differential fee since the subject device falls in Class-C
<b>149.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 31915741571  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein H. pylori Antigen Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved
<b>150.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad  (ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 4910539333  <b>Date of R&amp; I</b> 28-04-2025	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505 China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO:Valid till: 25-07-2026	Getein Total IgE. Fast Test Kit  Class B  Applied as: Kit  Shelf Life: 24 months	Approved
<b>151.</b>	Mian Scientific Corporation Pvt. Ltd., 534-Jinnah Colony Faisalabad	<b><u>Legal Manufacturer:</u></b> Getein Biotech, Inc. Address No. 9 Bofu Road, Luhe District, Nanjiang, 211505	Getein Testosterone Fast Test Kit	Approved

	(ELI-00442)  <b>Fees:</b> Rs 31000 Challan # 2605593911  <b>Date of R&amp; I</b> 28-04-2025	China  LOA: Sole Agency Agreement Validity: 31-12-2027  FSC: Spain Issue Date: 27-08-2024  ISO: Valid till: 25-07-2026	Class B  Applied as: Kit  Shelf Life: 24 months	
152.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21 <sup>st</sup> Floor Plot No. G-3, Khayaban- e-Iqbal, Block 09, Clifton Karachi  ELI-00273  <b>Fees:</b> Rs 62000 Challan # 18133453538  <b>Date of R&amp; I</b> 16-04-2025	<b><u>Legal Manufacturer:</u></b> M/s Medtronic., Inc. 710 Medtronic Parkway, Minneapolis, MN USA 55432  <b><u>Manufacturing Site:</u></b> <b>1<sup>st</sup> Site:</b> Medtronic Perfusion Systems Located at 7611 Northland Dr. Minneapolis MN USA 55428  <b>2<sup>nd</sup> Site:</b> Medtronic Perfusion Systems located at 18501 E Plaza Dr. Parker, Co., USA 80134  <b><u>LOA:</u></b> Issue date: 15-01-2025 (copy) <i>The firm claimed that          notarized attached in          application of Hugo™          Robotically Assisted Surgery          (RAS)          System dated 22-01-2025</i>  <b><u>FSC (USFDA):</u></b> Valid Until: 08-11-2025 (Copy) <i>(The firm claimed that          notarized attached with          shortcomings submission of          HMS Plus Instrument dated          10-03-2025.)</i>  EC Certificate valid until: 24- 08-2028 (Copy)  <b><u>ISO 13485:</u></b> Valid till: 31-03-2027 (copy) <i>The firm claimed that          notarized attached with</i>	<b>CLOTtrac HR control</b>  IVDD-Coagulation Control  Applied as: Not mentioned.  <b>Class C</b>  <b>Shelf Life: 52 Weeks</b>  <b>Codes/Sizes: 550-07</b>	Approved



		<i>shortcomings submission of HMS Plus Instrument dated 10-03-2025.</i>		
<b>153.</b>	<p>Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21<sup>st</sup> Floor Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton Karachi</p> <p>ELI-00273</p> <p><b>Fees:</b> Rs 62000 Challan # 5735104010</p> <p><b>Date of R&amp; I</b> 16-04-2025</p>	<p><b><u>Legal Manufacturer:</u></b> M/s Medtronic., Inc. 710 Medtronic Parkway, Minneapolis, MN USA 55432</p> <p><b><u>Manufacturing Site:</u></b> <b>1<sup>st</sup> Site:</b> Medtronic Perfusion Systems Located at 7611 Northland Dr. Minneapolis MN USA 55428</p> <p><b>2<sup>nd</sup> Site:</b> Medtronic Perfusion Systems located at 18501 E Plaza Dr. Parker, Co., USA 80134</p> <p><b><u>LOA:</u></b> Issue date: 15-01-2025 (copy) <i>The firm claimed that notarized attached in application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025</i></p> <p><b><u>FSC (USFDA):</u></b> Valid Until: 08-11-2025 (Copy) <i>(The firm claimed that notarized attached with shortcomings submission of HMS Plus Instrument dated 10-03-2025.)</i></p> <p>EC Certificate valid until:24-08-2028 (Copy)</p> <p><b><u>ISO 13485:</u></b> Valid till: 31-03-2027 (copy) <i>The firm claimed that notarized attached with shortcomings submission of HMS Plus Instrument dated 10-03-2025.</i></p>	<p><b>CLOTtrac HR control</b></p> <p>IVDD-Coagulation Control</p> <p>Applied as: Not mentioned.</p> <p><b>Class C</b></p> <p><b>Shelf Life:</b> 31 Weeks</p> <p><b>Codes/Sizes:</b> <b>551-08</b></p>	Approved
<b>154.</b>	<p>M/s. BIOMADICS, Karachi Address: Gate #1, 211/B Sindhi Muslim, Block B Corporation</p>	<p>M/s Diagon Solutions <b>Address:</b> No.H-1047 Budapest, Baross u, Street 48-52, Hungary</p>	<p><b>Diagon</b> Coagulation Analyzer Reagents.</p> <p>Applied as: Cluster</p>	<p>Deferred for the submission of the following: i.Valid Legalized FSc of the country of</p>

	<p>Housing Society, Karachi <b>ELI:00432</b></p> <p>Date of R&amp; I 17 April 2025</p> <p>Fee:107000/ Slip: 13475817647 (Rs. 50,000/-), 2953072816 (Rs. 12000/-) and 31576867202</p>	<p><b>FSC (Hungary):</b> Issued on 24-09-2019 (Copy) <i>The firm claimed that notarized attached with Coagulation Analyzer Dossier.</i></p> <p><b>LOA Validity:</b> 30/07/2026 (Copy) <i>The firm claimed that notarized attached with Coagulation Analyzer Dossier.</i></p> <p><b>DOC:</b> 24/ 08 / 2023 (Copy)</p> <p><b>ISO 13485 Validity:</b> 17/01/2027 (Copy)</p>	<p>Class C</p> <p>Dia-PT 5, Dia-PT 5 Dia-PT 10, Dia-PT LIQUID (<b>18 months</b>)</p> <p>Dia-PT R (<b>24 months</b>) , Dia-PT R Dia-PTT (<b>24 months</b>) Dia-PTT Dia-PTT LIQUID (<b>18 months</b>) Dia-FIB (<b>24 months</b>) , Dia-FIB 2 Dia-CONT I-II (<b>24 months</b>)</p> <p>Dia-CAL (<b>24 months</b>) Dia-D-DIMER (<b>13 months</b>)</p> <p>Dia-CONT DDI I-II (<b>26 months</b>) Dia-CAL II (<b>24 months</b>)</p>	<p>origin. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)</p> <p>iii. Valid notarized ISO 13485 iv. The products are in Class-C which can not be classified as cluster, therefore, the firm shall submit spearte application each &amp; along with prescribed fee.</p>
155.	<p>Orbit Diagnostics, 403, Plaza 55, Civic Centre, Bahria Town, Islamabad</p> <p>ELI-00630</p> <p>Fee: 62000 Challan no. 965737121856</p> <p>R&amp;I date: 18-04- 2025</p>	<p>AEHealth Limited, Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen P.R. China.</p> <p>LOA Valid till: 12-03- 2030(Copy)</p> <p>FSC (china) Valid till: 02-12- 2026(copy)</p> <p>FSC (Germany) Issue date: 25- 07-2023 (Copy)</p> <p>ISO Valid till: 06-02-2026 (Copy)</p>	<p>AEHealth</p> <p>Cancer Marker- Immuno fluorescence Assays</p> <p>Applied as: Cluster</p> <p>Class C</p> <p>Shelf Life: 2 years</p> <p>Code: • 25-(OH) - VD (25- OH-Vitamin D) Rapid Quantitative Test • CEA (Carcino embryonic Antigen) Rapid Quantitative Test • FER (Ferritin) Rapid Quantitative Test PGI/PII (Pepsinogen I/ Pepsinogen II) Rapid Quantitative</p>	<p>Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory Authority wherein the product shall be in free sale. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)</p> <p>iii. Valid notarized ISO 13485 iv. Noarized LOA v. The products applied in Class-C which can not be classified as cluster, therefore, the firm shall submit spearte application for</p>

			Test • MAU (Micro albumin) Rapid Quantitative Test	each & along with prescribed fee.
<b>156.</b>	Mian Scientific Corporation Pvt. LTd., 534-Jinnah Colony Faisalabad  ELI-00442  Fee. 62000  Challan No. 6560399998  R&I date: 18-04-2025	Assure Tech (Hangzhou) Co., Ltd., Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China  LOA Valid till: 18-02-2028 (Copy)  FSC (China) Valid till: 19-02-2027 (copy)  ISO Valid till: 28-11-2025 (Copy)	Inst Answer Malaria Pf/Pan Rapid Test  Malaria Pf/Pan Rapid Test  Applied as: Kit  Class C  Shelf Life 24 months  Code: not mentioned.	Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory Authority wherein the product shall be in free sale. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)  iii. Valid notarized ISO 13485 iv. Noarized LOA. v. Demanded codes along with FSC evidence
<b>157.</b>	Mian Scientific Corporation Pvt. LTd., 534-Jinnah Colony Faisalabad  ELI-00442  Fee. 62000  Challan No. 6900522539  R&I date: 18-04-2025	Assure Tech (Hangzhou) Co., Ltd., Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China  LOA Valid till: 18-02-2028 (Copy)  FSC (China) Valid till: 19-02-2027 (copy)  ISO Valid till: 28-11-2025 (Copy)	Inst Answer Malaria Pf/PV Rapid Test  Malaria Pf/Pan Rapid Test  Applied as: Kit  Class C  Shelf Life 24 months  Code: not mentioned.	Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory Authority wherein the product shall be in free sale. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)  iii. Valid notarized ISO 13485 iv. Noarized LOA. v. Demanded codes along with FSC evidence
<b>158.</b>	Mian Scientific Corporation Pvt. LTd., 534-Jinnah Colony Faisalabad  ELI-00442	Assure Tech (Hangzhou) Co., Ltd., Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China  LOA Valid till: 18-02-2028	Inst Answer Syphilis Rapid Test  Syphilis Rapid Test	Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory

	<p>Fee. 62000</p> <p>Challan No. 37082335540</p> <p>R&amp;I date: 18-04-2025</p>	<p>(Copy)</p> <p>FSC (China) Valid till: 19-02-2027 (copy)</p> <p>ISO Valid till: 28-11-2025 (Copy)</p>	<p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life 27 months</p> <p>Code:</p>	<p>Authority wherein the product shall be in free sale.</p> <p>ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)</p> <p>iii. Valid notarized ISO 13485</p> <p>iv. Noarized LOA.</p> <p>v. Demanded codes along with FSC evidence.</p>
159.	<p>Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061)</p> <p>Date of R&amp;I 18-04-2025 Rs.62000/- Slip# 6796855367</p>	<p><b><u>Legal Manufacturer:</u></b> STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany</p> <p><b><u>Manufacturing Site</u></b> Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16, 400 13 Castel Maggiore (BO) Italy</p> <p>Critical suppliers for production: _ RS ELETTRONICA SRL - Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN)</p> <p>FSC (Italy) No. DGDMF/3/P/I.5I.e.I/2024/234 7: Dated 19-11-2024 (Apostille)</p> <p>LOA Validity: 31-12-2027 (Original Notarized)</p> <p>CE Certificate (FQA) Validity: 26-05-2024 with Extension letter (Notarized)</p> <p>ISO 13485 for legal manufacturer Validity: 28-01-2025 (Notarized) &amp; copy of ISO 13485 valid up to 17-11-2027. ISO 13485 for manufacturing</p>	<p><b>Stema HF-U Pro Touch</b> Electrosurgical Unit</p> <p>Class C</p> <p>Apply as System</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes (if any) as mentioned in the remarks</p>	<p>Deferred for the submission of the following:</p> <p>i. Valid Legalized FSc of the country of origin or any other RRA wherein the applied product &amp; their legal manufacturer &amp; manufacturing site shall be clearly mentioned along with the free sale status.</p> <p>ii. Valid notarized ISO 13485 for manufacturing site.</p> <p>iii. Differential fee for system as per New SRO along with evidence &amp; components in the FSC.</p>

		site Validity: 19-12-2025 (Notarized)		
<b>160.</b>	<p>Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061)</p> <p>Date of R&amp;I 18-04-2025 Rs.62,000/- Slip# 17374570547</p>	<p><b><u>Legal Manufacturer:</u></b> STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany</p> <p><b><u>Manufacturing Site</u></b> Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16, 400 13 Castel Maggiore (BO) Italy</p> <p>Critical suppliers for production: _ RS ELETTRONICA SRL - Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN)</p> <p>FSC (Italy) No. DGDMF/3/P/I.5I.e.I/2024/234 7: Dated 19-11-2024 (Apostille)</p> <p>LOA Validity: 31-12-2027 (Original Notarized)</p> <p>CE Certificate (FQA) Validity: 26-05-2024 with Extension letter (Notarized)</p> <p>ISO 13485 for legal manufacturer Validity: 28-01- 2025 (Notarized) &amp; copy of ISO 13485 valid up to 17-11- 2027. ISO 13485 for manufacturing site Validity: 19-12-2025 (Notarized)</p>	<p>Stema HF-U PRO Electrosurgical Unit</p> <p>Class C</p> <p>Apply as System</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes (if any) as mentioned in the remarks</p>	<p>Deferred for the submission of the following: i.Valid Legalized FSc of the country of origin or any other RRA wherein the applied product &amp; their legal manufacturer &amp; manufacturing site shall be clearly mentioned along with the free sale status.</p> <p>ii. Valid notarized ISO 13485 for manufacturing site. iii. Differential fee for system as per New SRO along with evidence &amp; components in the FSC.</p>
<b>161.</b>	<p>M/s ACP Systems 13&amp;23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi</p> <p><b>Date of R&amp; I</b> 25.04.2025</p>	<p><b><u>Legal Manufacturer:</u></b> Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA</p> <p><b><u>Manufacturing Site</u></b> Thoratec Switzerland GmbH Technoparkstrasse 1</p>	<p>CentriMag System (Centrimag Acute Circulatory Support System)</p> <p>Applied as: System</p> <p>Class C</p>	<p>Approved</p>

	<p><b>Fee:</b> Rs.`100000/ through slip no. 6901460242</p>	<p>Zurich Switzerland. CH-8005</p> <p><b>FSC: (US FDA)</b> Validity Date: 28.03.2026 (Apostille)</p> <p><b>LOA:</b> Valid upto 31-12-2026 (Copy)</p> <p>ISO 13485 of Switzerland site - Validity Date: 06.02.2028 (Notarized)</p> <p><b>EU-QMS Certificate</b> Valid upto 30.03.2028 (Notarized)</p>	<p>Shelf Life : 3 years</p> <p><b>Components: Demanded &amp; confirmed from FSC:</b> 201-30500- Centimag Mag Monitor 201-10002- - Centimag Motor 201—900010- Centimag Single use blood pump 201—90751 2<sup>nd</sup> generation Centimag primary console, <b>Flow Probes:</b> i) 201-90401- Centrimag PC 2<sup>nd</sup> Gen w/3/8`` FP (<b>Adult</b>) ii) 201-90701- Centrimag PC 2<sup>nd</sup> Gen w/1/4`` FP (<b>Peds</b>)</p> <p><b>Demanded &amp; but not confirmed from FSC:</b></p> <p>Drainage &amp; return cannulas</p>	
162.	<p>M/s Snibe Diagnostic Pakistan (SMC- Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 06981546741</p>	<p>M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (<b>SNIBE Co., Ltd.,</b>) <b>Address as per FSC Germany</b> &amp; Form-7A: NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe Building,</b> No.23, Jinxiu East Road, <b>Jinsha Community,</b> Kengzi Street, Pingshan District, 518122. <b>Shenzhen,</b> P.R China</p> <p><b>LOA:</b> Valid till: 03-12-2029 (Notarized copy)</p> <p><b>FSC (China):</b> Validity Date: 03-08-2025</p>	<p><b>Maglumi</b> Tumor Marker Controls</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code/sizes: <b>Ref., No.1601010061:</b> Level 1: 1x2ml, Level 2: 1x2ml, Level 3: 1x2ml, <b>Ref., No.1601010062:</b> Level 1: 2x2ml, Level 2: 2x2ml, Level 3: 2x2ml, <b>Ref., No.1601010063:</b> Level 1: 3x2ml, <b>Ref., No.1601010064:</b> Level 1: 6x2ml,</p>	<p>Approved with the address mentioned in the FSC (Germany) &amp; Form-7A.</p>

		(Apostille)  <b>FSC (Germany)</b> Issue Date: 30-01-2025 (Embassy Attested)  ISO - Validity Date: 31-12-2025 (Notarized)  EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)	<b>Ref., No.1601010065:</b> Level 2: 3x2ml, <b>Ref., No.1601010066:</b> Level 2: 6x2ml, <b>Ref., No.1601010067:</b> Level 3: 3x2ml, <b>Ref., No.1601010068:</b> Level 3: 6x2ml	
<b>163.</b>	M/s Snibe Diagnostic Pakistan (SMC- Private) Limited, Office No. A107, 1 <sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi  ELI-01036  <b>Date of R&amp; I</b> 30.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 652151690892	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. <b>(SNIBE Co., Ltd.)</b> <b>Address as per FSC Germany</b> & Form-7A: NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China  Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe</b> <b>Building,</b> No.23, Jinxiu East Road, <b>Jinsha Community,</b> Kengzi Street, Pingshan District, 518122. <b>Shenzhen,</b> P.R China  <b>LOA:</b> Valid till: 03-12-2029 (Notarized copy)  <b>FSC (China):</b> Validity Date: 03-08-2025 (Apostille)  <b>FSC (Germany)</b> Issue Date: 30-01-2025 (Embassy Attested)  ISO - Validity Date: 31-12-2025 (Notarized)  EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)	<b>Maglumi</b> CMV IgM (CLIA) and CMV IgM (CLIA) Controls  Applied as: Kit  Class C  Shelf Life: 18 months  Code/sizes: CMV IgM (CLIA): <b>Cat.,No.:</b> 130262006M, 130662006M, 130762006M 100 tests/kit, 50 Tests/kit, 30 Test/kit  CMV IgM (CLIA) Controls <b>Cat.,No.:</b> 160201482MT Negative Controls: 1x1.0ml Positive Control: 1x1.0ml	Approved with the address mentioned in the FSC (Germany) & Form-7A.
<b>164.</b>	M/s Snibe Diagnostic Pakistan (SMC- Private) Limited, Office No. A107, 1 <sup>st</sup>	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. <b>(SNIBE Co., Ltd.)</b> <b>Address as per FSC Germany</b>	<b>Maglumi</b> Tacrolimus (CLIA) and Tacrolimus (CLIA) Controls	Approved with the address mentioned in the FSC (Germany) & Form-7A.

	<p>Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 265176771</p>	<p>&amp; Form-7A: NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe Building</b>, No.23, Jinxiu East Road, <b>Jinsha Community</b>, Kengzi Street, Pingshan District, 518122. <b>Shenzhen</b>, P.R China</p> <p><b>LOA:</b> Valid till: 03-12-2029 (Notarized copy)</p> <p><b>FSC (China):</b> Validity Date: 03-08-2025 (Apostille) &amp; copy of FSC (china) valid upto 28-09-2025 for control.</p> <p><b>FSC (Germany)</b> Issue Date: 30-01-2025 (Embassy Attested)</p> <p>ISO - Validity Date: 31-12-2025 (Notarized)</p> <p>EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)</p>	<p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life : 18 months</p> <p>Code/sizes: Tacrolimus (CLIA): 1302573003M, 1306573003M, 1307573003M, 100 tests/kit, 50 Tests/kit, 30 Test/kit</p> <p>Tacrolimus (CLIA) Controls: 1602011036MT Control 1: 1x1.0ml Control 2: 1x1.0ml</p>	
<b>165.</b>	<p>M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 5202566601</p>	<p>M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (<b>SNIBE Co., Ltd.</b>) <b>Address as per FSC Germany &amp; Form-7A:</b> NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe Building</b>, No.23, Jinxiu East Road, <b>Jinsha Community</b>, Kengzi Street, Pingshan District, 518122. <b>Shenzhen</b>, P.R China</p> <p><b>LOA:</b> Valid till: 03-12-2029</p>	<p>MAGLUMI Cyclosporine (CLIA) and Cyclosporine (CLIA) Controls</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life : 18 months</p> <p>Code/sizes: Cyclosporine (CLIA): 1302573001M, 1306573001M, 1307573001M 100 tests/kit, 50</p>	<p>Approved with the address mentioned in the FSC (Germany) &amp; Form-7A.</p>



		<p>(Notarized copy)</p> <p><b>FSC (China):</b> Validity Date: 03-08-2025 (Apostille) &amp; copy of FSC (china) valid upto 28-09-2025 for control.</p> <p><b>FSC (Germany) Issue Date:</b> 30-01-2025 (Embassy Attested)</p> <p>ISO - Validity Date: 31-12-2025 (Notarized)</p> <p>EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)</p>	<p>Tests/kit, 30 Test/kit</p> <p>Cyclosporine (CLIA) Controls: 1602011046MT Control 1: 1x1.0ml Control 2: 1x1.0ml</p>	
166.	<p>M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 188053464805</p>	<p>M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. <b>(SNIBE Co., Ltd.,)</b> <b>Address as per FSC Germany &amp; Form-7A:</b> NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe Building,</b> No.23, Jinxiu East Road, <b>Jinsha Community,</b> Kengzi Street, Pingshan District, 518122. <b>Shenzhen,</b> P.R China</p> <p><b>LOA:</b> Valid till: 03-12-2029 (Notarized copy)</p> <p><b>FSC (China):</b> Validity Date: 03-08-2025 (Apostille) &amp; copy of FSC (china) valid upto 28-09-2025 for control.</p> <p><b>FSC (Germany) Issue Date:</b> 30-01-2025 (Embassy Attested)</p> <p>ISO - Validity Date: 31-12-2025 (Notarized)</p>	<p>MAGLUMI Free PSA (CLIA) and Free PSA (CLIA) Controls:</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life : 24 months</p> <p>Code/sizes: Free PSA (CLIA): 130201035M, 130601035M, 130701035M, 100 tests/kit, 50 Tests/kit, 30 Test/kit</p> <p>Free PSA (CLIA) Controls: 160201222MT Control 1: 1x1.0ml Control 2: 1x1.0ml</p>	<p>Approved with the address mentioned in the FSC (Germany) &amp; Form-7A.</p>

		EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)		
<b>167.</b>	<p>M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 17180627</p>	<p>M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (<b>SNIBE Co., Ltd.,</b>) <b>Address as per FSC Germany &amp; Form-7A:</b> NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China</p> <p>Address as per FSC (China): <b>21<sup>st</sup> Floor, Snibe Building,</b> No.23, Jinxiu East Road, <b>Jinsha Community,</b> Kengzi Street, Pingshan District, 518122. <b>Shenzhen,</b> P.R China</p> <p><b>LOA:</b> Valid till: 03-12-2029 (Notarized copy)</p> <p><b>FSC (China):</b> Validity Date: 03-08-2025 (Apostille) &amp; copy of FSC (china) valid upto 28-09-2025 for control.</p> <p><b>FSC (Germany)</b> Issue Date: 30-01-2025 (Embassy Attested)</p> <p>ISO - Validity Date: 31-12-2025 (Notarized)</p> <p>EU Quality Management System Certificate (IVDR) Valid till: 14-12-2025 (Notarized)</p>	<p><b>MAGLUMI</b></p> <p>Rubella IgM (CLIA) and Rubella IgM (CLIA) Controls</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life : 18 months</p> <p>Code/sizes: Rubella IgM (CLIA): 130262004M, 130662004M, 130762004M 100 tests/kit, 50 Tests/kit, 30 Test/kit</p> <p>Rubella IgM (CLIA) Controls: 160201483MT Negative Control: 1x1.0ml Positive Control: 1x1.0ml</p>	Approved with the address mentioned in the FSC (Germany) & Form-7A.
<b>168.</b>	<p>M/s Alpha Initiative (Private) Limited, Suite No. 9, Ground Floor, Khudadad Heights, Main Margala Road, E-11, Islamabad</p> <p>ELI-01278</p>	<p>M/s The Fred Hollows Intraocular Lens Laboratory, Nepal Eye Program, Tilganga Eye Center, Gaushala, Bagmati Bridge, Kathmandu, Nepal</p> <p><b>LOA:</b> Issue date: 25-09-2024 valid for four years (Copy)</p>	<p><b>The Fred Hollows One Sterile Intraocular Lens (FH105)</b></p> <p>Sterile One Piece Rigid PMMA Intraocular Lens</p> <p>Applied as: Single</p>	Approved subject to submit valid and attested FSC.

	<b>Date of R&amp; I</b> 22.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 37972283912	<b>FSC:</b> Validity Date: 29-04-2025 (copy) <b>FSC:</b> Validity Date: 05-05-2027 (copy)  ISO 13585 - Validity Date: 08-12-2025 (Copy)  EC Certificate (FQA) valid up to 27-05-2024& extension letter provided (Copy)	Class C  Shelf Life: 5 Years  Code/sizes: FH105	
169.	M/s Alpha Initiative (Private) Limited, Suite No. 9, Ground Floor, Khudadad Heights, Main Margala Road, E-11, Islamabad  ELI-01278  <b>Date of R&amp; I</b> 22.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 37972283912	M/s The Fred Hollows Intraocular Lens Laboratory, Nepal Eye Program, Tilganga Eye Center, Gaushala, Bagmati Bridge, Kathmandu, Nepal  <b>LOA:</b> Issue date: 25-09-2024 valid for four years (Copy)  <b>FSC:</b> Validity Date: 29-04-2025 (copy) <b>FSC:</b> Validity Date: 05-05-2027 (copy)  ISO 13585 - Validity Date: 08-12-2025 (Copy)  EC Certificate (FQA) valid up to 27-05-2024& extension letter provided (Copy)	The Fred Hollows One Sterile Intraocular Lens FH106  Sterile One Piece Rigid PMMA Intraocular Lens  Applied as: Single  Class C  Shelf Life : 5 Years  Code/sizes: FH106	Approved subject to submit valid and attested FSC.
170.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  <b>Date of R&amp; I</b> 29.04.2025  <b>Fee:</b> Rs.`62000/ through	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.  <b>LOA:</b> Valid till: 21-04-2030 (Copy)  <b>FSC:</b> Not provided  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	<b>Pulse-Extra Sensitive</b>  Natural Rubber Latex Male Condoms Pulse – Extra Sensitive  Applied as: Family  Class C  Shelf Life : 5 Years  Code/sizes:	Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory Authority wherein the product shall be in free sale. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA) with correct address

	slip no. 6379675693			iii. Valid notarized ISO 13485 iv. Noarized LOA. v. Demanded codes along with FSC evidence
171.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  <b>Date of R&amp; I</b> 29.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 9182038880	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.  <b>LOA:</b> Valid till: 21-04-2030 (Copy)  <b>FSC:</b> Not provided  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	Pulse-Strawberry  Natural Rubber Latex Male Condoms Pulse – <b>Strawberry</b>  Applied as: Family Class C  Shelf Life : 5 Years  Code/sizes:	Deferred for the submission of the following: i. Valid Legalized FSc of the country of origin issued by the concerned Regulatory Authority wherein the product shall be in free sale. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA) with correct address  iii. Valid notarized ISO 13485 iv. Noarized LOA. v. Demanded codes along with FSC evidence
172.	M/s Raffay Associates, Office No. 04, 2 <sup>nd</sup> Floor Ahmed Plaza Range Road, Rawalpindi  ELI-00021  <b>Date of R&amp; I</b> 21.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 640707709741	M/s S&G Biotech Inc. 82 Bugok-ro, <b>Pogok-eup</b> , Cheoin-gu, Yongin-Si, Gyeonggi-do, Korea (PO), <b>17023</b>  <b>LOA:</b> Issue date: 16-01-2024 without any expiry/validity (Copy)  <b>FSC:</b> Issue date:06-03-2024 without validity (Apostille)  ISO - Validity Date: 19-12-2026 (Copy)  EC Certificate Not provided.	<b>Hercules Vascular Stent</b> Self-Expandable Metallic Vascular Stent  Applied as: Single Class C  Shelf Life: 3 Years  Code/sizes: VS-JZ-20-120, VS-JG-20-100, VS-JG-20-40, VS-JG-20-60, VS-JG-20-80, VS-JG-22-100, VS-JG-22-40, VS-JG-22-60, VS-JG-22-80, VS-JG-24-100, VS-JG-24-40, VS-JG-24-60, VS-JG-24-80, VS-JG-6-100, VS-JG-6-40,	Deferred for the submission of the following: i. Revised Form-7A with correct classification as per DOC. ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)  iii. Valid notarized ISO 13485 iv. Noarized LOA. v. Justification of the multiple codes in single application & fee along with FSC evidence

			<p>VS-JG-6-60, VS-JG-6-80, VS-JG-8-100, VS-JG-8-40, VS-JG-8-60, VS-JG-8-80, VS-CH-6-40, VS-CH-6-60, VS-CH-6-80, VS-JG-20-50, VS-JG-20-70, VS-JG-20-90</p> <p>VS-JG-22-120, VS-JG-22-50, VS-JG-22-70</p> <ul style="list-style-type: none"> <li>• VS-JG-22-90</li> <li>• VS-JG-24-120</li> <li>• VS-JG-24-50</li> <li>• VS-JG-24-70</li> <li>• VS-JG-24-90</li> <li>• VS-JG-6-120</li> <li>• VS-JG-6-50</li> <li>• VS-JG-6-70</li> <li>• VS-JG-6-90</li> <li>• VS-JG-8-120</li> <li>• VS-JG-8-50</li> <li>• VS-JG-8-70</li> <li>• VS-JG-8-90</li> <li>• VS-CH-6-50</li> <li>• VS-CH-6-70</li> </ul> <p>VS-CH-6-100</p> <ul style="list-style-type: none"> <li>• VS-CH-10-100</li> <li>• VS-CH-10-40</li> <li>• VS-CH-10-60</li> <li>• VS-CH-10-80</li> <li>• VS-CH-8-100</li> <li>• VS-CH-8-40</li> <li>• VS-CH-8-60</li> <li>• VS-CH-8-80</li> <li>• VS-JG-10-100</li> <li>• VS-JG-10-40</li> <li>• VS-JG-10-60</li> <li>• VS-JG-10-80</li> <li>• VS-JG-12-100</li> <li>• VS-JG-12-40</li> <li>• VS-JG-12-60</li> <li>• VS-JG-12-80</li> <li>• VS-JG-14-100</li> <li>• VS-JG-14-40</li> <li>• VS-JG-14-60</li> <li>• VS-JG-14-80</li> <li>• VS-JG-16-100</li> <li>• VS-JG-16-40</li> <li>• VS-JG-16-60</li> <li>• VS-JG-16-80</li> <li>• VS-JG-18-100</li> <li>• VS-JG-18-40</li> </ul> <p>VS-CH-6-120</p>	
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			<ul style="list-style-type: none"> <li>• VS-CH-10-120</li> <li>• VS-CH-10-50</li> <li>• VS-CH-10-70</li> <li>• VS-CH-10-90</li> <li>• VS-CH-8-120</li> <li>• VS-CH-8-50</li> <li>• VS-CH-8-70</li> <li>• VS-CH-8-90</li> <li>• VS-JG-10-120</li> <li>• VS-JG-10-50</li> <li>• VS-JG-10-70</li> <li>• VS-JG-10-90</li> <li>• VS-JG-12-120</li> <li>• VS-JG-12-50</li> <li>• VS-JG-12-70</li> <li>• VS-JG-12-90</li> <li>• VS-JG-14-120</li> <li>• VS-JG-14-50</li> <li>• VS-JG-14-70</li> <li>• VS-JG-14-90</li> <li>• VS-JG-16-120</li> <li>• VS-JG-16-50</li> <li>• VS-JG-16-70</li> <li>• VS-JG-16-90</li> <li>• VS-JG-18-120</li> <li>• VS-JG-18-50</li> <li>VS-JG-18-60, VS-JG-18-80, VS-JG-18-70, VS-JG-18-90</li> </ul>	
173.	<p>Moody global services: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p><b>(ELI-01038)</b></p> <p>Date of R&amp;I 18/4/2025</p> <p><b>Fee Details:</b> <b>Paid Fee:</b> 62,000/-</p> <p>Fee Challan No: 942016226423</p>	<p>Sansure Biotech Inc.</p> <p><b>Address:</b> No.680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province, Peoples Republic of China</p> <p><b>LOA Validity:</b> 20/08/2029 (copy) <i>The firm claimed that the notarized attached with the dossier of Sample Storage Reagent dated 31-01-2025.</i></p> <p><b>FSC</b> issued by <b>China Chamber of Commerce</b> for Import &amp; Export of Medicines &amp; health products. Validity: 21-12-2026 (copy) <i>The firm claimed that the notarized attached with the dossier of Human Immunodeficiency Virus Type 1</i></p>	<p><b>Sansure</b> Human Papillomavirus DNA Diagnostic kit (PCR-Fluorescence Probing)</p> <p>Class-C Applied as : Family <b>Shelf life:</b> 12 Months</p> <p><b>(Model and specification as per FSC)</b> S3057E (48tests, 24 tests)</p>	<p>Deferred for submission of legalized FSc from concerned regulatory authority.</p>

		<p><i>RNA Quantitative Fluorescence Diagnostic Kit (PCR-Fluorescence Probing)</i></p> <p><b>FSC (Belgium)</b> dated 31-10-2024 without validity. <b>(Apostille)</b> <b>ISO Validity:</b> 22-11-2025. <i>The firm claimed that the notarized attached with the dossier of Sample Storage Reagent dated 31-01-2025.</i></p>		
174.	<p>Moody global services: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p><b>(ELI-01038)</b></p> <p>Date of R&amp;I 18/4/2025</p> <p><b>Fee Details:</b> <b>Paid Fee:</b> 62,000/-</p> <p>Fee Challan No: 543710323</p>	<p>Sansure Biotech Inc. <b>Address:</b> No.680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province, Peoples Republic of China</p> <p><b>LOA Validity:</b> 20/08/2029 (copy) <i>The firm claimed that the notarized attached with the dossier of Sample Storage Reagent dated 31-01-2025.</i></p> <p><b>FSC</b> issued by <b>China Chamber of Commerce</b> for Import &amp; Export of Medicines &amp; health products. Validity: 21-12-2026 (copy) <i>The firm claimed that the notarized attached with the dossier of Human Immunodeficiency Virus Type 1 RNA Quantitative Fluorescence Diagnostic Kit (PCR-Fluorescence Probing)</i></p> <p><b>FSC (Belgium)</b> dated 31-10-2024 without validity. <b>(Apostille)</b> <b>ISO Validity:</b> 22-11-2025. <i>The firm claimed that the notarized attached with the dossier of Sample Storage Reagent dated 31-01-2025.</i></p>	<p><b>Sansure</b> Hepatitis C Virus Genotype Diagnostic Kit (PCR-Fluorescence Probing)</p> <p>Class-C</p> <p><b>Shelf life:</b> 12 Months</p> <p><b>(Model and specification as per FSC)</b> S3034E(12 Tests/kit)</p>	<p>Deferred for submission of legalized FSc from concerned regulatory authority.</p>
175.	<p>Health Tec, H. No. 10-B, Valley Road, St. 24,</p>	<p>SCW Medicath Ltd,  Address: No. 4, Baolong 6th Road,</p>	<p><b>Angiographic Catheter</b></p>	<p>Deferred for the submission of the following: i. Valid Legalized FSc</p>

	<p>Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00046</p> <p>Date of R&amp;I 22/4/2025</p> <p><b>Fee Details:</b> <b>Paid Fee:</b> 62,000/-</p> <p>Fee Challan No: 73333755806</p>	<p>Baolong Industrial Town, Longgang District, Shenzhen, <b>518116</b> Guangdong, P.R. China.</p> <p>FSC: China. Validity: 25-11-2026. (Apostille)</p> <p><b>LOA Validity:</b> 26/08/2029 (copy)</p> <p>EU Quality Management System Certificate (MDR) validity 26-09-2029. (<b>copy</b>)</p> <p><b>ISO Validity:</b> 08-07-2027 (copy)</p>	<p>Peripheral angiographic Catheter</p> <p>Class-B – Class-C</p> <p><b>Shelf life:</b> 12 Months</p> <p><b>(Model and specification as per FSC)</b></p>	<p>of the country of origin issued by the concerned Regulatory Authority wherein the product shall be mentioned &amp; on free sale.</p> <p>ii. Valid Legalized FSC of any RRA or notarized CE Certificate (FQA)</p> <p>iii. Valid notarized ISO 13485</p> <p>iv. Noarized LOA.</p> <p>v. Demanded codes/sizes along with FSC evidence.</p> <p>vi. Jsutify the Class of the product.</p> <p>vii. Separate application for Guiding Catheter with separate fee shall be submitted.</p>
<b>176.</b>	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p> <p><b>Date of R&amp;I</b> 23-Apr-2025</p> <p><b>Fee Details:</b> <b>Paid Fee &amp; Fee:</b> Challan No: Rs. 31,000/- 9174783355 &amp; Rs. 31,000/- 4950957083</p>	<p>Abbott Ireland Diagnostics Division, Lisnamuck, Longford Co. Longford, Ireland.</p> <p><b>FSC:</b> Ireland Issuance: 09-Jan-25 (Apostille)</p> <p><b>LOA</b> Issuance: 17-Jan-25 valid five years. (notarized)</p> <p>EU Quality Management System Certificate (IVDR) validity 25-11-2026. (notarized)</p> <p><b>ISO 13485</b> Validity: 31-08-26 (notarized)</p>	<p>Lipase2 &amp; Lipase2 Calibrator</p> <p>Applied as Kit</p> <p>Class: C</p> <p>Shelf Life: Lipase2 12 Months Lipase2 Calibrator 18 Months</p> <p>Codes/Sizes: Lipase2 04U0020</p> <p>Lipase2 Calibrator 04U0001</p>	<p>Approved subject to submission of revised Form-7A with correct name/code.</p>
<b>177.</b>	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center,</p>	<p>Abbott Ireland Diagnostics Division, Lisnamuck, Longford Co. Longford, Ireland.</p>	<p>Lipase2 Lipase2 Calibrator</p> <p>Class: C</p>	<p>Approved</p>



	<p>Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p> <p><b>Date of R&amp;I</b> 23-Apr-2025</p> <p><b>Fee Details:</b> <b>Paid Fee &amp; Fee:</b> Challan No: Rs. 31,000/- 964052279351 &amp; Rs. 31,000/- 54551207225</p>	<p><b>FSC:</b> Ireland Issuance: 09-Jan-25 (Apostille)</p> <p><b>LOA</b> Issuance: 17-Jan-25 valid five years. (notarized)</p> <p>EU Quality Management System Certificate (IVDR) validity 25-11 2026. (notarized)</p> <p><b>ISO 13485</b> Validity: 31-08-26 (notarized)</p>	<p>Shelf Life: Lipase2 12 Months Lipase2 Calibrator 18 Months</p> <p>Codes/Sizes: Lipase2 04U0020</p> <p>Lipase2 Calibrator 04U0001</p>	
<b>178.</b>	<p>Radiant Medical (Pvt) Ltd,</p> <p>06 Sher Shah Block, New Garden Town, Lahore.</p> <p>ELI-00135</p> <p>Date of R&amp;I 21-04-2025 Rs.62000/- Slip# 2447559053</p>	<p>Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.</p> <p>LOA Validity: 31-12-2025 (Notarized)</p> <p>FSC (Germany) Dated 01-07-2024 without validity (Apostille)</p> <p>EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized)</p> <p>ISO 13485 Validity: 03-04- 2027 (Notarized)</p>	<p><b>ERBE VIO 300S</b></p> <p>Electrosurgical Unit</p> <p>Class C</p> <p>Apply as Family</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes (if any): 10140-100 ERBE VIO 300 D 10140-200 ERBE VIO 200 D <b>10140-300 ERBE VIO 300 S</b> 10140-400 ERBE VIO 200 S 10140-550 ERBE VIO 50 C 10140-500 ERBE VIO 100 C 10160-000 VIO 3</p>	<p>Deferred the product for the following: Separate Application for each product along with fee as system &amp; the required components for each product as per FSC.</p>
<b>179.</b>	<p>Radiant Medical (Pvt) Ltd,</p> <p>06 Sher Shah Block, New Garden Town, Lahore.</p> <p>ELI-00135</p>	<p>Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.</p> <p>LOA Validity: 31-12-2025 (Notarized)</p>	<p><b>ERBE VIO 300D</b></p> <p>Electrosurgical Unit</p> <p>Class C</p> <p>Apply as Family</p>	<p>Deferred the product for the following: Separate Application for each product along with fee as system &amp; the required components for each product as per FSC.</p>

	<p>Date of R&amp;I 21-04-2025 Rs.62000/- Slip# 219703842410</p>	<p>FSC (Germany) Dated 01-07-2024 without validity (Apostille)</p> <p>EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized)</p> <p>ISO 13485 Validity: 03-04- 2027 (Notarized)</p>	<p>Shelf Life: N/A</p> <p>Codes/Sizes (if any): <b>10140-100 ERBE VIO 300 D</b> 10140-200 ERBE VIO 200 D 10140-300 ERBE VIO 300 S 10140-400 ERBE VIO 200 S 10140-550 ERBE VIO 50 C 10140-500 ERBE VIO 100 C 10160-000 VIO 3</p>	
<b>180.</b>	<p>Radiant Medical (Pvt) Ltd,  06 Sher Shah Block, New Garden Town, Lahore.  ELI-00135  Date of R&amp;I 21-04-2025 Rs.62000/- Slip# 3624385046</p>	<p>Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.  LOA Validity: 31-12-2025 (Notarized)</p> <p>FSC (Germany) Dated 01-07-2024 without validity (Apostille)</p> <p>EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized)</p> <p>ISO 13485 Validity: 03-04- 2027 (Notarized)</p>	<p><b>ERBE VIO 3</b> Electrosurgical Unit  Class C  Apply as Family  Shelf Life: N/A  Codes/Sizes (if any): 10140-100 ERBE VIO 300 D 10140-200 ERBE VIO 200 D 10140-300 ERBE VIO 300 S 10140-400 ERBE VIO 200 S 10140-550 ERBE VIO 50 C 10140-500 ERBE VIO 100 C <b>10160-000 VIO 3</b></p>	<p>Deferred the product for the following: Separate Application for each product along with fee as system &amp; the required components for each product as per FSC.</p>
<b>181.</b>	<p>Radiant Medical (Pvt) Ltd,  06 Sher Shah Block, New Garden Town, Lahore.  ELI-00135  Date of R&amp;I 21-04-2025</p>	<p>Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.  LOA Validity: 31-12-2025 (Notarized)</p> <p>FSC (Germany) Dated 01-07-2024 without</p>	<p><b>ERBE CRYO 2</b> Cryosurgical Unit  Class C  Apply as Family  Shelf Life: N/A</p>	<p>Deferred the product for the following: Separate Application for each product along with fee as system &amp; the required components for each product as per FSC.</p>

	Rs.62000/- Slip# 81413971	validity (Apostille)  EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized)  ISO 13485 Validity: 03-04- 2027 (Notarized)	Codes/Sizes (if any): <b>10402-000</b>	
<b>182.</b>	Radiant Medical (Pvt) Ltd,  06 Sher Shah Block, New Garden Town, Lahore.  ELI-00135  Date of R&I 21-04-2025 Rs.62000/- Slip# 5272771253	Asclepion Laser Technologies GmbH, Brusseler Strasse 10, 07747 Jena, Germany.  LOA Validity: 31-12-2026 (Notarized)  FSC (Germany) Dated 14-01-2025 without validity wherein it has been mention that “may be marketed in the Union” (Apostille)  EU Certificate (FQA) Validity: 26-05-2024 (Notarized)  ISO 13485 Validity: 02-12- 2027 (Notarized)	<b>Multi Pulse PRO 40/60</b>  CO2 Laser Surgery Instrument  Class C  Apply as Family  Shelf Life: <b>5 Year</b>  Codes/Sizes (if any):  <b>Multi Pulse PRO 40/60</b> <b>Multi Pulse PRO DUO</b>	Deferred the product for the following: Separate Application for each product along with fee as system & the required components for each product as per FSC.
<b>183.</b>	Tahir Scientific Supplies, 13, Karachi, Market, Khyber Bazaar, Peshawar  ELI-00334  Date of R&I 25-04-2025  Fee Details: Paid Fee: 62000/- Fee Challan No: 5034271070	Hangzhou Tongzhou Biotechnology Co., Ltd. Room 102, Building No. 4., No. 191 Xintain Road, Yunhe Street, Linping District, Hangzhou People’s Republic of China.  LOA Validity: 28-10-2027 (Notarized)  FSC: Spain: Issue date 16-10-2024 (Apostille)  China issued by China Chamber of Commerce Validity: 07-11-2026 (Apostille)	Hindering Dengue IgG/IgM Rapid test, Dengue NSI Rapid Test, & Dengue IgG/IgM and NSI Cambo Rapid Test  Apply as Cluster  Class-C  Shelf life: 5 Years	Deferred the product for the following: Separate Application for each product along with fee. The shall also valid legalized FSC from concerned regulatory authority.

		ISO Validity: 19-07-2026 (Notarized)  EU QA Certificate Validity: (Notarized)		
184.	<p><b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p><b>Date of R&amp; I</b> 23-04-2025</p> <p><b>Fee:</b> PKR 62,000/- <b>Slip #</b> 556695026 <b>Dated:</b> 08-04-2025</p>	<p><b>Legal Manufacturer:</b> Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France.</p> <p><b>Manufacturing Site:</b> Diagnostic Stago S.A.S ZAC des Chataigniers – 23/29 rue Constantin Pecqueur- 95150 Taverny- <u>France</u>.</p> <p><b>LOA validity:</b> 31-Dec-2025 (copy) Original received separately vide Dy No. 4547 dated 24-02-2025.</p> <p><b>ISO 13485 certificate validity:</b> 23-05-2025 (Copy) Original received separately vide Dy No. 4547 dated 24-02-2025.</p> <p><b>FSC country of origin (France) validity:</b> <b>Date of Issue:</b> 08-02-2024 (Copy) Original received separately vide Dy No. 4547 dated 24-02-2025.</p>	<p><b>SethmO PT M</b></p> <p>12 x 10 mL vials of sthemO PT M (R1) 12 x 10 mL vials of solvent (R2)</p> <p><b>Models/ Specification:</b> <b>01218</b></p> <p>Applied as : Kit</p> <p><b>Class-C</b></p> <p><b>Shelf life:</b> 24 Months</p>	Approved subject to submission of valid ISO 13485.
185.	<p>Miraj Corporation, 13-14, 2nd Floor, Jinnah Business Centre, Chandni Chowk, Murree Road, Rawalpindi - Pakistan.</p> <p>ELI-00326</p> <p><b>Date of R&amp;I</b> 23-04-2025</p> <p><b>Fee Details:</b> Paid Fee: 62030/- Fee Challan No: 46970630250</p>	<p>Chemelex S.A, Pol. Ind. Can Castells - C/ Industria, 113, Nave J. 08420 CANOVELLES (Barcelona), Spain</p> <p>General Distribution Agreement Validity: 31-12-2028 (copy)</p> <p>LOA valid upto 31-12-2027 (copy)</p> <p>FSC: Spain Validity: 15-08-2021 (copy)</p> <p>ISO Validity: 13-05-2021 (copy)</p>	<p>Serology CRP Latex (CRP Latex with controls, CRP Latex only)</p> <p>Serology CRP Latex</p> <p>Applied as : not mentioned</p> <p>Class C</p> <p>Shelf Life: 24 Month</p> <p>Models/ Specification</p>	<p>Deferred for submission of the followings:</p> <p>Deferred for submission of the followings:</p> <p>i. Valid notarized LOA by the product license holder (Legal manufacturer) wherein the applied products shall be mentioned.</p> <p>ii. Valid legalized FSC of the country of origin (Spain) issued by the concerned Regulatory Authority which shall clearly indicate the free</p>

				sale status & applied products along with codes shall be mentioned. iii.valid notarized ISO 13485 certificates. iv. Demanded codes along with FSC evidence.
<b>186.</b>	<p>Miraj Corporation, 13-14, 2nd Floor, Jinnah Business Centre, Chandni Chowk, Murree Road, Rawalpindi - Pakistan.</p> <p>ELI-00326</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 21240423371</p>	<p>Chemelex S.A, Pol. Ind. Can Castells - C/ Industria, 113, Nave J. 08420 CANOVELLES (Barcelona), Spain</p> <p>General Distribution Agreement Validity: 31-12-2028 (copy)</p> <p>LOA valid upto 31-12-2027 (copy)</p> <p>FSC: Spain Validity: 15-08-2021 (copy)</p> <p>ISO Validity: 13-05-2021 (copy)</p>	<p>CK-NAC LQ</p> <p>Serology CRP Latex</p> <p>Class C</p> <p>Shelf Life: 24 Month</p> <p>Applied as : not mentioned</p> <p>Models/ Specification</p>	<p>Deferred for submission of the followings: Deferred for submission of the followings: i. Valid notarized LOA by the product license holder (Legal manufacturer) wherein the applied products shall be mentioned. ii.Valid legalized FSc of the country of origin (Spain) issued by the concerned Regulatory Authority which shall clearly indicate the free sale status &amp; applied products along with codes shall be mentioned. iii.valid notarized ISO 13485 certificates. iv. Demanded codes along with FSC evidence.</p>
<b>187.</b>	<p>Miraj Corporation, 13-14, 2nd Floor, Jinnah Business Centre, Chandni Chowk, Murree Road, Rawalpindi - Pakistan.</p> <p>ELI-00326</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee Details: Paid Fee: 62030/-</p>	<p>Chemelex S.A, Pol. Ind. Can Castells - C/ Industria, 113, Nave J. 08420 CANOVELLES (Barcelona), Spain</p> <p>General Distribution Agreement Validity: 31-12-2028 (copy)</p> <p>LOA valid upto 31-12-2027 (copy)</p> <p>FSC: Spain Validity: 15-08-2021 (copy)</p> <p>ISO Validity: 13-05-2021</p>	<p>RF Latex (RF Latex with controls, RF Latex with only)</p> <p>RF Latex</p> <p>Class C</p> <p>Shelf Life: 24 Month</p> <p>Applied as:</p> <p>Models/ Specification</p>	<p>Deferred for submission of the followings: Deferred for submission of the followings: i. Valid notarized LOA by the product license holder (Legal manufacturer) wherein the applied products shall be mentioned. ii.Valid legalized FSc of the country of origin (Spain) issued by the concerned Regulatory Authority which shall</p>

	Fee Challan No: 03411450624	(copy)		clearly indicate the free sale status & applied products along with codes shall be mentioned. iii.valid notarized ISO 13485 certificates. iv. Demanded codes along with FSC evidence.
188.	<p>Varitron,  First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.</p> <p>ELI-00510</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 60614559 16-04-2025</p>	<p><b>Legal Manufacturer :</b> Varian Medical Systems, Inc</p> <p>Address: 3100, Hansen Way Palo Alto CA 94304 USA.</p> <p><b>CH REP:</b>  Siemens Healthineers Intl. AG.</p> <p>Hinterbergstrasse 14,6312 Steinhausen, Switzerland (CHRN-AR-2000721)</p> <p>Manufacturing Sites:</p> <p>Varian Medical Systems, Inc Address: 911, Hansen Way Palo Alto CA 94304 USA.</p> <p>Varian Medical Systems China</p> <p>Co., Ltd. No.8 Yuncheng Street BDA Beijing, Beijing CHINA 100176</p> <p>Varian Medical Systems Imaging Laboratory GmbH</p> <p>Taefernstrasse 7 Daettwil, Argovia, Aargau SWITZERLAND CH-5405</p> <p>Varian Medical Systems, Inc 3290 Northside Parkway NW Suite 400 Atlanta, GA USA 30327</p> <p>Varian Medical Systems, Inc</p>	<p>Ethos Radiotherapy System</p> <p>Linear Accelerator</p> <p>Class C</p> <p>Shelf Life: N/A</p> <p>Applied as: Single</p> <p>Models/ Specification</p>	<p>Deferred for submission of the followings:</p> <p>i.Differential fee for the product as a system as per new SRO along with required components as per FSC.</p> <p>ii.Valid notarized ISO 13485 of the the applied manufacturing sites.</p> <p>iii. The firm shall clearly submit the demanded manufacturing sites as per FSC.</p>

		<p>6212 Hellyer Ave San Jose, CA USA 95138</p> <p>Varian Medical System Haan GmbH Rheinische Strasse 2 Haan, North Rhine-Westphalia GERMANY 42781</p> <p>Varian Medical Systems, Inc Corredor Tijuana-Rosarito, No 21702 col. El Realito Tijuana, Baja California MEXICO 22250</p> <p>Varian Medical Systems Haan GmbH Manufacturing site Kemnath Building C10 Roentgenstrasse 19-21, Kemnath, Bavaria Germany 95478</p> <p>LOA Validity: 30-06-2027 (copy)</p> <p>FSC: USA Date of Validity: 06-01-2027. (Apostille)</p> <p>FSC: Neterlands Date of Issuance: 15-07-2026 (Apostille)</p> <p>ISO Validity: 10-02-2027 (Notarized) of Mexico site</p> <p>ISO Validity: 10-02-2027 (Notarized) of Germany site</p> <p>ISO Validity: 10-02-2027 (copy) of Legal manufacturer &amp; USA site</p> <p>EU QMS certificate 15-07-2026 (copy)</p>		
189.	<p>Varitron,</p> <p>First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.</p>	<p>Legal Manufacturer:</p> <p>Varian Medical Systems, Inc 3100, Hansen Way Palo Alto CA 94304 USA.</p>	<p>True Beam</p> <p>TrueBeam Radiotherapy Delivery System</p>	<p>Deferred for submission of the followings:</p> <p>i. Differential fee for the product as a system</p>

	<p>ELI-00510</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 1300787541 16-04-2025</p>	<p>Other Manufacturing SITE:</p> <p>EU Representative: Varian Medical Systems Nederland B.V</p> <p>Kokermolen 2 3994 DH Houten, The Netherlands</p> <p>Manufacturing Sites:</p> <p>Varian Medical Systems China Co., Ltd. No.8 Yuncheng Street BDA Beijing, Beijing CHINA 100176</p> <p>Varian Medical Systems Imaging Laboratory GmbH</p> <p>Taefernstrasse 7 Daettwil, Argovia, Aargau SWITZERLAND CH-5405</p> <p>Varian Medical Systems, Inc 3290 Northside Parkway NW Suite 400 Atlanta, GA USA 30327</p> <p><b>Varian Medical Systems, Inc 6212 Hellyer Ave San Jose, CA USA 95138</b></p> <p>Varian Medical System Haan GmbH</p> <p>Rheinische Strasse 2 Haan, North Rhine-Westphalia GERMANY 42781</p> <p><b>Varian Medical Systems, Inc Corredor Tijuana- Rosarito, No 21702 col. El Realito Tijuana, Baja California MEXICO 22250</b></p> <p>Varian Medical Systems Haan GmbH Manufacturing site Kemnath Building C10 Roentgenstrasse 19-21, Kemnath,</p>	<p>Class C</p> <p>Shelf Life: N/A</p> <p>Applied as: Single</p> <p>Models/ Specification: True Beam</p>	<p>as per new SRO along with required components as per FSC.</p> <p>ii. Valid notarized ISO 13485 of the the applied manufacturing sites.</p> <p>iii. The firm shall clearly submit the demanded manufacturing sites as per FSC.</p>
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		<p>Bavaria Germany 95478</p> <p>LOA Validity: 30-06-2027 (copy)</p> <p>FSC: USA Date of Validity: 06-01-2027. (Apostille)</p> <p>FSC: Neterlands Date of Issuance: 15-07-2026 (Apostille)</p> <p>ISO Validity: 10-02-2027 (Notarized) of Mexico site</p> <p>ISO Validity: 10-02-2027 (copy) of Legal manufacturer &amp; USA site</p> <p>EU QMS certificate 15-07-2026 (copy)</p>		
190.	<p>Novatek Pakistan, P-20, 1st Floor, Chenab Market, Susan Road, Madina Town, Faisalabad, Pakistan.</p> <p>ELI-00454</p> <p>Date of R&amp;I 24-04-2025</p> <p>Fee Details: Paid Fee: 31030/- Fee Challan No: 782822404</p>	<p>Labtech Kft. Vag utca 4. 4031, Debrecen, Hungary</p> <p>LOA date of issue: 25-07-2023 valid for two years. (copy) <i>(The claimed in the dossier that the Original, attached with registration application of ETT by Labtech)</i></p> <p>FSC: Hungary. Date of Issuance: 19-03-2020 without validity (copy) <i>(The claimed in the dossier that the Original, attached with registration application of ETT by Labtech)</i></p> <p>ISO Validity: 15-06-2027 (notarized)</p> <p>EC (FQA) certificate 15-06-2023 (Noatrized)</p>	<p>EC ABP Ambulatory Blood Pressure Systems</p> <p>EC-ABP</p> <p>Class C</p> <p>Shelf Life: 3 + 6 Year</p> <p>Applied as: Single</p> <p>Models/ Specification: EC-ABP</p>	<p>Deferred for submission of the followings:</p> <p>i. Differential fee for the product as a system in Class-C as per new SRO along with required components as per FSC.</p> <p>ii. Valid legalized FSc of country of origin</p> <p>iii. Valid legalized FSc of the RRA or valid notarized EC certificate (FQA).</p>
191.	<p>Novatek Pakistan, P-20, 1st Floor, Chenab Market, Susan Road, Madina</p>	<p>Labtech Kft.</p> <p>Address: Vag utca 4. 4031, Debrecen, Hungary</p>	<p><b>EC Type Holter Systems</b></p> <p>EC-2H, EC-3H, EC-12H, EC-3H/ABP</p>	<p>Deferred for submission of the followings:</p> <p>i. Differential fee for</p>

	<p>Town, Faisalabad, Pakistan.</p> <p>ELI-00454</p> <p>Date of R&amp;I 24-04-2025</p> <p>Fee Details: Paid Fee: 31030/- Fee Challan No: 45138925393</p>	<p>LOA date of issue: 25-07-2023 valid for two years. (copy) (The claimed in the dossier that the Original, attached with registration application of ETT by Labtech)</p> <p>FSC: Hungary. Date of Issuance: 19-03-2020 without validity (copy) (The claimed in the dossier that the Original, attached with registration application of ETT by Labtech)</p> <p>ISO Validity: 15-06-2027 (notarized)</p> <p>EC (FQA) certificate 15-06-2023 (Noatrized)</p>	<p>Class C</p> <p>Shelf Life: 3 + 6 Year</p> <p>Applied as: Single</p> <p>Models/ Specification: EC-2H, EC-3H, EC-12H, EC-3H/ABP</p>	<p>the product as a system in Class-C as per new SRO along with required components as per FSC.</p> <p>ii. Valid legalized FSc of country of origin</p> <p>iii. Valid legalized FSc of the RRA or valid notarized EC certificate (FQA).</p> <p>iv. The firm shall justify that products are family as per MDR 2017 &amp; are registered as family in the country of origin along documented evidence.</p>
192.	<p>Aston Medical Pakistan 4-A 4th Floor 38c Bukhari Commercial, Lane 8, Phase 6, Dha, Karachi</p> <p>(ELI-00797)</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 135864189</p>	<p>Semikal Teknoloji Sanayi VE Ticaret Anonim Sirketi, AOSB 3, Kisim 25, Cad. No: 14/11, Dosemealti, Antalya/Turkiye</p> <p>LOA Validity: 25-03-2033 (notarized)</p> <p>FSC Valid till: 30-01-2028 (notarized)</p> <p>ISO Validity: 17-03-2026 (notarized)</p> <p>EC (FQA) certificate 27-05-2024 (notarized)</p> <p>Design Examination Certificate valid up to 27-05-2024 (notarized)</p>	<p>Sectalon Intra-Articular Gel</p> <p>Sodium Hyaluronate 30mg/2ml, Sodium Hyaluronate 40mg/2ml, Sodium Hyaluronate 60mg/2.5ml, Sodium Hyaluronate 75mg/3ml, Sodium Hyaluronate 90mg/3ml, Sodium Hyaluronate Cross Linked % 2.4/2.5ml, Sodium Hyaluronate Cross Linked % 2.5/3ml, Sodium Hyaluronate Cross Linked % 3/3.0ml</p> <p>Class C</p> <p>Shelf Life: 5 years Applied as: Single</p> <p>Models/ Specification;</p>	<p>Deferred for submission of the followings:</p> <p>Deferred for submission of the followings:</p> <p>i. Revised Form-7A duly signed with correct classification of the applied.</p> <p>ii. Valid legalized FSc of the RRA or valid notarized EC certificate (FQA) wherein applied product shall be mentioned in the scope.</p> <p>iii. Valid notarized Designed Examination certificate.</p> <p>iv. The firm shall submit differential fee as per new SRO as family.</p> <p>v. Complete Stability Study Data</p>

			as above	
<b>193.</b>	<p>Medical Equipment &amp; Systems,</p> <p>60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan.</p> <p>ELI-00554</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: - Fee Challan No:</p>	<p>APELEM SAS 9 Avenue du canal Philippe Lamour - 30660 - Gallargues-le-Montueux-France.</p> <p>LOA Validity: 04-05-2027 (copy)</p> <p>FSC: France Validity: 20-03-2023 without validity (copy)</p> <p>ISO Validity: 13-05-2021 (copy)</p> <p>EC (FQA) certificate valid upto 04-05-2023 (copy)</p>	<p><b>OPTIMA dRF</b> Digital Remote controlled radiology system</p> <p>Class C</p> <p>Shelf Life: N/A</p> <p>Applied as: System</p> <p>Models/ Specification: List of standard accessories Footrest • Tabletop handle supports • Fluoroscopy pedal</p>	<p>Deferred for submission of the followings: Deferred for submission of the followings: i. Valid notarized LOA wherein the applied products shall be mentioned. ii. Valid legalized FSc of the country of origin (France). iii. valid notarized ISO 13485 certificates. iv. The firm shall submit evidence of submission fee as per new SRO for system &amp; justification along with evidence that the applied product is system in the country of origin.</p>
<b>194.</b>	<p>Medical Equipment &amp; Systems,</p> <p>60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan.</p> <p>ELI-00554</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: - Fee Challan No:</p>	<p>APELEM SAS 9 Avenue du canal Philippe Lamour - 30660 - Gallargues-le-Montueux-France.</p> <p>LOA Validity: 04-05-2027 (copy)</p> <p>FSC: France Validity: 20-03-2023 without validity (copy)</p> <p>ISO Validity: 13-05-2021 (copy)</p> <p>EC (FQA) certificate valid upto 04-05-2023 (copy)</p>	<p><b>PLATINUM dRF</b> (Platinum NEO)</p> <p>Digital Remote Controlled radiology system</p> <p>Class C</p> <p>Shelf Life: 10 years</p> <p>Applied as: System</p> <p>Models/ Specification: List of standard accessories Footrest • Tabletop handle supports • Fluoroscopy pedal</p>	<p>Deferred for submission of the followings: Deferred for submission of the followings: i. Valid notarized LOA wherein the applied products shall be mentioned. ii. Valid legalized FSc of the country of origin (France). iii. valid notarized ISO 13485 certificates. iv. The firm shall submit evidence of submission fee as per new SRO for system &amp; justification along with evidence that the applied product is system in the country of origin.</p>
<b>195.</b>	<p>Royal Medical, Office No. 26th, 3rd</p>	<p>Shenzhen Antmed Co., Ltd., 18 Jinhul Ave., Pingshan New</p>	<p>Antmed Disposable Pressure Transducer</p>	<p>Deferred for submission of the</p>

	<p>Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi</p> <p>(ELI-00691)</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 27370964</p>	<p>District, Shenzhen 518122, China</p> <p>Other Manufacturing Site: No. 3 Hualian Ave, Songshanhu District 523800 Dongguan</p> <p>LOA Validity: 16-02-2030 (Notarized)</p> <p>FSC (china) Valid till: 26-10-2025 (Apostille)</p> <p>ISO Validity: 30-10-2026 (Notarized)</p> <p>EU QMS certificate 05-02-2029 (Notarized)</p>	<p>Class C</p> <p>Shelf Life: 5 years</p> <p>Applied as: Single</p> <p>Models/ Specification: PT-01, PT-012, PT-013, PT-02, PT-022, PT-023, PT-03, PT-032, PT-033,</p>	<p>followings: Deferred for submission of the followings:</p> <p>i. Valid legalized FSC of the RRA or notarized copy of EC certificate (FQA) wherein applied product shall be mentioned in the scope.</p> <p>ii. Clarification regarding the 2<sup>nd</sup> manufacturing site &amp; evidence of the site in FSC.</p>
<b>196.</b>	<p>Applicant Name:</p> <p>Moody Global Services, No. 14, 2<sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad</p> <p>(ELI-00926)</p> <p>Date of R&amp;I 18-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 6718927514</p>	<p>Name of Manufacturer:</p> <p>Sansure Biotech Inc. No. 680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province, Peoples Republic of China</p> <p>LOA Validity: 20-08-2029 (Copy)</p> <p>FSC: China Validity: 20-11-2026 (Original Notarized)</p> <p>ISO Validity: 22-11-2025 (Copy)</p> <p>EU FQA Certificate Validity: 26-05-2025 (Original Notarized)</p> <p>EU Design Examination Certificate(2934 warszau wa) Validity: 26-05-2025 (Original Notarized)</p>	<p>Brand name:</p> <p>Sansure Biotech</p> <p>Generic Name: Human Immunodeficiency Virus Type 1 RNA Quantitative Fluorescence</p> <p>Class-D</p> <p>Shelf life: 12 months</p> <p>Applied as: Kit</p> <p>Models/ Specification S3046E-48</p>	<p>Deferred for submission of the following documents: Apostile/ legalized FSC form the regulatory authority of country of origin mentioning the Free sale of the product. Since the free sale status of the product not mentioned in the submitted FSC. Provide link of the Nando data base from the European commission regarding the notified body who has issued the Design examination certificate</p>
<b>197.</b>	<p>Applicant Name:</p> <p>FM Health Care, 203 Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat</p>	<p>Name of Manufacturer:</p> <p>Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province.</p>	<p>Brand name:</p> <p>X-Med Haemodialysis Catheter Kit</p> <p>Generic Name:</p>	<p>Deferred for submission of the following documents: Notarized and valid design examination certificate, certificate.</p>

	<p>Road Karachi (ELI-00082)</p> <p>Date of R&amp;I 21-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 92246227821</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 221430273</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 3314846377</p>	<p>P.R. China</p> <p>LOA Validity: 13-03-2030(Copy)</p> <p>FSC: China Validity: 10-02-2027 (Notarized)</p> <p>ISO Validity: 12-03-2026 (Copy)</p> <p>EU QA Certificate : not given</p> <p>extension letter provided</p>	<p>Haemodialysis Catheter Kit Single Lumen</p> <p>Haemodialysis Catheter Kit Second Lumen</p> <p>Haemodialysis Catheter Kit Triple Lumen</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: System</p> <p>Models/ Specification As per FSC</p>	<p>Submit Apostile/ Legalized FSC in the country of origin the submitted is not Apostilled/ legalized.</p> <p>Clarify the relation of the two companeiswho has granted LOA and whose name are also mentioned on the label</p>
198.	<p>Applicant Name:</p> <p>FM Health Care, 203 Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road Karachi (ELI-00082)</p> <p>Date of R&amp;I 21-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 79982204</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 49935561085</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 119044311535</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 5032253137</p>	<p>Name of Manufacturer:</p> <p>Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province. P.R. China</p> <p>LOA Validity: 13-03-2030(Original Notarized)</p> <p>FSC: China Validity: 16-07-2026 (Original Notarized)</p> <p>ISO Validity: 12-03-2026 (Original Notarized)</p> <p>EU QA Certificate : not given</p> <p>extension letter provided</p>	<p>Brand name:</p> <p>X-Med Central Venous Catheter Kit</p> <p>Generic Name: X-Med Central Venous Catheter Kit Single Lumen</p> <p>X-Med Central Venous Catheter Kit Double Lumen</p> <p>X-Med Central Venous Catheter Kit Triple Lumen</p> <p>X-Med Central Venous Catheter Kit Quad Lumen</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: Single</p> <p>Models/ Specification</p>	<p>Deferred for submission of the following documents: Notarized and valid design examination certificate, certificate.</p> <p>Submit Apostile/ Legalized FSC in the country of origin the submitted is not Apostilled/ legalized.</p> <p>Clarify the relation of the two companeiswho has granted LOA and whose name are also mentioned on the label</p>

<b>199.</b>	<p><b>Applicant Name:</b></p> <p>Johnson &amp; Johnson Pakistan (Pvt) Ltd., Office No. 506, 5<sup>th</sup> Floor, Horizon Tower, Block 3, Scheme 5, Clifton Karachi</p> <p>(ELI-00154)</p> <p><b>Date of R&amp;I</b> 23-04-2025</p> <p><b>Fee Details:</b> Paid Fee: 62,000/- Fee Challan No: 914920945832</p>	<p><b>Name of Manufacturer:</b></p> <p>Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA</p> <p><b>Physical Manufacturer:</b> Circuito Interior Norte, No. 1820 Parque Industrial Salvarcare Juarez, Chihuahua Mexico 32574</p> <p><b>LOA Validity:</b> 25-11-2034(Copy)</p> <p><b>FSC: USA</b> Validity: 21-10-2026 (Copy)</p> <p><b>ISO Validity:</b> 01-10-2027 (Copy)</p> <p><b>EU QA Certificate</b> Validity: 16-05-2029 (Copy)</p> <p><b>EU technical doc</b> Validity 8.11.2027</p>	<p><b>Brand name:</b></p> <p>Optrell Mapping Catheter with TruEref Technology</p> <p><b>Generic Name:</b> Optrell Mapping Catheter with TruEref Technology D142901 D142902</p> <p><b>Class-D</b></p> <p><b>Shelf life: 3 Years</b></p> <p><b>Applied as: Set</b></p> <p><b>Models/ Specification</b></p>	<p>Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents including Valid LOA. ISO 13485, EU QA Certificate and design Examination certificate ate</p>
<b>200.</b>	<p><b>Applicant Name:</b></p> <p>Johnson &amp; Johnson Pakistan (Pvt) Ltd., Office No. 506, 5<sup>th</sup> Floor, Horizon Tower, Block 3, Scheme 5, Clifton Karachi</p> <p>(ELI-00154)</p> <p><b>Date of R&amp;I</b> 23-04-2025</p> <p><b>Fee Details:</b> Paid Fee: 62,000/- Fee Challan No: 049133449</p>	<p><b>Name of Manufacturer:</b></p> <p>Deputy Ireland UC, Loughbeg, Ringaskiddy, Co, Cork, Ireland</p> <p><b>Physical Manufacturer:</b> Johnson &amp; Johnson Med-ical (Suzhou) No. 299, Changyang Street, Suzhou Indus-trial Park, Suzhou, 215126, China</p> <p><b>LOA Issue date:</b> 19-01-2023(Copy)</p> <p><b>FSC: Ireland</b> Issue date: 30-06-2023(Copy)</p> <p><b>ISO Validity:</b> 15-07-2027 (Copy)</p> <p><b>EU QA Certificate</b> Validity: 10-06-2025 (Copy)</p> <p><b>EU technical doc</b> Validity 8.11.2027</p>	<p><b>Brand name:</b></p> <p>Smart Oval Dome Patella</p> <p><b>Generic Name:</b> Sigma Oval Dome Patella</p> <p><b>Class-D</b></p> <p><b>Shelf life: 5 Years</b></p> <p><b>Applied as: System</b></p> <p><b>Models/ Specification</b> 960100 960101 960102 960103</p>	<p>Deferred for submission of the differential fee of RS 38000/-and clarify the name applied and in the FSC Name in the FSC is Sigma Oval Dome Ptella 3- Peg Cemented Also submit valid and notarized documentsalso submit apostilled FSC.</p>

<b>201.</b>	<p><b>Applicant Name:</b></p> <p>Johnson &amp; Johnson Pakistan (Pvt) Ltd., Office No. 506, 5<sup>th</sup> Floor, Horizon Tower, Block 3, Scheme 5, Clifton Karachi</p> <p>(ELI-00154)</p> <p><b>Date of R&amp;I</b> 23-04-2025</p> <p><b>Fee Details:</b> Paid Fee: 62,000/- Fee Challan No: 849950997620</p>	<p><b>Name of Manufacturer:</b></p> <p>Deputy Ireland UC, Loughbeg, Ringaskiddy, Co, Cork, Ireland</p> <p><b>LOA Issue date:</b> 19-01-2023(Copy)</p> <p><b>FSC:</b> Ireland <b>Issue date:</b> 30-06-2023(Copy)</p> <p><b>ISO Validity:</b> 15-07-2027 (Copy)</p> <p><b>EU QA Certificate</b> <b>Validity:</b> 10-06-2025 (Copy)</p> <p><b>EU tec doc Certificate</b> <b>Validity:</b> 08.11.2027 (Copy)</p>	<p><b>Brand name:</b></p> <p>PFC Sigma Tibial Insert Rotating Platform Stabilized</p> <p><b>Generic Name:</b> PFC Sigma Tibial Insert Rotating Platform Stabilized</p> <p><b>Codes as per FSC</b> Class-D</p> <p><b>Shelf life:</b> 5 Years</p> <p><b>Applied as:</b> System</p> <p><b>Models/ Specification</b></p>	<p>Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents including Valid LOA . ISO 13485, EU QA Certificate and design Examination certificate ate</p>
<b>202.</b>	<p><b>Applicant Name:</b></p> <p>Ferozsos Laboratories Limited, P.O. Ferozsos Amangarh, Nowshera (KPKP)</p> <p>(ELI-00120)</p> <p><b>Date of R&amp;I</b> 18-04-2025</p> <p><b>Fee Details:</b> Paid Fee: 62,000/- Fee Challan No: 22661968775</p>	<p><b>Name of Manufacturer:</b></p> <p>CenterPoint Systems, LLC 3338 Parkway Blvd West Valley City UT 84119 USA</p> <p><b>Manufacturing Site:</b> CenterPoint Systems, LLC 3338 Parkway Blvd West Valley City UT 84119 USA</p> <p><b>LOA exp date:</b> 31-12-2025(Copy)</p> <p><b>FSC:</b> USA <b>Expiry date:</b> 09-08-2025(Original Notarized)</p> <p><b>ISO Validity:</b> 28-12-2024 (Notarized)</p> <p><b>EU QA Certificate</b> <b>Validity:</b> 26-05-2024(Notarized)</p>	<p><b>Brand name:</b></p> <p>Site Selective Pacing Catheters</p> <p><b>Generic Name:</b> Intravascular Guiding Catheters</p> <p><b>Class-D</b></p> <p><b>Shelf life:</b> 24 months</p> <p><b>Applied as:</b> System</p> <p><b>Models/ Specification</b></p>	<p>Deffered for clarification of the applied brand name and name in the FSC. Models/codes</p>
<b>203.</b>	<p><b>Applicant Name:</b></p> <p>Opal Enterprises, Office No. 28, 5<sup>th</sup> Floor, Gold Mine Plaza Near Ichhra Police Station,</p>	<p><b>Name of Manufacturer:</b></p> <p>Rivomed Medical GmbH, Rivomed Platz 1 78434, Tuttlingen, Germany.</p>	<p><b>Brand name:</b></p> <p>Rivomed</p> <p><b>Generic Name:</b> Temporary Pacemaker Lead</p>	<p>Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents</p>

	<p>Ferozepur Road, Lahore</p> <p>(ELI-01397)</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 211839692972</p>	<p>LOA Issue date: 31-12-2025(Copy)</p> <p>FSC: Germany Validity: 09-08-2025 (Copy )</p> <p>ISO Validity: 28-12-2024 (Copy )</p> <p>EU QA Certificate Validity: 26-05-2024(Copy )</p> <p>Design examination copy valid till 11.12.2026</p>	<p>Class-D</p> <p>Shelf life: 2 Years</p> <p>Applied as: Single</p> <p>Models/ Specification</p>	<p>including Valid LOA . ISO 13485, EU QA Certificate and design Examination certificate ate</p>
<b>204.</b>	<p>Applicant Name:</p> <p>Best Way Enterprises, Flat No. 314, 3<sup>rd</sup> Floor, Empress Tower, 46 Empress Road, Lahore</p> <p>(ELI-01270)</p> <p>Date of R&amp;I 28-03-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 510310181881</p>	<p>Name of Manufacturer:</p> <p>HuaianPingan Medical Instrument Co.Ltd., No. 128 West Meigao Road, Huaian Jiangsu China</p> <p>LOA Issue date: 20-01-2025(Copy)</p> <p>FSC: China Validity: 15-01-2026 (Original Notarized)</p> <p>FSC : Spain Issue date: 02-08-2024 (copy)</p> <p>ISO Validity: 26-04-2027 (Copy)</p> <p>EU QA Certificate Validity: 13-05-2024 (Copy)</p>	<p>Brand name:</p> <p>Bestsilk</p> <p>Generic Name: Sterile Non-Absorbable Silk Braided Sutures</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: Family</p> <p>Models/ Specification</p>	<p>Approved</p>
<b>205.</b>	<p>Applicant Name:</p> <p>Best Way Enterprises, Flat No. 314, 3<sup>rd</sup> Floor, Empress Tower, 46 Empress Road, Lahore</p> <p>(ELI-01270)</p> <p>Date of R&amp;I 28-03-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p>	<p>Name of Manufacturer:</p> <p>HuaianPingan Medical Instrument Co.Ltd., No. 128 West Meigao Road, Huaian Jiangsu China</p> <p>LOA Issue date: 20-01-2025(Copy)</p> <p>FSC: China Validity: 15-01-2026 (Original Notarized)</p> <p>FSC : Spain Issue date: 02-08-2024 (apostle)</p>	<p>Brand name:</p> <p>Bestrolin</p> <p>Generic Name: Sterile Non-Absorbable Polypropylene Monofilament Sutures</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: Family</p> <p>Models/ Specification</p>	<p>Deffered for clarification of the brand name as per FSC and applied name Name In Spain FSC is Sterile, Non- absorbable Sutures, Brand: PALENE, Polypropylene monofilament (PM)</p>



	Fee Challan No: 8547015756	ISO Validity: 26-04-2027 (notarised)  EU fQA Certificate Validity: 13-05-2024 (notarised) EU Design examin Certificate Validity: 13-05-2024 (Notarized )		
<b>206.</b>	<p>Applicant Name:</p> <p>Best Way Enterprises, Flat No. 314, 3<sup>rd</sup> Floor, Empress Tower, 46 Empress Road, Lahore</p> <p>(ELI-01270)</p> <p>Date of R&amp;I 28-03-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 8547015756</p>	<p>Name of Manufacturer:</p> <p>HuaianPingan Medical Instrument Co.Ltd., No. 128 West Meigao Road, Huaian Jiangsu China</p> <p>LOA Issue date: 20-01-2025(Original Notarized)</p> <p>FSC: China Validity: 15-01-2026 (Original Notarized)</p> <p>FSC : Spain Issue date: 02-08-2024 (Original Notarized.)</p> <p>ISO Validity: 26-04-2027 (Original Notarized)</p> <p>EU QA Certificate Validity: 13-05-2024 Original Notarized)</p> <p>EU Design examin Certificate Validity: 13-05-2024 (Notarized )</p>	<p>Brand name:</p> <p>Bestcryn</p> <p>Generic Name: Sterile Absorbable Polyglycolic Acid Sutures</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: Family</p> <p>Models/ Specification</p>	Approved
<b>207.</b>	<p>M/s EV Solutions (Private) Limited, Apartment # 307, 3<sup>rd</sup> Floor, Gulberg Empire, Civic Center, Gulberg Greens, Islamabad.</p> <p>ELI-01382</p> <p>R&amp; I dated 26-03- 2025</p> <p><b>Fee details:</b></p>	<p>M/S Jiangsu Guanchuang Medical Technology Co., Ltd. 2D, Wujin Science &amp; Technology Park No 256, Mingxin Middle Road, Hutang, Changzhou, Jiangsu Peoples Republic of China.</p> <p><b>Free Sale Certificate valid upto 17/02/2026 issued by Peoples Republic of China (</b> <b>apostille )</b></p> <p><b>ISO 13485 valid up to</b></p>	<p>Disposable Trocar for Laparoscope</p> <p>Class-D</p> <p>Shelf life: Storage Conditions: 36 Months (Room temperature)</p>	Deffered for submission of clarification of the class. Provide notarized CE certificate as per relevant class

	Amount paid: PKR 62,000 /- Paid Slip/ challan No. 716429844983: Dated: (24/03/2025)	15/03/2027.(Notarized )  <b>Letter of authorization valid upto 13/01/2028 ( Notarized)</b>		
<b>208.</b>	M/s EV Solutions (Private) Limited, Apartment # 307, 3 <sup>rd</sup> Floor, Gulberg Empire, Civic Center, Gulberg Greens, Islamabad.  ELI-01382  R& I dated 28-03-2025  Fee details: Amount paid: PKR 62,000 /- Paid Slip/ challan No. 1515188633: Dated: (24/03/2025)	M/S Jiangsu Guanchuang Medical Technology Co., Ltd. 2D, Wujin Science & Technology Park No 256, Mingxin Middle Road, Hutang, Changzhou, Jiangsu Peoples Republic of China.  Free Sale Certificate valid upto 17/02/2026 issued by  ISO 13485 valid up to 15/03/2027. Copy  Letter of authorization valid up to 13/01/2028 copy	Disposable Endoscopic Cutting Stapler And Reload.  Class-D  Shelf life: Storage Conditions: 36 Months (Room temperature)	Deffered for submission of clarification of the class. Provide notarized CE certificate as per relevant class
<b>209.</b>	M/s Global Marketing Services (ELI- 00109)  R&I 3.13.2020	<b>Legal Manufacturer</b> BioMerieux, Inc. 100 Rodolphe Street Durham, NC 27712 USA  <b>Manufacturing Site:</b> BioMerieux, Inc., 595 Anglum Rd Hazelwood, Missouri 63042 – USA  Copy FSC 02.07.2024 issue date  <b>Copy ISO 13485:2016</b> valid til 17.12.2027  <b>Copy LOA valid till 31.03.2026</b>	<b>Brand Name</b> BacT/ALERT Virtuo Microbial Detection System  <b>Generic Name:</b> Blood culture analyzer IVD, and firmware software  <b>Class: A</b>  <b>Shelf life: N/A</b>  <b>Codes as per FSC:</b> 411660, 411661, 423376, 423378, 423559, 424306	Approved.
<b>210.</b>	Applicant Name:  Hoora Pharma (Pvt.) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi	Name of Manufacturer:  Legal Manufacturer: Cordis US Corp. 14201 North West 60 <sup>th</sup> Avenue Miami Lakes, FL 33014, USA	Brand name:  Brite TIP Catheter Sheath Introducer  Avanti+ Catheter	Deferred for submission of the clarify the the applied name and name in the FSC. also justify the family under the MDR 2017.

	<p>(ELI-01270)</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 69819159155</p>	<p>Manufacturing Site: Cardinal Health Mexico 244 S. De RL De CV Santiago Troncoso # 808 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua C.P. 32574 Mexico</p> <p>LOA Issue date: 13-01-2025(Original Notarized)</p> <p>FSC: USA Validity: 21-01-2027(Original Notarized)</p> <p>ISO Validity: 07-02-2028 (Original Notarized)</p> <p>EU QA Certificate Validity: 05-04-2027 Original Notarized)</p> <p>EU TECHNICAL DOCUMENTATION ASSESSMENT Certificate Validity: 01-10-2029 Original Notarized)</p>	<p>Sheath Introducer</p> <p>Vessel Dilators</p> <p>Generic Name: Cardio Vascular Introducing Sheath Valved</p> <p>Arterial Introduction Sheath</p> <p>Class-D</p> <p>Shelf life: 2 Years</p> <p>Applied as: Set</p> <p>Models/ Specification Brite TIP Catheter Sheath Introducer Avanti+ Catheter Sheath Introducer: Co502</p> <p>Vessel dilator CO504</p>	<p>Clarify the name of the LOA issuance company which is Cordis Medical Holding unlimited Company Cahir road cashal tipperary E25 RC92 Ireland since it is different than the name of the manufacturer</p>
<b>211.</b>	<p>Applicant Name:</p> <p>Digital Imaging Systems, Habitat Apartments Shadman II, Ghaus-ul-Azam Road, Lahore</p> <p>(ELI-00094)</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 73259505</p>	<p>Name of Manufacturer:</p> <p>Legal Manufacturer: Abbott Vascular 3200 Lakeside Drive Santa Clara, California, USA</p> <p>Manufacturing Site: Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol, Alajuela Costa Rica, 20102</p> <p>Abbott Vascular Clashel Road, Clonmol, Tipperary Ireland</p> <p>LOA Issue date: 6.02.2025. validtill 31-03-2025(Original Notarized)</p> <p>FSC: USA Validity: 23-01-</p>	<p>Brand name:</p> <p>NC Trek NEO Coronary Dilatation Catheter</p> <p>Generic Name: Coronary Dilatation Catheter</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Applied as: Set</p> <p>Models/ Specification 1400150-06</p> <p>1400150-08</p> <p>1400150-12</p>	<p>Deferred for submission of valid and notarized LOA since the submitted LOA as expired before submission of the application.</p>

		2027(Apostilled )	1400150-15	
		ISO Validity: 07-01-2027(Original Notarized)	1400150-20	
		EU QA Certificate Validity: 27-08-2028 Original Notarized)	1400200-06	
		EU technical doc Certificate Validity: 27-08-2028 Original Notarized)	1400200-08	
			1400200-12	
			1400200-15	
			1400200-20	
			1400225-06	
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			1400375-08	
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			1400500-12 1400500-15 1400500-20 1400550-12 1400550-15 1400550-20 1400600-12 1400600-15 1400600-20	
<b>212.</b>	<p>Applicant Name:</p> <p>Health Tec, H. No. 10-B, Valley Road, St: 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi</p> <p>(ELI-00046)</p> <p>Date of R&amp;I 22-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 01034147086</p>	<p>Name of Manufacturer:</p> <p>SCW Medicath Ltd., No. 4 Baolong 6<sup>th</sup> Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116 Guangdong, P.R.China.</p> <p>LOA Issue date: 31-03-2025(Original Notarized)</p> <p>FSC: USA Validity: 14-10-2026 (Original Notarized)</p> <p>ISO Validity: 26-01-2026(Original Notarized)</p> <p>EU QA Certificate Validity: 26-09-2029 (Original Notarized)</p>	<p>Brand name:</p> <p>Guiding Catheter</p> <p>Generic Name:</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Applied as:</p> <p>Models/ Specification GC-6F-100-JL4.0 GC-6F-100-JR4.0 GC-6F-100-AL0.75 GC-6F-100-AL1.0 GC-6F-100-AL1.5 GC-6F-100-AL2.0 GC-6F-100-EBU3.5 GC-6F-100-XB3.5 GC-6F-100-SAL0.75 GC-6F-100-SAL1.0 GC-6F-100-SAL1.5 GC-6F-100-IL GC-6F-100-IR GC-6F-100-TIG</p>	Approved in class C.
<b>213.</b>	<p>Endoaid Biomedica,</p> <p>85-D, DHA EME Sector, Phase XII, Multan Road, Lahore.</p>	<p>Name of Manufacturer:</p> <p>Suzhou Laishi Transfusion Equipment Co. LTd., Chansheng Road, Tongli Town, Wujiang District,</p>	<p>Pricks</p> <p>Disposable Plastic Blood Bags</p>	Deferred for submission of the notarized FQA and Design examination certificate.

	<p>ELI-00169</p> <p>Date of R&amp;I 04-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 441381522818</p>	<p>Suzhou City, 215217 Jiangsu Province, P.R. China</p> <p>LOA VALIDITY date: 24-12-2027(Original Notarized)</p> <p>FSC: China Validity: 22-10-2025(APOSTILLED)</p> <p>ISO Validity: 11-08-2026(Original Notarized)</p> <p>EU QA Certificate Validity: ( Notarized)</p>	<p>ith CPDA anticoagulant</p> <p>Each 100ml CPDA-1 USP contains:</p> <p>Citiric Acid(Anhyddrous) 0.299g</p> <p>Sodium citrate(dehydrate) 2.63g</p> <p>Monobasic Sodium Phosphate(onohydrate) 0.222 g</p> <p>Dextrose(monohydrate)</p> <p>Adenine 0.0275 g Class-D</p> <p>Shelf life: 36 months</p> <p>Applied as:</p> <p>Models/ Specification</p> <p>As per FSC.</p>	
<b>214.</b>	<p>Applicant Name:</p> <p>Shams Scientific Traders, 22-Y-J Madina Town Faisalabad (ELI-00459)</p> <p>Date of R&amp;I 29-04-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 2605185872</p> <p>Submitted date 29.4.2025</p>	<p>Name of Manufacturer:</p> <p>Rapid Labs Ltd., Unit 2, Hall Farm Church Road, Little Bentley Colchester, Essex, CO7 8SD, United Kingdom</p> <p>LOA Validity: 13-03-2030 (Original Notarized)</p> <p>FSC: UK Validity: 27-05-2026 (Apostilled )</p> <p>ISO Validity: 15-10-2027 (Original Notarized)</p> <p>EU QA Certificate Validity: 27-05-2025 (Original Notarized)</p> <p>EU Design examination</p>	<p>Brand name:</p> <p>Rapid Biotec</p> <p>Generic Name: Blood Grouping Reagents</p> <p>Class-D</p> <p>Shelf life: 30 months</p> <p>Applied as Family</p> <p>Models/ Specification; 1) BG-A10 Anti-A Monoclonal Reagent, 10ml/vial, 1 vials/pack or 10 vials/Pack</p> <p>2) BG-B10 Anti-B Monoclonal Reagent,</p>	<p>Deferred for submission of the following .</p> <p>Brand name clarification as per FSC and applied name in Form7A is required along with justification of the cluster under the MDR 2017.</p> <p>Also clarify/ submit the complete stability studies of the applied reagent.</p>

		Certificate Validity: 27-05-2025 (Original Notarized)	10ml/vial, 1 vials/pack or 10 vials/Pack  3) BG-D10 Anti-D Monoclonal Reagent, 10ml/vial, 1. vials/pack or 10 vials/Pack  4) BG-AB10 Anti-A,B Monoclonal Reagent, 10ml/vial, 1 vials/pack or 10 vials/Pack  5) RAPID Biotec Blood Grouping Set 3 vials: Anti-A, Anti-B & Anti- D, 10ml/vial, 3 vials/pack	
215.	M/s Snibe Diagnostic Pakistan (SMC- Private) Limited, Office No. A107, 1 <sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi  ELI-01036  <b>Date of R&amp; I</b> 30.04.2025  <b>Fee:</b> Rs.`62000/ through slip no. 510750113	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.) NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China  <b>LOA:</b> Valid till: 03-12-2029 (Copy)  <b>FSC:</b> Validity Date: 03-08-2025 (Copy) Reference Country FSC Issue Date: 30-01-2025 (Copy)  ISO - Validity Date: 31-12-2025 (Copy)  EC Certificate Valid till: 14- 12-2025 (Copy)	Brand Name:  MAGLUMI  Generic: Toxo IgM (CLIA) and Toxo IgM (CLIA) controls  Applied as: Kit  Class C  Shelf Life : 18 months  Code/sizes: Toxo IgM (CLIA): 100 tests/kit, 50 Tests/kit, 30 Test/kit  Toxo IgM (CLIA) Controls Negative Controls: 1x1.0ml Positive Control: 1x1.0ml	Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents including Valid LOA . ISO 13485, EU QA Certificate along with clarification of the class of the Medical device.  Also clarify the name applied and name in the FSC it shall be similar.
216.	M/s Snibe Diagnostic Pakistan (SMC- Private) Limited, Office No. A107, 1 <sup>st</sup> Floor, Fortune Towers, PECHS,	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.) NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China	Brand Name:  MAGLUMI  Generic: Total PSA (CLIA) and	Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other



	<p>Shahra-e-Faisal, Karachi</p> <p>ELI-01036</p> <p><b>Date of R&amp; I</b> 30.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 8969203595</p>	<p><b>LOA:</b> Valid till: 03-12-2029 (Copy)</p> <p><b>FSC:</b> Validity Date: 03-08-2025 (Copy) Reference Country FSC Issue Date: 30-01-2025 (Copy)</p> <p>ISO - Validity Date: 31-12-2025 (Copy)</p> <p>EC Certificate Valid till: 14- 12-2025 (Copy)</p>	<p>Total PSA (CLIA) controls</p> <p>Applied as: Kit</p> <p>Class C</p> <p>Shelf Life : 24 months</p> <p>Code/sizes: Total PSA (CLIA): 100 tests/kit, 50 Tests/kit, 30 Test/kit</p> <p>Total PSA (CLIA) Controls Negative Controls: 1x1.0ml Positive Control: 1x1.0ml</p>	<p>notarized documents including Valid LOA . ISO 13485, EU QA Certificate along with clarification of the class of the Medical device.</p> <p>Also clarify the name applied and name in the FSC it shall be similar.</p>
217.	<p>M/s Ear Technic Pvt. Ltd., Office No. 03, 2<sup>nd</sup> Floor, G.8 Square Plaza, G.8 Markaz Islamabad</p> <p>ELI-00956</p> <p><b>Date of R&amp; I</b> 25.04.2025</p> <p><b>Fee:</b> Rs.`62000/ through slip no. 241458572445</p>	<p>Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic A.s. Universiteler mah. 1596 Cad. Safir Blokkan E Blok Ofis No. 02/03 Zemin Kat Kapi No. 6 Beytepe – Cankaya – Ankara Turkiye.</p> <p><b>LOA:</b> Valid till: 10-03-2026 (Copy)</p> <p><b>FSC: Turkiye issue date</b> <b>25.01.2024.</b> Validity Date: 24-01- 2027(Copy)</p> <p>ISO - Validity Date: 21-10-2027 (Copy)</p> <p>EC Certificate Valid till:</p>	<p>Brand Name:</p> <p>Desu Medical Shunt Valves and Catheters with accessories</p> <p>Generic: Total PSA (CLIA) and Total PSA (CLIA) controls</p> <p>Applied as: Kit</p> <p>Class D</p> <p>Shelf Life :</p> <p>Code/sizes:</p>	<p>Deferred for submission of the following Fee of Rs 62000/- the submitted slip is not paid.</p> <p>Justify the family of the application as per MDR 2017. Submit complete and apostilled and valid FSC and notarized Design examination of the applied product. Since name/ code of the applied product not clear in design examination. Also clarify the Stability studies and claim shelf life</p>
218.	<p>National Enterprises, Office No. 409, 4th Floor, Al-Sehat Center, Shahra-e- Faisal/Rafiquee Shaheed Rd. Karachi</p>	<p>HP-Bioprotoses Ltda. Rua Maria Jose Rangel, 83 - Vila Sao Paulo, Sao Paulo - SP, 04650-180 Brazil</p> <p>Sterilization site: Oximed Tecnologia em</p>	<p>Brand Name:</p> <p>Sphera12 Hydrocephalus valve burr hole type medium/low/high pressure shunt 12mm</p>	<p>Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents</p>

	<p>(ELI-0043)</p> <p>Date of R&amp;I 02-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 5565978969</p>	<p>Esterilizacao</p> <p>Address: R. Ulisses Jamil Cury , 920-Distrito Industrial Dr. Ulysses da silveira Guimaraes, Sao jose do Rio Preto-SP Brazil CEP:15092-601</p> <p>LOA Validity: Issue date: 06-11-2023 (Copy) expiry not found</p> <p>ISO Validity: 017-01-2025 (Copy)</p> <p>EC validity: 04-07-2023 Copy</p>	<p>Class D</p> <p>Shelf Life : 4 years Applied as: Kit</p> <p>Models/ Specification</p>	<p>including Valid LOA . ISO 13485, EU QA Certificate and design Examination certificate ate and stability studies and DOC. The Application submitted as family need brochure and justification under the MDR 2017</p>
<b>219.</b>	<p>Iqbal and Company,</p> <p>Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector, E- 11/4, Islamabad, Pakistan.</p> <p>ELI-00117</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 0349520396</p>	<p>Legal Manufacturer:</p> <p>MEDICAL COMPONENTS INC DBA-Medcomp</p> <p>Address: 1499 DELP DRIVE HARLEYSVILLE,PA 19438, USA.</p> <p>LOA Validity: 31-12-2025 (Copy)</p> <p>FSC: USA Validity: 27-05-2026 (notarized)</p> <p>ISO Validity: 28-09-2025</p> <p>EC validity: 26-05-2024 (Copy)</p>	<p>Brand Name:</p> <p>Duo-Flow Soft-line Catheter Set T73M - 7F X 7CM DUO-FLOW® SOFT- LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T73MGL - 7F X 7CM DUO-FLOW® SOFT- LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T74M - 7F X 10CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T74MGL - 7F X 10CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T94M - 9F X 12CM DUO-FLOW® SOFT-LINE®</p>	<p>Deferred for submission of the following Apostilled/ embassy attested valid FSC along with all other notarized documents including Valid ISO 13485, EU QA Certificate and design Examination certificate ate.</p> <p>Further the LOA is issued by the Medcomp 1499 Delp Drive Harleysville,PA 19438, USA. and not by the Medical Componenets Inc Dba-Medcomp 1499 delp drive harleysville,pa 19438, usa.</p> <p>Clarify</p> <p>The Application submitted as family need brochure and justification under the MDR 2017</p>

			<p>DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T94MGL - 9F X 12CM DUO-FLOW® SOFT-LINE®</p> <p>DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T96M - 9F X 15CM DUO-FLOW® SOFT-LINE®</p> <p>DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T96MGL - 9F X 15CM DUO-FLOW® SOFT-LINE®</p> <p>DOUBLE LUMEN HEMODIALYSIS CATHETER.</p> <p>Double Lumen Hemodialysis Catheter Set</p> <p>Class D</p> <p>Shelf Life : 5 Years</p> <p>Applied as: Family</p> <p>Models/ Specification</p>	
220.	<p>Roche Pakistan Limited, 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi</p> <p>(ELI-000009)</p> <p>Date of R&amp;I 30-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 222357924</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim Germany</p> <p>LOA Validity: 02-02-2023 (issue date )</p> <p>FSC: Germany Issue date : 09-10-2024 (copy)</p> <p>ISO Validity: 12-06-2024</p> <p>EU QMS certificate validity: 23-09-2026</p>	<p>Brand Name:</p> <p>Elecsys Anti-HBs III</p> <p>Class D</p> <p>Shelf Life : 15 month</p> <p>Applied as: Kit</p> <p>Models/ Specification 09810471190</p> <p>09810480190</p> <p>09810501190</p>	Approved

		(notarized)		
<b>221.</b>	<p>Tech Zone, 764 Askari 9, Zarar Shaheed Road Cantt Lahore. ELI-00040</p> <p>Date of R&amp;I 28-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 968000045229</p>	<p>Legal Manufacturer: Adeor Medical AG Address: Martinshof 5, 83626 Valley Germany</p> <p>LOA Validity(Notarised): 31-12-2027</p> <p>FSC: Germany Issuance date : 05-02-2025 (Original) expiry not mentioned</p> <p>ISO Validity: 30-12-2025(notarized)</p> <p>EU QMS certificate validity: 26-05-2024 (Original) EU Design Examination certificate validity: 26-05-2024 (Original) Extension letter given</p>	<p>Brand Name: Perneczky Aneurysm Clip 2 Aneurysm Clip Class D Shelf Life: 10 years Applied as: Single Models/ Specification AS per FSC</p>	Deffered for clarification of the applied name and as per FSC.
<b>222.</b>	<p>M/s. ICare Health, 512 Pak Medical Centre, Khyber Bazar Peshawar KP, Pakistan. (ELI- 00336)</p> <p><b>R&amp;I detail</b> 18-04-2025 <b>Fee: 25,000</b> <b>Slip:</b> 030635674182 <b>Dated:</b> 16-04-2025</p>	<p><b>Name of Manufacturer:</b> M/s. Shenzhen Fumingwei Industrial Co. Ltd. 1&amp;5/F, Block 109, 1<sup>st</sup> Industrial Park, Liantang, Guowei Road, LuoHu, Shenzhen, P. R. China</p> <p><b>LOA Validity:</b> 01-07-2029</p> <p><b>FSC Validity (China):</b> 18-06-2025</p> <p><b>ISO Validity:</b> 19-08-2025</p>	<p><b>Brand name:</b> Fumingwei</p> <p><b>Generic Name:</b> Medical X-ray Film</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> 8x10in, 10x12in, 11x14in, 1215in, 14x17in, 6.5x8.5in</p> <p><b>Shelf life:</b> 02 Years</p>	Approved subject to submission of valid FSC, Issued by concerned regulatory authority.
<b>223.</b>	<p>M/s. ICare Health, 512 Pak Medical Centre, Khyber Bazar Peshawar KP, Pakistan. (ELI- 00336)</p> <p><b>R&amp;I detail</b></p>	<p><b>Name of Manufacturer:</b> M/s. Weifang Hengcai Digital Photo Materials Co., Ltd. Yingzi Village South 500 Meters Yishan Road East, Dongcheng Subdistrict Office, Linqu County, Weifang City, Shandong, P.R. China.</p>	<p><b>Brand name:</b> Hengyicai</p> <p><b>Generic Name:</b> Medical X-ray Film</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b></p>	Deffered for submission of and valid ISO 13485 and valid legalized FSC, Issued by concerned regulatory authority.

	18-04-2025 <b>Fee: 25,000</b> <b>Slip:</b> 90939666393 <b>Dated:</b> 16-04-2025	<b>LOA Validity:</b> 12-12-2026  <b>FSC Validity (China):</b> 10-06-2026  <b>ISO Validity:</b> 16-06-2025	20x25cm(8*10in), 25x30cm(10*12in), 28x35cm(11*14in), 30x38cm(12*15in), 35x43cm(14*17in)  <b>Shelf life:</b> 02 Years	
224.	M/s. ICare Health, 512 Pak Medical Centre, Khyber Bazar Peshawar KP, Pakistan.  <b>(ELI- 00336)</b>  <b>R&amp;I detail</b> 18-04-2025 <b>Fee: 25,000</b> <b>Slip:</b> 0555384482 <b>Dated:</b> 16-04-2025	<b>Name of Manufacturer:</b>  M/s. Weifang Hengcai Digital Photo Materials Co., Ltd. Yingzi Village South 500 Meters Yishan Road East, Dongcheng Subdistrict Office, Lingu County, Weifang City, Shandong, P.R. China.  <b>LOA Validity:</b> 12-12-2026  <b>FSC Validity (China):</b> 08-09-2026  <b>ISO Validity:</b> 16-06-2025	<b>Brand name:</b> Hengyicai  <b>Generic Name:</b> Medical Thermal Dry Image Film  <b>Class:</b> A  <b>Codes/Sizes:</b> 20cmx25cm (8x10inch), 25cmx30cm (10x12inch), 28cmx35cm (11x14inch), 35cmx43cm (14x17inch)  <b>Shelf life:</b> 02 Years	Deffered for submission of valid Legalised FSC, Issued by concerned regulatory authority.
225.	M/s. Kashif Traders, GF-48, Pak Medical Center, Karachi Market, Khyber Bazar, Peshawar, 44000, Pakistan.  <b>(ELI- 01040)</b>  <b>R&amp;I detail</b> 24-04-2025 <b>Fee: N/Available</b> <b>Slip:</b> <b>Dated:</b>	<b>Name of Manufacturer:</b>  M/s. Shenzhen Mindray Bio- Medical Electronics Co., Ltd. Mindray Building, Keji 12 <sup>th</sup> Road South, High-Tech Industrial Park, Nanshan, Shenzhen 518057, People's Republic of China.  <b>LOA Validity:</b> Date not mentioned  <b>FSC Validity (China):</b> 11-12-2024  <b>ISO Validity:</b> 30-06-2026	<b>Brand name:</b> Mindray M-30PCFL LYSE  <b>Generic Name:</b> Isotonic Hematology Diluent Solution  <b>Class:</b> A  <b>Codes/Sizes:</b> M-30PCFL LYSE 250 ML, 500 ML  <b>Shelf life:</b> 03 Years	Deffered.  Firm shall submit following documents.  Original fee challan.  Valid Legalised FSC, issued by concerned regulatory authority.  Notarised ISO Certificate, and ISO Certificate.
226.	M/s. Kashif Traders, GF-48, Pak Medical Center, Karachi Market, Khyber	<b>Name of Manufacturer:</b>  M/s. Shenzhen Mindray Bio- Medical Electronics Co., Ltd.	<b>Brand name:</b> Mindray M-30D Diluent	Deffered.  Firm shall submit following documents.

	<p>Bazar, Peshawar, 44000, Pakistan.</p> <p><b>(ELI- 01040)</b></p> <p><b>R&amp;I detail</b> 24-04-2025 <b>Fee: N/Available</b> <b>Slip:</b> <b>Dated:</b></p>	<p>Mindray Building, Keji 12<sup>th</sup> Road South, High-Tech Industrial Park, Nanshan, Shenzhen 518057, People's Republic of China.</p> <p><b>LOA Validity:</b> Date not mentioned</p> <p><b>FSC Validity (China):</b> 11-12-2024</p> <p><b>ISO Validity:</b> 30-06-2026</p>	<p><b>Generic Name:</b> Isotonic Hematology Diluent Solution</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> M-30D Diluent 5.5 Ltr. 5.5 Ltr. X 2 20 Ltr.</p> <p><b>Shelf life:</b> 03 Years</p>	<p>Original fee challan.</p> <p>Valid Legalised FSC, issued by concerned regulatory authority.</p> <p>Notarised ISO Certificate, and ISO Certificate.</p>
227.	<p>M/s. Mian Scientific Corporation (Pvt.) Ltd. 534-Jinnah Colony Faisalabad 38030, Pakistan</p> <p><b>(ELI- 00442)</b></p> <p><b>R&amp;I detail</b> 18-04-2025 <b>Fee:</b> 6000 <b>Slip:</b> 185604344 <b>Dated:</b> 08-04-2025</p>	<p><b>Name of Manufacturer:</b> M/s. ERBA Lachema s.r.o Brno, Karasek 2219/1d, Czech Republic</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>FSC Validity (China):</b> 31-03-2026</p> <p><b>ISO Validity:</b> 01-12-2027</p>	<p><b>Brand name:</b> ERBA</p> <p><b>Generic Name:</b> Chem 5VE Analyzer</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> (As per dossier and mentioned in FSC) 8592156CCIN0058SW</p> <p><b>Shelf life:</b> N/A</p>	<p>Approved Subject to submission of service life.</p>
228.	<p>M/s. Aqib Trading Company (Pvt.) Ltd. Main GT Road, Adamzai, Akora Khattak, District Nowshera, KPK</p> <p><b>(ELI- 00628)</b></p> <p><b>R&amp;I detail</b> 30-04-2025 <b>Fee:</b> 6000 <b>Slip:</b> 3555332649 <b>Dated:</b> N/A</p>	<p><b>Name of Manufacturer:</b> M/s. Jiangxi Hongda Medical Equipment Group Ltd. 39 South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China 331700</p> <p><b>LOA Validity:</b> 03-09-2029</p> <p><b>FSC Validity (China):</b> 03-09-2026</p> <p><b>ISO Validity:</b> 24-05-2025</p>	<p><b>Brand name:</b> AT-CAP</p> <p><b>Generic Name:</b> Heparin Cap for Single Use</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> (As per dossier and mentioned in FSC) φ 7.55x4.3mm AT-CAP</p> <p><b>Shelf life:</b> 05 Years</p>	<p>Approved subject to submission of attested free sale certificate from concerned regulatory authority.</p>
229.	<p>M/s. Total Technologies (Pvt) Ltd.. 696, J-2 Johar Town, District Lahore, Pakistan</p>	<p><b>Name of Manufacturer:</b> M/s. SOLTEC S.r.l. Via Rontgen 16 –20136 MILAN</p> <p>M/s SOLTEC S.r.l. Via Castelbarco 17 – 20136</p>	<p><b>Brand name:</b> SONICA S4 ETH/ EP Series</p> <p><b>Generic Name:</b> SONICA Ultrasonic</p>	<p>Approved, subject to submission of valid ISO 13485 certificate product codes.</p>

	<b>(ELI- 00129)</b>  <b>R&amp;I detail</b> 21-04-2025 <b>Fee: 6000</b> <b>Slip: 497542482494</b> <b>Dated: N/A</b>	MILAN  <b>LOA Validity:</b> 31-10-2029  <b>FSC issuance (Italy):</b> 28-11-2024  <b>ISO Validity:</b> 21-05-2025	Cleaner  <b>Class: A</b>  <b>Codes/Sizes:</b>  <b>Shelf life:</b> 05 Years	
230.	M/s. Total Technologies (Pvt) Ltd.. 696, J-2 Johar Town, District Lahore, Pakistan  <b>(ELI- 00129)</b>  <b>R&amp;I detail</b> 21-04-2025 <b>Fee: 6000</b> <b>Slip: 438414107</b> <b>Dated: N/A</b>	<b>Name of Manufacturer:</b> M/s. SOLTEC S.r.l. Via Rontgen 16 –20136 MILAN  M/s SOLTEC S.r.l. Via Castelbarco 17 – 20136 MILAN  <b>LOA Validity:</b> 31-10-2029  <b>FSC issuance (Italy):</b> 28-11-2024  <b>ISO Validity:</b> 21-05-2025	<b>Brand name:</b> Sonica S.A.M. 3 BASIC Sonica S.A.M. 3 BASIC USB Sonica S.A.M. 3 Basic USB 18LT Vasche A Ultrasuoni Sonica Sonica Trendmatic 9-18 LT  <b>Generic Name:</b> SONICA Ultrasonic Cleaner  <b>Class: A</b>  <b>Codes/Sizes:</b>  <b>Shelf life:</b> 05 Years	Deffered for clarification regarding grouping and and accordingly submission of defferential fee and valid ISO 13485 certificate and product code/model.
231.	M/s. Total Technologies (Pvt) Ltd.. 696, J-2 Johar Town, District Lahore, Pakistan  <b>(ELI- 00129)</b>  <b>R&amp;I detail</b> 21-04-2025 <b>Fee: 6000</b> <b>Slip: 05386647209</b> <b>Dated: N/A</b>	<b>Name of Manufacturer:</b> M/s. SOLTEC S.r.l. Via Rontgen 16 –20136 MILAN  M/s SOLTEC S.r.l. Via Castelbarco 17 – 20136 MILAN  <b>LOA Validity:</b> 31-10-2029  <b>FSC issuance (Italy):</b> 28-11-2024  <b>ISO Validity:</b> 21-05-2025	<b>Brand name:</b> SONICA S3 Series  <b>Generic Name:</b> SONICA Ultrasonic Cleaner  <b>Class: A</b>  <b>Codes/Sizes:</b>  <b>Shelf life:</b> 05 Years	Approved, subject to submission of valid ISO 13485 certificate product codes.
232.	M/s. Orbit	<b>Name of Manufacturer:</b>	<b>Brand name:</b>	Deffered for

	<p>Diagnostics, 403, Plaza 55, Civic Centre, Bahria Town, Islamabad</p> <p><b>(ELI- 01330)</b></p> <p><b>R&amp;I detail</b> 18-04-2025 <b>Fee: 6000</b> <b>Slip: 96878403647</b> <b>Dated: 14-04-2025</b></p>	<p>M/s. AEHEALTH Limited, Floor 11, Building 1B, BTR Technology Park, Longtian Street, Pingshan District, Shenzhen, P.R. China</p> <p><b>LOA Validity:</b> 12-03-2030</p> <p><b>FSC issuance (China):</b> 02-12-2026</p> <p><b>ISO Validity:</b> 06-02-2026</p>	<p>Lamuno Plus</p> <p><b>Generic Name:</b> Fluorescence Immunoassay Analyzer</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> N/A</p> <p><b>Shelf life:</b> As per stability studies</p>	<p>following.</p> <p>Firm shall submit codes / sizes of the applied product.</p> <p>Shelf life/service</p> <p>Valid and legalized FSC from concerned regulatory authority.</p>
233.	<p>M/s. EA Global Star (Pvt.) Ltd., Basement # 12-DD, Sector D, Bahria Town, Lahore</p> <p><b>(ELI- 01363)</b></p> <p><b>R&amp;I detail</b> 18-04-2025 <b>Fee: 6000</b> <b>Slip: 41182354675</b> <b>Dated: 14-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s Zhejiang J&amp;J Mobility Co., Baiyang Street, Wuyi, Jinhua City, Zhejiang, China.</p> <p><b>LOA Validity:</b> 19-12-2029</p> <p><b>FSC issuance (China):</b> 19-12-2026</p> <p><b>ISO Validity:</b> 10-01-2027</p>	<p><b>Brand name:</b> J&amp;J Electric Wheelchair</p> <p><b>Generic Name:</b> Electric Wheelchair</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> DESIRE, DESIRE SPORTS, BOLD, FRONT WHEEL, A2 PLUS, DELUXE, DELUXE BIG WHEEL, DELUXE SPORT, EXTREME, SUPER DELUXE, A2 PLUS RECLINING</p> <p>JJW-5001, JJW-500111, JJW-500112, JJW-500113, JJW-500114, JJW-500115, JJW-500116, JJW-500117, JJW-500118, JJW-500121, JJW-500131, JJW-500141, JJW-500151, JJW-500161, JJW-500171, JJW-500181, JJW-500155, JJW-500156,</p> <p>HPIE</p> <p>JJW-5001157, JJW-500118, JJW-500311, JJW-500312, JJW-500313,</p>	<p>Deffered for following.</p> <p>Firm shall apply separately for multiple types / models and instant application to e considered for which type.</p> <p>Legalized/notrized FSC from concerned regulatory authority.</p>



			JJW-6001, JJW-600111, JJW-600112, JJW-600113, JJW-600114, JJW-600115, JJW-600116, JJW-600117, JJW-600118, JJW-600183, JJW-600184, JJW-600185, JJW-600186, JJW-600211, JJW-600221, JJW-600227, JJW-600127, JJW-600129, JJW-600321, JJW-600322, JJW-600325  COOMHE  JJW-7001, JJW-700221, JJW-700223, JJW-700225, JJW-700227, JJW-700229, JJW-700321, JJW-700323, JJW-700325, JJW-700327, JJW-700329 JJW-1001, JJW-100111, JJW-100112, JJW-100113, JJW-100114, JJW-100115, JJW-100116, JJW-100117, JJW-100118, JJW-100119  <b>Shelf life:</b> 05 Years	
234.	M/s. Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1 <sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi.  <b>(ELI- 01036)</b>  <b>R&amp;I detail</b> 30-04-2025 <b>Fee: 6000</b> <b>Slip: 227952009</b> <b>Dated: 29-04-2025</b>	<b>Name of Manufacturer:</b> M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.), No. 23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China  <b>LOA Validity:</b> 03-12-2029  <b>FSC Validity (China):</b> 03-08-2025  <b>FSC Issuance (Germany):</b> <b>30-01-2025</b>	<b>Brand name:</b> Biossays Automatic Biochemistry Analyzer  <b>Generic Name:</b> Automatic Biochemistry Analyzer  <b>Class: A</b>  <b>Codes/Sizes/model:</b> TRB829903, TRB829904, TRB829905, TRB829906, TRB829907, TRB829908, TRB829909,	Approved TRB829903. Firm shall apply separately for rest of models

		<b>ISO Validity:</b> 31-08-2026	TRB829910,  <b>Shelf life:</b> Service life 10 Years	
<b>235.</b>	M/s. 3C International, 1620, Main Double Road, Sector I-10/1, Islamabad  <b>(ELI- 00752)</b>  <b>R&amp;I detail</b> 20-04-2025 <b>Fee: 25000</b> <b>Slip: 7263970180</b> <b>Dated: 10-12-2024</b>	<b>Name of Manufacturer:</b> M/s SGS International Kft. 1047, Budapest, Karolyi Istvan utca 1-3 Hungary.  <b>LOA Validity:</b> 31-12-2026  <b>FSC Issuance (Hungary):</b> 12-08-2021  <b>ISO Validity:</b> 03-10-2025	<b>Brand name:</b> SGS  <b>Generic Name:</b> Analog  <b>Class:</b> A  <b>Codes/Sizes:</b> A1, A1D, A1N-2.1  <b>Shelf life:</b> N/A	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority.  Shelf life details concluding the shelf life.
<b>236.</b>	<b>Applicant Name:</b>  Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi  ELI-01214  Date of R&I 24-04-2025 <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 0068550 Dated:	M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel A Road, Yaohal Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China  <b>LOA Validity:</b> 31-12-2030  <b>FSC: China</b> <b>Validity:</b> 13-03-2026  <b>ISO Validity:</b> 13-07-2026	<b>Brand name:</b> Bowie Dick Test  Generic Name: Bowie Dick Test  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Sizes and codes.  Brand name, and brief description of the applied product.
<b>237.</b>	<b>Applicant Name:</b>  Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi  ELI-01214  Date of R&I 24-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 76754542336 Dated:	M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel A Road, Yaohal Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China  <b>LOA Validity:</b> 31-12-2030  <b>FSC: China</b> <b>Validity:</b> 13-03-2026  <b>ISO Validity:</b> 13-07-2026	<b>Brand name:</b> Indicator Card  Generic Name: Indicator Card  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Sizes and codes.  Brand name, and brief description of the applied product.
<b>238.</b>	<b>Applicant Name:</b>	M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel	<b>Brand name:</b> Wrapping Paper	Deffered for following.

	<p>Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi</p> <p>ELI-01214</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 87097182 Dated:</p>	<p>A Road, Yaohal Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China</p> <p><b>LOA Validity:</b> 31-12-2030</p> <p><b>FSC: China</b> <b>Validity:</b> 13-03-2026</p> <p><b>ISO Validity:</b> 13-07-2026</p>	<p>Generic Name: Wrapping Paper</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification:</p> <p>110mmx280mm, 50mmx200mm, 75mmx200mm, 100mmx200mm, 135mmx280mm, 90mmx260mm, 60mmx130mm, 190mmx360mm, 240mmx300mm, 400mmx500mm</p>	<p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Brand name, and brief description of the applied product.</p>
239.	<p><b>Applicant Name:</b></p> <p>Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi</p> <p>ELI-01214</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 7831981242 Dated:</p>	<p>M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel A Road, Yaohal Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China</p> <p><b>LOA Validity:</b> 31-12-2030</p> <p><b>FSC: China</b> <b>Validity:</b> 13-03-2026</p> <p><b>ISO Validity:</b> 13-07-2026</p>	<p><b>Brand name:</b> Sterilization Flat Roll</p> <p>Generic Name: Sterilization Flat Roll</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Sizes and codes.</p> <p>Brand name, and brief description of the applied product.</p>
240.	<p><b>Applicant Name:</b></p> <p>Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi</p> <p>ELI-01214</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b></p>	<p>M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel A Road, Yaohal Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China</p> <p><b>LOA Validity:</b> 31-12-2030</p> <p><b>FSC: China</b> <b>Validity:</b> 13-03-2026</p> <p><b>ISO Validity:</b> 13-07-2026</p>	<p><b>Brand name:</b> Sterilization Roll/Self Sealing Pouch</p> <p>Generic Name: Sterilization Roll/Self Sealing Pouch</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Sizes and codes.</p> <p>Brand name, and brief description of the applied product.</p>

	Fee Challan No: 7318373075 Dated:			
241.	<b>Applicant Name:</b>  Medives Enterprises, House No. 45, N/A, Block 6, P.E.C.H.S, Karachi  ELI-01214  Date of R&I 24-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 28922035599 Dated:	M/s. Hefei Mlush Sanitary Products Co., LTd., West Wel A Road, Yaohai Industrial Park, Xinzhuang District, Hefei City, Anhui Province, China  <b>LOA Validity:</b> 31-12-2030  <b>FSC: China</b> <b>Validity:</b> 13-03-2026  <b>ISO Validity:</b> 13-07-2026	<b>Brand name:</b> Sterilization Guesseted Roll  Generic Name: Sterilization Guesseted Roll  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Sizes and codes.  Brand name, and brief description of the applied product.
242.	<b>Applicant Name:</b>  Link Trader, Office No. 1&2, Mezzanine Floor, Ahmad Trade Center, 2-B, Commercial Area Nazimabad No. 2, Karachi  ELI-00727  Date of R&I 24-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 74346801 Dated:	M/s. Wuhan Hangu Technology Co., No. 308, 3 <sup>rd</sup> Floor, Building No. 9, Chuanglifang Industrial Park, No. 18, SHiqiao Road No. 1, Houhu, Jiangnan, Wuhan, Hubei China  <b>LOA Validity:</b> 01-05-2028  <b>FSC: China</b> <b>Validity:</b> 16-04-2027  <b>ISO Validity:</b> 08-08-2027	<b>Brand name:</b> Medical IV Dressing  Generic Name: Medical IV Dressing  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Sizes and codes.  Brand name, and brief description of the applied product.
243.	<b>Applicant Name:</b>  Link Trader, Office No. 1&2, Mezzanine Floor, Ahmad Trade Center, 2-B, Commercial Area Nazimabad No. 2, Karachi  ELI-00727	M/s. Wuhan Hangu Technology Co., No. 308, 3 <sup>rd</sup> Floor, Building No. 9, Chuanglifang Industrial Park, No. 18, SHiqiao Road No. 1, Houhu, Jiangnan, Wuhan, Hubei China  <b>LOA Validity:</b> 01-05-2028  <b>FSC: China</b> <b>Validity:</b> 16-04-2027	<b>Brand name:</b> Wound Dressing  Generic Name: Wound Dressing  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Sizes and codes.

	<p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 643739410488 Dated:</p>	<p><b>ISO Validity:</b> 08-08-2027</p>		<p>Brand name, and brief description of the applied product.</p>
244.	<p><b>Applicant Name:</b></p> <p>Link Trader, Office No. 1&amp;2, Mezzanine Floor, Ahmad Trade Center, 2-B, Commercial Area Nazimabad No. 2, Karachi</p> <p>ELI-00727</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 18062185839 Dated:</p>	<p>M/s. Wuhan Hangu Technology Co., No. 308, 3<sup>rd</sup> Floor, Building No. 9, Chuanglifang Industrial Park, No. 18, SHiqiao Road No. 1, Houhu, Jiangnan, Wuhan, Hubei China</p> <p><b>LOA Validity:</b> 01-05-2028</p> <p><b>FSC: China</b> <b>Validity:</b> 16-04-2027</p> <p><b>ISO Validity:</b> 08-08-2027</p>	<p><b>Brand name:</b> Surgical Incise Drape</p> <p>Generic Name: Surgical Incise Drape</p> <p>Class-A</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Sizes and codes.</p> <p>Brand name, and brief description of the applied product.</p>
245.	<p><b>Applicant Name:</b></p> <p>Link Trader, Office No. 1&amp;2, Mezzanine Floor, Ahmad Trade Center, 2-B, Commercial Area Nazimabad No. 2, Karachi</p> <p>ELI-00727</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 439635900 Dated:</p>	<p>M/s. Wuhan Hangu Technology Co., No. 308, 3<sup>rd</sup> Floor, Building No. 9, Chuanglifang Industrial Park, No. 18, SHiqiao Road No. 1, Houhu, Jiangnan, Wuhan, Hubei China</p> <p><b>LOA Validity:</b> 01-05-2028</p> <p><b>FSC: China</b> <b>Validity:</b> 16-04-2027</p> <p><b>ISO Validity:</b> 08-08-2027</p>	<p><b>Brand name:</b> Urine Bag</p> <p>Generic Name: Urine Bag</p> <p>Class-A</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Sizes and codes.</p> <p>Brand name, and brief description of the applied product.</p>
246.	<p><b>Applicant Name:</b></p> <p>IMCO Technologist,</p>	<p>M/s. Guangdong Huankai Microbial Sci. &amp; Tech. Co., Ltd., No. 788, Shenzhou</p>	<p><b>Brand name:</b> HKM</p>	<p>Deffered for following.</p>

	<p>Plot No. 155, Sector 31/C1, Korangi Industrial Area, Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 48899216 Dated: 18-04-2025</p>	<p>Road, Guangzhou Science city, Guangzhou, Guangdong Provicne, China</p> <p><b>LOA Validity:</b> 01-09-2026</p> <p><b>FSC:</b></p> <p><b>ISO Validity:</b> 21-06-2025</p>	<p>Generic Name: Culture Media (Trypticase (Tryptic_Soy Broth (TSB)</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification:</p>	<p>Firm shall submit Valid, legalized FSC issued by concerned regulatory authority of the country of origin.</p> <p>Sizes and codes.</p> <p>Valid notarized ISO 134858 Certificate.</p>
247.	<p><b>Applicant Name:</b></p> <p>IMCO Technologist, Plot No. 155, Sector 31/C1, Korangi Industrial Area, Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 3823928634 Dated: 18-04-2025</p>	<p>M/s. Guangdong Huankai Microbial Sci. &amp; Tech. Co., Ltd., No. 788, Shenzhou Road, Guangzhou Science city, Guangzhou, Guangdong Provicne, China</p> <p><b>LOA Validity:</b> 01-09-2026</p> <p><b>FSC:</b></p> <p><b>ISO Validity:</b> 21-06-2025</p>	<p><b>Brand name:</b> HKM</p> <p>Generic Name: Culture Media (Tryptic Soy Agar (Casein Soya Bean Digest Agar) (Soybean Casein Digest Agar)</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Firm shall submit Valid, legalized FSC issued by concerned regulatory authority.</p> <p>Sizes and codes.</p> <p>Valid notarized ISO 134858 Certificate.</p>
248.	<p><b>Applicant Name:</b></p> <p>IMCO Technologist, Plot No. 155, Sector 31/C1, Korangi Industrial Area, Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 42214552482</p>	<p>M/s. Hangzhou Rollmed Co., Ltd., 913, Yuanmao Mansion NO. 05, Wen'er west Road, Hangzhou P.R. of China</p> <p><b>LOA Validity:</b> 30-12-2027</p> <p><b>FSC:</b></p> <p><b>ISO Validity:</b> 27-01-2026</p>	<p><b>Brand name:</b> GD Vacunator &amp; GD Lab Ware</p> <p>Generic Name: Vacuum Blood Collection Tube, Heparin</p> <p>Class-A</p> <p><b>Shelf life: 36 months</b></p> <p>Models/ Specification:0.5ml, 1ml, 2ml, 3ml, 4ml,</p>	<p>Deffered for following.</p> <p>Firm shall submit Valid, legalized FSC issued by concerned regulatory authority.</p> <p>Sizes and codes.</p> <p>Valid notarized ISO 134858 Certificate.</p>

	Dated: 18-04-2025		5ml, 6ml, 7ml, 8ml, 9ml, 10ml	
249.	<p><b>Applicant Name:</b> IMCO Technologist, Plot No. 155, Sector 31/C1, Korangi Industrial Area, Karachi</p> <p>ELI-00778</p> <p>Date of R&amp;I 24-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 219531518 Dated: 18-04-2025</p>	<p>M/s. Hangzhou Rollmed Co., Ltd., 913, Yuanmao Mansion NO. 05, Wen'er west Road, Hangzhou P.R. of China</p> <p><b>LOA Validity:</b> 30-12-2027</p> <p><b>FSC: China</b> <b>Issue date:</b> Not provided</p> <p><b>ISO Validity:</b> 27-01-2026</p>	<p><b>Brand name:</b> GD Vacunator &amp; GD Lab Ware</p> <p>Vacuum Blood Collection Tube, plain Red</p> <p>Class-A</p> <p><b>Shelf life: 36 months</b></p> <p>Models/ Specification: 0.5ml, 1ml, 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml</p>	<p>Deffered for following.</p> <p>Firm shall submit Valid, legalized FSC issued by concerned regulatory authority.</p> <p>Sizes and codes.</p> <p>Valid notarized ISO 134858 Certificate.</p>
250.	<p><b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p><b>ELI-00160</b></p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee: PKR 6000/- Slip # 6002383577 Dated: 07-04-2025</p>	<p>Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: Diagnostic Stago S.A.S .125, 131 Avenue Louis Roche 92230 Gennevilliers FRANCE.</p> <p><b>LOA validity:</b> 31-Dec-2025</p> <p><b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025</p> <p><b>ISO Certificate Validity</b> 23-05-2025</p>	<p>sthemO 201 Automated Clinical Analyzer</p> <p>Model No: 59032</p> <p>Class-A</p> <p><b>Shelf life:</b> Not applicable for analyzer</p> <p><b>Storage Conditions:</b> +15°C to +30°C</p>	<p>Approved Subject to submission of valid notarized ISO 13485 certificate.</p>
251.	<p><b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal,</p>	<p>Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France</p> <p>Manufacturing Site: Diagnostic Stago S.A.S .125, 131 Avenue Louis Roche</p>	<p>sthemO 301 Automated Clinical Analyzer</p> <p>Model No: 59018</p> <p>Class-A</p>	<p>Approved Subject to submission of valid notarized ISO 13485 certificate.</p>

	Karachi  <b>ELI-00160</b>  Date of R& I 23-04-2025  Fee: PKR 6000/- Slip # 5310314255 <b>Dated:</b> 07-04-2025	92230 Gennevilliers FRANCE.  <b>LOA validity:</b> 31-Dec-2025  <b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025  <b>ISO Certificate Validity</b> 23-05-2025	<b>Shelf life:</b> Not applicable for analyzer  <b>Storage Conditions:</b> +15°C to +30°C	
252.	<b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi  <b>ELI-00160</b>  Date of R& I 23-04-2025  Fee: PKR 6000/- Slip # 978785930 <b>Dated:</b> 07-04-2025	Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  Manufacturing Site: Tcoag Ireland Limited IDA Business Park Bray – Co. Wicklow, Ireland, France  <b>LOA validity:</b> 31-Dec-2025  <b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025  <b>ISO Certificate Validity</b> 23-05-2025	sthemO CaCl <sub>2</sub> M Calcium Solution (24 x 15-mL bottles)  Model No: 01464 Size: 24x15ml bottles.  Class-A  <b>Shelf life:</b> 24 Months  <b>Storage Conditions:</b> 2-8°C	Approved Subject to submission of valid notarized ISO 13485 certificate
253.	<b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi  <b>ELI-00160</b>  Date of R& I 23-04-2025  Fee: PKR 6000/- Slip # 62998797840 <b>Dated:</b> 07-04-2025	Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  Manufacturing Site: Tcoag Ireland Limited IDA Business Park Bray – Co. Wicklow, Ireland, France  <b>LOA validity:</b> 31-Dec-2025  <b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025  <b>ISO Certificate Validity</b>	sthemO Cleaner Washing Solution (6 x 2.5L)  Model No: 01266 Sizes: 6x2.5L  Class-A  <b>Shelf life:</b> 24 Months  <b>Storage Conditions:</b> 2-40°C	Approved Subject to submission of valid notarized ISO 13485 certificate



		23-05-2025		
254.	<b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi  <b>ELI-00160</b>  Date of R& I 23-04-2025  Fee: PKR 6000/- Slip #65355260423 <b>Dated:</b> 07-04-2025	Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  Manufacturing Site: Tcoag Ireland Limited IDA Business Park Bray – Co. Wicklow, Ireland, France  <b>LOA validity:</b> 31-Dec-2025  <b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025  ISO Certificate Validity 23-05-2025	sthemO Desorb Decontaminant Solution (4 x 250ml)  Model No: 01263 Size: 4x250ml  Class-A  <b>Shelf life:</b> 24 Months  <b>Storage Conditions:</b> 2-8°C	Approved Subject to submission of valid notarized ISO 13485 certificate
255.	<b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi  <b>ELI-00160</b>  Date of R& I 23-04-2025  Fee: PKR 6000/- Slip #1153484756 <b>Dated:</b> 07-04-2025	Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  Manufacturing Site: Tcoag Ireland Limited IDA Business Park Bray – Co. Wicklow, Ireland, France  <b>LOA validity:</b> 31-Dec-2025  <b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025  <b>ISO Certificate Validity</b> 23-05-2025	sthemO Owren Koller M Buffered Solution (24 x 15ml)  Model No: 01463 24X15ml  Class-A  <b>Shelf life:</b> 24 Months <b>Storage Conditions:</b> 2-8°C	Approved Subject to submission of valid notarized ISO 13485 certificate
256.	<b>M/s Martin Dow Specialties (Pvt) Limited</b> 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6,	Legal Manufacturer: M/s. Diagnostic Stago S.A.S. 3 Allée Thérés - 92600 Asnières sur Seine France  Manufacturing Site:	sthemO Spare parts & Accessories (sthemO Cuvettes) (Microcontainer) (sthemO Beads dispenser)	Deffered for following.  Justification for applying multiple types / models

	<p>PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p><b>ELI-00160</b></p> <p>Date of R&amp; I 23-04-2025</p> <p>Fee: PKR 6000/- Slip #95036619274 <b>Dated:</b> 07-04-2025</p>	<p>DIAGNOSTICA STAGO S.A.S. 125, 131 avenue Louis Roche 92230 Gennevilliers France.</p> <p><b><u>Microcontainer:</u></b> SARSTEDT AG &amp; Co. KG Sarstedtstraße 1 51588 Nümbrecht Germany</p> <p><b><u>sthemO Beads dispenser:</u></b> RSP 9 rue des Corroyes ZI les Corroyes FR-78730 St Arnoult en Yvelines France</p> <p><b><u>sthemO Microcups:</u></b> Stevanato Group Nuova Ompi S.r.l. Unipersonale Via Molinella, 17 35017 Piombino Dese (PD) Italy</p> <p><b><u>sthemO mini-Reducer:</u></b> Tcoag Deutschland GmbH Lehbrinksweg 59, 32657 Lemgo Germany</p> <p><b>LOA validity:</b> 31-Dec-2025</p> <p><b>FSC (France):</b> <b>Date of Issue:</b> 07-Feb-2025</p> <p><b>ISO Certificate Validity</b> 23- 05-2025</p>	<p>(sthemO Microcups) (sthemO mini-Reducer)</p> <p>Model No: sthemO Cuvettes: 86931 Microcontainer: 00741 sthemO Beads dispenser: 86933 sthemO Microcups: 01523 sthemO mini-Reducer: 01351</p> <p>Class-A</p> <p><b>Shelf life:</b> Not applicable</p> <p><b>Storage Conditions:</b> Not applicable</p>	<p>otherwise apply seperatlety.</p> <p>Shelf life details.</p> <p>Valid and notarized ISO 13485 certificate.</p>
257.	<p><b>M/s M Zafar Steel Furniture, Shop No. 05, Modern Complex, UP Society NO. 1, Karachi Central North, Karachi</b></p> <p><b>ELI-01263</b></p> <p>Date of R&amp;I 18-04-2025</p>	<p>M/s. Hebei Webian Medical Instrument Trading Co., Ltd., No. 10 Xiwaihuan Road, Zaoqiang Country and Hengshui City, Hebei Province, China</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>FSC: China</b> <b>Validity:</b> 25-05-2026</p> <p><b>ISO Validity:</b></p>	<p><b>Brand name:</b> Medical Trolley</p> <p>Generic: Medical Trolley</p> <p>Class-A</p> <p><b>Shelf life: N/A</b></p> <p>Models/ Specification: YC01、 J103、 J104、</p>	<p>Deffered for following.</p> <p>Valid , Legalized FSC certificate issued by concerned regulatory authority, mentioning the applied product.</p> <p>Justification for applying for multiple types / models &amp; in the same application otherwise apply</p>

	<b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 67939279 Dated:	05-02-2026	ET750-28、ET750-01 、ET850-01、MT750-01、MT850-01. ITT750-04、ITT850-04、AT750-01、AT850-01、AT750-02、AT850-02、HS-02CHT25D、HS-02CHT25D2、HS-02CHT50D、HS-02CHT50D2、HS-03CHT20D、HS-03CHT36D、HS-03CHT36BD、101A、101B、101C、101D、101G、101H、101J、101K、201A、201B、201C、201D、201G、201H、201J、201K、D105、D107、D108、D109、G08、WB-LCT01、WB-LCT02、WB-LCT03、WB-C1、WB-C2、WB-C3、WB-C4、WB-WT01、WB-WT02、WB-WW01、WB-WW02、WB-ST01、WB204、GWC01、GWC02、GWC03、GWC04、GWC05、GWC06、WBL005	seperately.  Shelf life details.  Brand name.
258.	<b>M/s M Zafar Steel Furniture, Shop No. 05, Modern Complex, UP Society NO. 1, Karachi Central North, Karachi</b>  <b>ELI-01263</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b>	M/s. Hebei Webian Medical Instrument Trading Co., Ltd., No. 10 Xiwaihuan Road, Zaoqiang Country and Hengshui City, Hebei Province, China  <b>LOA Validity:</b> 31-12-2026  <b>FSC: China</b> <b>Validity: 25-05-2026</b>  <b>ISO Validity:</b> 05-02-2026	<b>Brand name:</b> Manual Hospital Bed  Generic: Manual Hospital Bed  Class-A  <b>Shelf life:</b> <b>Service life 10 Years</b>	Deffered for following.  Valid , Legalized FSC certificate issued by concerned regulatory authority, mentioning the applied product.  Justification for applying for multiple types / models & in the same application otherwise apply seperately.

	Fee Challan No: 2518009006 Dated:		Models/ Specification: A01、N01(A)、 N01(B)、A02、A02-1 、A02-2、A02- 2A.A02-3、A02-4、 A02-5、A02-6 A02-7 、A02-8、A02-10、 A03-2、A03-3、N03 、R03、A03、A03-1 、A04、A04-1. A04-2 、A06、A06-1、A06- 2、A07、A08、A08-1 、A09、A09-1、A09- 2、A11、804、B04-1 、B04-2、B04-3、 B04-4、B04-5、B04-6 、B04W、B05、805-1 、N04B、N04A、 A05、A05-1、A05-2 、A10、A12、B02、 B02-1、B02-2、B02-3 、B02-4、B02-5、 B02-6. B03、B03-1、 N02A、N02B、R02、 W02、ZO2、NO2、 B01、B01-1、B01-2 、B01-3、B01-4、 B01-5、R01	Brand name.
259.	<b>M/s M Zafar Steel Furniture, Shop No. 05, Modern Complex, UP Society NO. 1, Karachi Central North, Karachi</b>  <b>ELI-01263</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 56714762 Dated:	M/s. Hebei Webian Medical Instrument Trading Co., Ltd., No. 10 Xiwaihuan Road, Zaoqiang Country and Hengshui City, Hebei Province, China  <b>LOA Validity:</b> 31-12-2026  <b>FSC: China</b> <b>Validity:</b> 25-05-2026  <b>ISO Validity:</b> 05-02-2026	<b>Brand name:</b> Electric Wheelchair  Generic: Electric Wheelchair  Class-A  <b>Shelf life: 5 Years</b>  Models/ Specification: LYI-WBECG-1, LYI-WBECG-6, LYAL-WBECG-1, LYAL-WBECG-2, LYAL-WBECG-3, LYAL-WBECG-4, LYPS-WBECG-1, LYPS-WBECG-2, LYPS-WBECG-3, LYPS-	Deffered for following.  Valid , Legalized FSC certificate issued by concerned regulatory authority, mentioning the applied product.  Justification for applying for multiple types / models & in the same application otherwise apply seperately.  Brand name.

			WBECG-4, LYPS-WBECG-5, LYPS-WBECG-6, LYPS-WBECG-7, LYPS-WBECG-8, LYPS-WBECG-9, LYPS-WBECG-10, LYPS-WBECG-11, LYPS-WBECG-12, LYPS-WBECG-13, LYPS-WBEZX-1	
260.	<b>M/s Euro Nano Diagnostics Private Limited, Plot No. 225/1/F, Block-2, P.E.C.H. Society, Karachi</b>  <b>ELI-00461</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 597885235594 Dated: 16-04-2025	M/s. AnatoliaTani ve Biyoteknoloji Urunleri Arastirma ve Gelisirme Sanayi ve Ticaret Anonim Sirketi, Hasanpasa Mh. BeydagiSk. No.: 1/9h (Sultanbeyli Istanbul)  <b>LOA Validity:</b> 01-12-2028  <b>FSC: Turkey Validity:</b> 14-11-2027  <b>ISO Validity:</b> 26-11-2025	<b>Brand name:</b> UNIO  Generic: UNIO M32 Viral DNA/RNA Extraction Kit  Class-A  <b>Shelf life:</b>   Models/ Specification: UM32V1	Deffered for following.  Legalized FSC certificate issued by concerned regulatory authority.  Shelf life details.  Brand name.  Documentary evidence of class
261.	<b>M/s Euro Nano Diagnostics Private Limited, Plot No. 225/1/F, Block-2, P.E.C.H. Society, Karachi</b>  <b>ELI-00461</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 13290189956 Dated: 16-04-2025	M/s. AnatoliaTani ve Biyoteknoloji Urunleri Arastirma ve Gelisirme Sanayi ve Ticaret Anonim Sirketi, Hasanpasa Mh. BeydagiSk. No.: 1/9h (Sultanbeyli Istanbul)  <b>LOA Validity:</b> 01-12-2028  <b>FSC: Turkey Validity:</b> 14-11-2027  <b>ISO Validity:</b> 26-11-2025	<b>Brand name:</b> UNIO  Generic: UNIO 96 Nucleic acid extraction and PCR Setup Robot  Class-A  <b>Shelf life:</b>   Models/ Specification: AUH96	Deffered for following.  Legalized, FSC certificate issued by concerned regulatory authority.  clarification regarding the applied device and differential fee accordingly  Shelf life details.  Brand name.  Documentary evidence of class
262.	<b>M/s Euro Nano</b>	M/s. AnatoliaTani ve	<b>Brand name:</b>	Deffered for

	<b>Diagnostics Private Limited, Plot No. 225/1/F, Block-2, P.E.C.H. Society, Karachi</b>  <b>ELI-00461</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 42586825 Dated: 16-04-2025	Biyoteknoloji Urunleri Arastirma ve Gelisirme Sanayi ve Ticaret Anonim Sirketi, Hasanpasa Mh. BeydagiSk. No.: 1/9h (Sultanbeyli Istanbul)  <b>LOA Validity:</b> 01-12-2028  <b>FSC: Turkey.</b> <b>Validity:</b> 14-11-2027  <b>ISO Validity:</b> 26-11-2025	UNIO  Generic: UNIO Bacterial DNA Extraction Kit  Class-A  <b>Shelf life:</b>   Models/ Specification: UBDR600	following.  Legalized , FSC certificate issued by concerned regulatory authority.  Shelf life details.  Brand name.  Documentary evidence of class
263.	<b>M/s Euro Nano Diagnostics Private Limited, Plot No. 225/1/F, Block-2, P.E.C.H. Society, Karachi</b>  <b>ELI-00461</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 6794290376 Dated: 16-04-2025	M/s. AnatoliaTani ve Biyoteknoloji Urunleri Arastirma ve Gelisirme Sanayi ve Ticaret Anonim Sirketi, Hasanpasa Mh. BeydagiSk. No.: 1/9h (Sultanbeyli Istanbul)  <b>LOA Validity:</b> 01-12-2028  <b>FSC: Turkey</b> <b>Validity:</b> 14-11-2027  <b>ISO Validity:</b> 26-11-2025	<b>Brand name:</b> UNIO  Generic: UNIO Viral DNA/RNA Extraction Kit 600mcl  Class-A  <b>Shelf life:</b>   Models/ Specification: UVDR600	Deffered for following.  Legalized , FSC certificate issued by concerned regulatory authority.  Shelf life details.  Brand name. Documentary evidence of class
264.	<b>M/s Euro Nano Diagnostics Private Limited, Plot No. 225/1/F, Block-2, P.E.C.H. Society, Karachi</b>  <b>ELI-00461</b>  Date of R&I 18-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 94618986507 Dated: 16-04-2025	M/s. AnatoliaTani ve Biyoteknoloji Urunleri Arastirma ve Gelisirme Sanayi ve Ticaret Anonim Sirketi, Hasanpasa Mh. BeydagiSk. No.: 1/9h (Sultanbeyli Istanbul)  <b>LOA Validity:</b> 01-12-2028  <b>FSC: Turkey.</b> <b>Validity:</b> 04-09-2027  <b>ISO Validity:</b> 26-11-2025	<b>Brand name:</b> UNIO  Generic: UNIO M32 Extraction System  Class-A  <b>Shelf life:</b>   Models/ Specification: AUM32	Deffered for following.  Legalized , FSC certificate issued by concerned regulatory authority.  Justification regarding the applied system and differential fee  Shelf life details.  Brand name.
265.	<b>M/s Rafi Sultan Enterprises, Plot</b>	M/s. Wenzhou Bokang Instruments, Co., Ltd., No.	<b>Brand name:</b> Bokang Stethoscope	Deffered for following.

	<b>No. 19-1-A, Office No. M-1, Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi</b>  <b>ELI-00232</b>  Date of R&I 28-04-2025  <b>Fee Details:</b> <b>Paid Fee: 25,000/-</b> Fee Challan No: 7846570615 and 7058095981 Dated: 21-04-2025	1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province, China  <b>LOA Validity:</b> 16-03-2028  <b>FSC: China</b> <b>Validity:</b> 16-12-2026 FSC: Germany Issue date:26-05-2021  <b>ISO Validity:</b> 01-04-2026	Generic: Non Invasive Stethoscope  Class-A  Family.  <b>Shelf life: N/a</b>  Models/ Specification: BK3003  BK3013	Legalized , FSC certificate issued by concerned regulatory authority.  Shelf life details.
266.	<b>M/s Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1, Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi</b>  <b>ELI-00232</b>  Date of R&I 28-04-2025  <b>Fee Details:</b> <b>Paid Fee: 25,000/-</b> Fee Challan No: 98788267 and 22306425 Dated: 21-04-2025	M/s. Wenzhou Bokang Instruments, Co., Ltd., No. 1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province, China  <b>LOA Validity:</b> 16-03-2028  <b>FSC: China</b> <b>Validity:</b> 16-12-2026 FSC: Germany Issue date:26-05-2021  <b>ISO Validity:</b> 01-04-2026	<b>Brand name:</b> Bokang Aneroid Sphygmomanometer  Generic: Non Invasive Sphygmomanometer  Class-A  Family.  <b>Shelf life:</b> <b>Service life 3 Years</b>  Models/ Specification: BK2001, BK2002, BK2003, BK2004, BK2005, BK2006, BK2007, BK2008, BK2009, BK2010, BK2011, BK2012, BK2013, BK2014, BK2015, BK2066, BK2001-3001, BK2003, BK2009	Deffered for following.  Legalized , FSC certificate issued by concerned regulatory authority.  Justification as Firm has applied multiple models in single application.  Class  Revised form according to class and differential fee
267.	<b>Applicant Name:</b>  PAK Mobilizers  Address: Shop # G-34, Jeff Heights, Main	<b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co.,Ltd  <b>Address:</b>	<b>Brand name:</b>  Wounderfu  Generic Name: Single Axis Hip Joint	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory

	<p>Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 633244061096</p> <p>Dated: 21-04-2025</p>	<p>Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (7E7/C7E7-S)</p>	<p>authority</p> <p>Justification regarding the various applied models otherwise apply separately for each.</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
268.	<p><b>Applicant Name:</b></p> <p>PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 969833159</p> <p>Dated: 21-04-2025</p>	<p><b>Name of Manufacturer:</b></p> <p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co.,Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b></p> <p>Wounderfu</p> <p>Generic Name: Four Bar Hip Joint</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (7E6/C7E6-S)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification regarding the various applied models otherwise apply separately for each.</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
269.	<p><b>Applicant Name:</b></p> <p>PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff</p>	<p><b>Name of Manufacturer:</b></p> <p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p>	<p><b>Brand name:</b></p> <p>Wounderfu</p> <p>Generic Name: Female Three Jaws</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by</p>



	<p>Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 985392323819 Dated: 21-04-2025</p>	<p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4F41)</p>	<p>concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
270.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 2089131286 Dated: 21-04-2025</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Female Four Jaws for Children</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4S63-F)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
271.	<p><b>Applicant Name:</b> PAK Mobilizers</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device</p>	<p><b>Brand name:</b> Wounderfu</p>	<p>Deffered for following.</p> <p>Firm shall submit</p>

	<p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>77519063744</b> <b>Dated: 21-04-2025</b></p>	<p>Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Generic Name: Single Axis Knee Joint with Manual Lock</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (3F17)</p>	<p>Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
272.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>436735795</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Four Axis Knee Joint</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4F20)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>

273.	<b>Applicant Name:</b> PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>0815835285</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products</b> <b>(Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b> Wounderfu  Generic Name:  Locked Four Axis Knee Joint  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (3F35B)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.
274.	<b>Applicant Name:</b> PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>34188012</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products</b> <b>(Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b> Wounderfu  Generic Name:  Knee Joint For Knee Disarticulation with/without lock  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (3F21/3F22)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.  Justification regarding the applied models otherwise apply separately for each.

275.	<b>Applicant Name:</b> PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>574479249863</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b> Wounderfu  Generic Name:  Aluminium Four Bar Knee Joint For Children With/without Lock .  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (3F65/3F65-1)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.  Justification regarding the applied models otherwise apply separately for each.
276.	<b>Applicant Name:</b> PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>098460896</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b> Wounderfu  Generic Name:  Aluminium Knee Disarticulation For Children With/without Lock .  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (3F66/3F66-1)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.  Justification regarding the applied models otherwise apply separately for each.
277.	<b>Applicant Name:</b>	<b>Name of Manufacturer:</b>	<b>Brand name:</b>	Deffered for

	<p>PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>30979212618</b></p> <p><b>Dated: 21-04-2025</b></p>	<p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Wounderfu</p> <p>Generic Name: Lock Tube Adapter</p> <p>Class-A</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification (4F21/3S21)</p>	<p>following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
278.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>74552426487</b></p> <p><b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Integrate Tube</p> <p>Class-A</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification (2F3/2F2,3S4/3S2)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
279.	<b>Applicant Name:</b>	<b>Name of Manufacturer:</b>	<b>Brand name:</b>	Deffered for

	<p>PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>0652588686850</b> <b>Dated: 21-04-2025</b></p>	<p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Wounderfu</p> <p>Generic Name: Sach Foot Adapter CNC</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (2R8-M10, 2R8-M8)</p>	<p>following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
280.	<p><b>Applicant Name:</b></p> <p>PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>88489062465</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b></p> <p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b></p> <p>Wounderfu</p> <p>Generic Name: Double Axis Foot Adapter</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (As per applied dossier and same is mentioned in FSC)  (2F11)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
281.	<p><b>Applicant Name:</b></p>	<p><b>Name of Manufacturer:</b></p>	<p><b>Brand name:</b></p>	<p>Deffered for following.</p>

	<p>PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>61914934</b> <b>Dated: 21-04-2025</b></p>	<p><b>M/s. Shijiazhuang Wounderfu</b> Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Wounderfu</p> <p>Generic Name: SYME Foot Adapter</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (SF-M10)</p>	<p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
282.	<p><b>Applicant Name:</b></p> <p>PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>11593366770</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b></p> <p><b>M/s. Shijiazhuang Wounderfu</b> Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b></p> <p>Wounderfu</p> <p>Generic Name:</p> <p>Cap For Sach Foot</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (1FSC)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
283.	<p><b>Applicant Name:</b></p> <p>PAK Mobilizers</p>	<p><b>Name of Manufacturer:</b></p> <p><b>M/s. Shijiazhuang Wounderfu</b></p>	<p><b>Brand name:</b></p> <p>Wounderfu</p>	<p>Deffered for following.</p>

	<p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197)</p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>21068833624</b> <b>Dated: 21-04-2025</b></p>	<p>Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Generic Name: Cap For Dynamic Foot Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (1FDC)</p>	<p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
284.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197)</p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>321187642220</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Prosthetic Sach Foot</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (1F10)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
285.	<p><b>Applicant Name:</b> PAK Mobilizers</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device</p>	<p><b>Brand name:</b> Wounderfu</p>	<p>Deffered for following.</p> <p>Firm shall submit</p>



	<b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>6253786257</b> <b>Dated: 21-04-2025</b>	Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	Generic Name: Single Axis Foot  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (1F41)	Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.
286.	<b>Applicant Name:</b>  PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>63690240800</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b>  Wounderfu  Generic Name: Prosthetic Syme Foot Beige  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification (1SY10P)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.
287.	<b>Applicant Name:</b>  PAK Mobilizers  <b>Address:</b>	<b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd	<b>Brand name:</b>  Wounderfu  Generic Name:	Deffered for following.  Firm shall submit Legalized FSC

	<p>Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>73278976247</b> <b>Dated: 21-04-2025</b></p>	<p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>AK Cosmetic Foam Cover Water Proof</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (AKFC-6F22)</p>	<p>certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
288.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>61005270609</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Velvet Beauty Decoration AK Socks</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (3CSS-AK)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
289.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Male Four Jaws</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by</p>

	<p>Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>74798017630</b> <b>Dated: 21-04-2025</b></p>	<p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4F63-M/3S63)</p>	<p>concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
290.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>522871614</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Male Three Jaws</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4F42)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
291.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b></p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: BK Cosmetic Foam Cover (Water Proof)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory</p>

	<p>Boulevard Road, Gulberg III, Lahore. (ELI-01197)</p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>0254614220</b> <b>Dated: 21-04-2025</b></p>	<p>Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (BKFC-6F19)</p>	<p>authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
292.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197)</p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>3450524343</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Double Mouth Tube Adapter</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (4F27)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
293.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road,</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Shuttle Lock</p> <p>Class-A</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p>

	<p>Gulberg III, Lahore. <b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>7612794746</b> <b>Dated: 21-04-2025</b></p>	<p>Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (GCL602/GCL603)</p>	<p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
294.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>42767566</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products</b> (Certificate of free sale of prosthetic and orthopaedic products). <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: Drop Ring Lock</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (17B38)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
295.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: Ankle Foot Fixator</p> <p>Class-A</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p>

	<p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>73275519306</b> <b>Dated: 21-04-2025</b></p>	<p>Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of</b> <b>Assistive products</b> <b>(Certificate of free sale of</b> <b>prosthetic and orthopaedic</b> <b>products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (WDF-309L)</p>	<p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
296.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>7363634590</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of</b> <b>Assistive products</b> <b>(Certificate of free sale of</b> <b>prosthetic and orthopaedic</b> <b>products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: VELCRO</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (FLBV)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
297.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: Soft Ankle Joint</p> <p>Class-A</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p>

	<p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>72854356</b> <b>Dated: 21-04-2025</b></p>	<p>Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of</b> <b>Assistive products</b> <b>(Certificate of free sale of</b> <b>prosthetic and orthopaedic</b> <b>products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (FSAJ-1)</p>	<p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
298.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>6177168559</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of</b> <b>Assistive products</b> <b>(Certificate of free sale of</b> <b>prosthetic and orthopaedic</b> <b>products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: PVA sheeting</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (PVAS -001)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
299.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park,</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: PP Sheet</p> <p>Class-A</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class</p>

	<b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>01815686</b> <b>Dated: 21-04-2025</b>	Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Shelf life: 05 years</b>  Models/ Specification  (FPP-S)	and revised form and fee and relevant CE/RRA FSC documents accordingly.
300.	<b>Applicant Name:</b>  PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>  Date of R&I 23-04-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>5280261291</b> <b>Dated: 21-04-2025</b>	<b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,  <b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030  <b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b>  <b>ISO Validity:</b> 05-05-2027	<b>Brand name:</b>  Wounderfu  Generic Name: Low Temperature Thermoplastic plate  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification  (FLTTP)	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.
301.	<b>Applicant Name:</b>  PAK Mobilizers  <b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  <b>(ELI-01197)</b>	<b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd  <b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng	<b>Brand name:</b>  Wounderfu  Generic Name: EVA SHET  Class-A	Deffered for following.  Firm shall submit Legalized FSC certificate issued by concerned regulatory authority  Justification for class and revised form and



	<p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>60581765313</b> <b>Dated: 21-04-2025</b></p>	<p>District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (FPP-S)</p>	<p>fee and relevant CE/RRA FSC documents accordingly.</p>
302.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  (ELI-01197)</p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>96835352752</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Plaster File</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification (PFR-1/PEHR-1/PFF-1)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
303.	<p><b>Applicant Name:</b> PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.  (ELI-01197)</p>	<p><b>Name of Manufacturer:</b> M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p>	<p><b>Brand name:</b> Wounderfu</p> <p>Generic Name: Prosthetic Hand</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant</p>

	<p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>72068339610</b> <b>Dated: 21-04-2025</b></p>	<p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Models/ Specification  (CCA EH/CCMH/MAE H-2/MBEH-2)</p>	<p>CE/RRA FSC documents accordingly.</p> <p>Justification regarding the applied models otherwise apply separately for each.</p>
304.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p> <p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>03058911</b> <b>Dated: 21-04-2025</b></p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: SILICONE GLOVE</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  (FMHGS)</p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC documents accordingly.</p>
305.	<p><b>Applicant Name:</b>  PAK Mobilizers</p> <p><b>Address:</b> Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p><b>(ELI-01197)</b></p>	<p><b>Name of Manufacturer:</b>  M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p><b>Address:</b> Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p>	<p><b>Brand name:</b>  Wounderfu</p> <p>Generic Name: Transfer Paper</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p>	<p>Deffered for following.</p> <p>Firm shall submit Legalized FSC certificate issued by concerned regulatory authority</p> <p>Justification for class and revised form and fee and relevant CE/RRA FSC</p>

	<p>Date of R&amp;I 23-04-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: <b>546726388321</b> <b>Dated: 21-04-2025</b></p>	<p><b>China LOA Validity:</b> 01-03-2025 _ 01-03-2030</p> <p><b>FSC issued by:</b> <b>China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products).</b> <b>Validity: 31-12-2025</b></p> <p><b>ISO Validity:</b> 05-05-2027</p>	<p>Models/ Specification (FTP)</p>	<p>documents accordingly. description</p>
306.	<p><b>Applicant Name:</b>  Surgical World, Office No. 105, 1<sup>st</sup> Floor, Rehmani Chambers, Altaf Hussain Road, New Chali Karachi</p> <p>ELI-00462</p> <p>Date of R&amp;I 18-03-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 19925402652</p>	<p>M/s. Blue Sail Medical Ltd., No. 21, Qingtian Road, Qilu Chemical Industrial Park, 255414 Zibo City, Shandong Province Peoples Republic of China</p> <p><b>LOA Validity:</b> 05-01-2030 (Original Notarized)</p> <p><b>FSC: China Validity:</b> 19-05-2026 (Notarized)</p> <p><b>ISO Validity:</b> 31-07-2025 (Notarized)</p> <p><b>EC Certificate:</b> Validity: 06-06-2028 (Notarized)</p>	<p><b>Brand name:</b>  <b>Life Source</b>  Generic Name: Nitrile Examination Gloves</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  XS, S, M, L XL</p>	<p>Approved subject to Legalized/apostile FSC certificate.</p>
307.	<p><b>Applicant Name:</b>  Surgical World, Office No. 105, 1<sup>st</sup> Floor, Rehmani Chambers, Altaf Hussain Road, New Chali Karachi</p> <p>ELI-00462</p> <p>Date of R&amp;I 18-03-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b></p>	<p>M/s. Blue Sail Medical Ltd., No. 21, Qingtian Road, Qilu Chemical Industrial Park, 255414 Zibo City, Shandong Province Peoples Republic of China</p> <p><b>LOA Validity:</b> 05-01-2030 (Original Notarized)</p> <p><b>FSC: China Validity:</b> 19-05-2026 (Original Notarized)</p>	<p><b>Brand name:</b>  <b>Life Source</b>  Generic Name: Vinly Examination Gloves</p> <p>Class-A</p> <p><b>Shelf life: 05 years</b></p> <p>Models/ Specification  XS, S, M, L XL</p>	<p>Approved subject to Legalized/apostile FSC certificate.</p>

	<b>Fee Challan No:</b> 3279886867	<b>ISO Validity:</b> 31-07-2025 (Original Notarized)  <b>EC Certificate:</b> Validity: 06-06-2028 (Original Notarized)		
<b>308.</b>	<b>Applicant Name:</b>  Surgical World, Office No. 105, 1 <sup>st</sup> Floor, Rehmani Chambers, Altaf Hussain Road, New Chali Karachi  ELI-00462  Date of R&I 18-03-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 8020334008	M/s. Top Glove Sdn Bhd, Lot No. 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 KLang Selangor D.C Malaysia.  <b>LOA Validity:</b> 23-12-2029 (Copy)  <b>FSC: Malaysia</b> <b>Validity:</b> 27-01-2030 (Original)  <b>ISO Validity:</b> 30-04-2026 (Copy)  <b>EC Certificate:</b> Validity: 06-08-2023 (Copy)	<b>Brand name:</b>  <b>Top Glove</b>  Generic Name: Nitrile Examination Gloves  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification  XS, S, M, L XL	Approved subject to nortized ISO13485.
<b>309.</b>	<b>Applicant Name:</b>  Surgical World, Office No. 105, 1 <sup>st</sup> Floor, Rehmani Chambers, Altaf Hussain Road, New Chali Karachi  ELI-00462  Date of R&I 18-03-2025  <b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 35990820	M/s. Top Glove Sdn Bhd, Lot No. 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 KLang Selangor D.C Malaysia.  <b>LOA Validity:</b> 23-12-2029 (Copy)  <b>FSC: Malaysia</b> <b>Validity:</b> 27-01-2030 (Original)  <b>ISO Validity:</b> 30-04-2026 (Copy)  <b>EC Certificate:</b> Validity: 06-08-2023 (Copy)	<b>Brand name:</b>  Top Glove Latex Examination Gloves  Generic Name: Latex Examination Gloves  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification  XS, S, M, L XL	Approved subject to nortized ISO13485.
<b>310.</b>	<b>Applicant Name:</b>  Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah-e- Faisal, Karachi	M/s. Medtrade Products Ltd., Electra House, Electra Way, Crewe CW1 6GL, UK  <b>LOA Validity:</b>	<b>Brand name:</b>  <b>Celox - A (Applicator 6g)</b>  Generic Name:	Approved

	<p>ELI-00010</p> <p>Date of R&amp;I 04-03-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 62,000/-</b> Fee Challan No: 85321744965</p>	<p>15-09-2029 (Copy)</p> <p><b>FSC: UK</b> <b>Validity:</b>15-03-2028 (Original Notarized)</p> <p><b>ISO Validity:</b> 26-04-2027 (Copy)</p> <p><b>EC Certificate:</b> Validity: 15-03-2027</p>	<p>Celox –A Applicator 6g Haemostatic Granules</p> <p>Class-C</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification: FG08832021</p>	
311.	<p><b>Applicant Name:</b></p> <p>Summit Inter Trade, Suit No. 12-A First Floor, Nadir House I.I. Chundrigarh Road, Karachi</p> <p>ELI-00463</p> <p>Date of R&amp;I 10-03-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 41500037</p>	<p>M/s. BF Medikal Sanayi Ithalat Ihracat Ticaret Ltd., Sti SteriVision Company, Feridunn Celik Mah. 1048. Cad. No. 139/BAltindag/Ankara/ Turkey</p> <p><b>LOA Validity:</b> 23-02-2028 (Copy)</p> <p><b>FSC: Turkiye</b> <b>Validity:</b>06-11-2027 (Copy)</p> <p><b>ISO Validity: 27-07-2025</b> (Copy)</p> <p><b>EC Certificate:</b> Validity: 27-07-2025 (Copy)</p>	<p><b>Brand name:</b></p> <p><b>SteriVision</b></p> <p>Generic Name: SteriVision</p> <p>Class-A</p> <p><b>Shelf life:</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Legalized FSC</p> <p>Firm shall submit codes &amp; sizes details,</p> <p>Shelf life.</p> <p>Brand name.</p> <p>DESCRIPTION</p>
312.	<p><b>Applicant Name:</b></p> <p>Summit Inter Trade, Suit No. 12-A First Floor, Nadir House I.I. Chundrigarh Road, Karachi</p> <p>ELI-00463</p> <p>Date of R&amp;I 03-03-2025</p> <p><b>Fee Details:</b> <b>Paid Fee: 6,000/-</b> Fee Challan No: 86385144937</p>	<p>M/s. Anqing Yipak Packaging Material Co., Ltd., Intersection of Fangxing Road, and Huangpu Road, Development Zone, Anqing, 246008 Anhui, P.R.China</p> <p><b>LOA Validity:</b> 26-02-2028 (Copy)</p> <p><b>FSC: China</b> <b>Validity:</b>23-02-2027 (Copy)</p> <p><b>ISO Validity:</b></p>	<p><b>Brand name:</b></p> <p><b>MaxiCare</b></p> <p>Generic Name: Sterilization Packaging and Control Products</p> <p>Class-A</p> <p><b>Shelf life: 05</b> years</p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.</p> <p>Firm shall submit codes &amp; sizes details,</p> <p>Notarized copy of ISO 13485 certificate and LOA.</p>
313.	<p><b>Applicant Name:</b></p> <p>Quantum, Office No.</p>	<p>M/s. BTL Industries JSC, 30 Peshterskos House blvd Plovdiv 4002 Bulgaria</p>	<p><b>Brand name:</b></p> <p><b>Neutral Electrode</b></p>	<p>Deffered for following.</p>

	301, 3 <sup>rd</sup> Floor Building No. 2C, 34 <sup>th</sup> Street, Tauheed Commercial Area, Phase V, DHA, Karachi.  ELI-01368  Date of R&I 07-03-2025  <b>Fee Details:6000</b> <b>Paid Fee:</b> <b>71054796221</b>	<b>LOA Validity:</b> 23-04-2026 (Copy)  <b>FSC:UK</b> <b>Validity:</b> 14-04-2025 (Copy)  <b>ISO Validity: 08-04-2027</b> <b>(copy)</b>  <b>EC Certificate:</b> Validity: 31-07-2026 (copy)	<b>(BTL-NE-170)</b>  Generic Name: Patient Return Electrode or Neutral electrode  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Valid, legalized FSC issued by concerned regulatory authority that mentioning the applied product.  Firm shall submit codes & sizes details,  Notarized copy of ISO 13485 certificate and LOA.  Brief description of the product.
314.	<b>Applicant Name:</b>  Quantum, Office No. 301, 3 <sup>rd</sup> Floor Building No. 2C, 34 <sup>th</sup> Street, Tauheed Commercial Area, Phase V, DHA, Karachi.  ELI-01368  Date of R&I 07-03-2025  <b>Fee Details:6000</b> <b>Paid Fee:</b> <b>2966733791</b>	M/s. BTL Industries JSC, 30 Peshterskos House blvd Plovdiv 4002 Bulgaria  <b>LOA Validity:</b> 23-04-2026 (Copy)  <b>FSC:UK</b> <b>Validity:</b> 14-04-2025 (Copy)  <b>ISO Validity: 08-04-2027</b> <b>(copy)</b>  <b>EC Certificate:</b> Validity: 31-07-2026 (copy)	<b>Brand name:</b>  <b>Emface Fore Head</b> <b>Applicator, Check</b> <b>Applicator and</b> <b>Submentum</b> <b>applicator (BTL</b> <b>Industries)</b>  Generic Name: Emface forehead applicator, Cheek applicator Submentum applicator  Class-A  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Valid, legalized FSC issued by concerned regulatory authority mentioning the applied product.  Firm shall submit codes & sizes details,  Notarized copy of ISO 13485 certificate, LOA.  Brief description of the product.
315.	<b>Applicant Name:</b>  Qasim Traders, Shop No. 7 Medicine Center, Kuchi Gali No. 1, Marriot Road, Karachi  (ELI-00832)  Date of R&I 18-03-2025  <b>Fee Details:31000</b>	M/s. Jiangsu Kangyou Medical Instrument Co., Ltd., Tangzhuang, Yaotang Town, Jintan City Jiangsu Province, China  <b>LOA Validity:</b> 26-12-2030 (Original Notarized)  <b>FSC:China</b> <b>Validity:</b> 05-07-2026 (Original Notarized)	<b>Brand name:</b>  <b>Pacco Plus</b>  Generic Name: Sterile Hypodermic Needles for Single Use  Class-B  <b>Shelf life: 05 years</b>  Models/ Specification:	Deffered for following.  Firm shall submit valid ISO 13485 Certificate.  Valid EC Certificate.  Legalized/apostile FSC

	<b>Paid Fee: 005031954</b>	<b>ISO Validity: 30-06-2025</b> <b>(Original Notarized)</b>  <b>EC Certificate:</b> Validity: 26-05-2024 (Original Notarized)	1ml, 2ml, 3ml, 5ml , 10ml, 20ml, 30ml , 50ml ( needles: 0.3, 0.33, 0.36 0.4, 0.45 , 0.5, 0.55, 0.6, 0.7, 0.8, 0.9, 1.1, 1.2	
<b>316.</b>	<b>Applicant Name:</b>  Sawanki & Co., C-211, Sector 35-A, Korangi Township, Karachi  (ELI-00521)  Date of R&I 06-03-2025  <b>Fee Details:31,000</b> <b>Paid Fee:</b> <b>74480240301</b>	M/s. Super Health Medical (Qingdao) Co. Ltd., No. 236, Heyuan Road, High-tech Zone Qingdao 266510 Shandong P.R. China  <b>LOA Validity:</b> 10-11-2029 (Original Notarized)  <b>FSC: China</b> <b>Validity :</b> 27-04-2025 (Original Notarized)  <b>ISO Validity: 29-03-2026</b> <b>(Original Notarized)</b>  <b>EC Certificate:</b>	<b>Brand name:</b>  KS IV Catheter Disposable Intravenous Catheter  Generic Name: Disposable Intravenous Catheter  Class-B  <b>Shelf life: 3 years</b>  Models/ Specification: Regular Type (Three way) Regular Type (Straight) Positive Pressure Type II Positive Pressure Type II (Straight)  26G, 24G, 22G, 20G, 18G	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority.  Valid, notarized EC Certificate.  <b>JUSTIFICATION</b> <b>FOR</b> applied multiple model and sizes in one applications
<b>317.</b>	<b>Applicant Name:</b>  Sawanki & Co., C-211, Sector 35-A, Korangi Township, Karachi  (ELI-00521)  Date of R&I 06-03-2025  <b>Fee Details:31,000</b> <b>Paid Fee:</b> <b>1971327684</b>	M/s. Chongqing Moffy Innovation Technology Co. Ltd., No. 292 Jingdongfang Rd. Beidei Dist Chongqing, China  <b>LOA Issue:</b> 04-09-2024 (Original Notarized) Validity not mentioned.  <b>FSC China</b> Validity:13-03-2026  <b>ISO Validity: 22-02-2026</b> <b>(Original Notarized)</b>	<b>Brand name:</b>  Respiratory Muscle Trainer  Generic Name: Mucus Removal Device  Class-A  <b>Shelf life: 5 years</b>  Models/ Specification: MFBT-01, MFBT-02, MFBT-04	Deffered for following.  submit valid, legalized FSC Certificate issued by concerned regulatory authority.  multiple model and sizes in one applications so Justification of multiple model / types / sizes required.

318.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>  ELI-00852  Date of R&I 28-04-2025  <b>Fee Details:6,000 Paid Fee: 18987466279</b>	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.  <b>LOA Validity:</b> 20-04-2030  <b>FSC : China</b> Validity:26-05-2025  <b>ISO Validity:</b> 31-07-2026  EC Certificate:	<b>Brand name:</b>  Ardent Seliva Ejector  <b>Generic Name:</b> Seliva Ejector  Class-A  <b>Shelf life:</b>  Models/ Specification:	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.  Codes and sizes.  Shelf life.
319.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>  ELI-00852  Date of R&I 28-04-2025  <b>Fee Details:6,000 Paid Fee: 87159908095</b>	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.  <b>LOA Validity:</b> 20-04-2030  <b>FSC : China</b> Validity:26-05-2025  <b>ISO Validity:</b> 31-07-2026  EC Certificate: Validity	<b>Brand name:</b>  Ardent Dental Bibflim  <b>Generic Name:</b> Dental Bib  Class-A  <b>Shelf life:</b>  Models/ Specification:	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.  Codes and sizes.  Shelf life.
320.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>  ELI-00852  Date of R&I 28-04-2025	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.  <b>LOA Issue:</b> 20-04-2030  <b>FSC : China</b>	<b>Brand name:</b>  Ardent Barior Film  <b>Generic Name:</b> Barior Film  Class-A  <b>Shelf life:</b>  Models/ Specification: 10cm x 15xm, 1200pcs	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.



	<b>Fee Details:6,000</b> <b>Paid Fee:</b> <b>112759862958</b>	Validity:26-05-2025 <b>ISO Validity:</b> 31-07-2026  EC Certificate: Validity		Product Codes  Shelf life.
321.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>  ELI-00852  Date of R&I 28-04-2025  <b>Fee Details:6,000</b> <b>Paid Fee:</b> <b>3044016484</b>	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.  <b>LOA Issue:</b> 20-04-2030  <b>FSC : China</b> Validity:26-05-2025  <b>ISO Validity:</b> 31-07-2026  EC Certificate: Validity	<b>Brand name:</b>  Ardent Cotton Roll  Generic Name: Cotton Roll  Class-A  <b>Shelf life:</b>  Models/ Specification:	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.  Codes and sizes.  Shelf life.
322.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>  ELI-00852  Date of R&I 28-04-2025  <b>Fee Details:6,000</b> <b>Paid Fee:</b> <b>0258844764</b>	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.  <b>LOA Issue:</b> 20-04-2030  <b>FSC : China</b> Validity:26-05-2025  <b>ISO Validity:</b> 31-07-2026  EC Certificate: Validity	<b>Brand name:</b>  Ardent Pouchs & Roll  Generic Name: Pouchs & Roll  Class-A  <b>Shelf life:</b>  Models/ Specification:	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.  Codes and sizes.  Shelf life.  Justification of different products in one application
323.	<b>Al Razzaq Dental Supply,</b>  <b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b>	Hefei Mlush Sanitary Product Company Ltd.,  Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui	<b>Brand name:</b>  Ardent Dental Needle  Generic Name: Dental Needle	Deffered for following.  Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory

	<p>ELI-00852</p> <p>Date of R&amp;I 28-04-2025</p> <p><b>Fee Details:6,000</b> <b>Paid Fee: 39654834</b></p>	<p>Province, China.</p> <p><b>LOA validity:</b> 20-04-2030</p> <p><b>FSC : China</b> Validity:26-05-2025</p> <p><b>ISO Validity:</b> 31-07-2026</p> <p>EC Certificate: Validity</p>	<p>Class-A</p> <p><b>Shelf life:</b></p> <p>Models/ Specification: 27G(0.4mm) 30G(0.3mm)</p>	<p>authority showing the applied product.</p> <p>Notarized copy of ISO certificate, LOA letter.</p> <p>Shelf life.</p>
324.	<p><b>Al Razzaq Dental Supply,</b></p> <p><b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b></p> <p>ELI-00852</p> <p>Date of R&amp;I 28-04-2025</p> <p><b>Fee Details:6,000</b> <b>Paid Fee: 1937044660</b></p>	<p>Hefei Mlush Sanitary Product Company Ltd.,</p> <p>Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.</p> <p><b>LOA validity:</b> 20-04-2030</p> <p><b>FSC : China</b> Validity:26-05-2025</p> <p><b>ISO Validity:</b> 31-07-2026</p> <p>EC Certificate: Validity</p>	<p><b>Brand name:</b></p> <p>Ardent Non Woen Sponge</p> <p>Generic Name: Non Woven Sponge</p> <p>Class-A</p> <p><b>Shelf life:</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.</p> <p>Notarized copy of ISO certificate, LOA letter.</p> <p>Codes and sizes.</p> <p>Shelf life.</p>
325.	<p><b>Al Razzaq Dental Supply,</b></p> <p><b>Opp Nishter Dental College of Dentistry, Distric Jail Road Multan.</b></p> <p>ELI-00852</p> <p>Date of R&amp;I 28-04-2025</p> <p><b>Fee Details:6,000</b> <b>Paid Fee: 45778589470</b></p>	<p>Hefei Mlush Sanitary Product Company Ltd.,</p> <p>Address: West of Wei A Road, Yaohai Industrial Park Xinzhan District, Hefei City, Anhui Province, China.</p> <p><b>LOA validity:</b> 20-04-2030</p> <p><b>FSC : China</b> Validity:26-05-2025</p> <p><b>ISO Validity:</b> 31-07-2026</p> <p>EC Certificate: Validity</p>	<p><b>Brand name:</b></p> <p>Ardent Disposable Examination Kit</p> <p>Generic Name: Disposable Dental Examination Kit</p> <p>Class-A</p> <p><b>Shelf life:</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Firm shall submit valid, legalized FSC Certificate issued by concerned regulatory authority showing the applied product.</p> <p>Notarized copy of ISO certificate, LOA letter.</p> <p>Codes and sizes.</p> <p>Shelf life. Justification of class</p>
326.	<p><b>Snibe Diagnostic Pakistan (SMC-Private) Limited,</b></p>	<p>Shenzhen New Industries Biomedical Engineering Co.,Ltd., (SNIBE Co., LTd.,)</p>	<p><b>Brand name:</b></p> <p>Satlars</p>	<p>Deffered for following.</p>

	<b>Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</b>  ELI-01036  Date of R&I 30-04-2025  <b>Fee Details:6,000</b> <b>Paid Fee: 83922473</b>	No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R.China.  <b>LOA Issue:</b> 03-12-2029  <b>FSC : China</b> Validity:03-11-2026 FSC: Germany Issue date: 30-01-2025  <b>ISO Validity: 31-12-2025</b>  EC Certificate: Validity:14-12-2025	Generic Name: Laboratory Automation System  Class-A  <b>Shelf life: 10 years</b>  Models/ Specification:	Firm shall submit legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Differential fee for system  Notarized copy of ISO certificate, LOA letter.  Codes/ sizes. Justification of class Brief description of applied product.
327.	<b>Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1<sup>st</sup> Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi</b>  ELI-01036  Date of R&I 30-04-2025  <b>Fee Details:6,000</b> <b>Paid Fee: 227952009</b>	Shenzhen New Industries Biomedical Engineering Co.,Ltd., (SNIBE Co., LTd.,) No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R.China.  <b>LOA Issue:</b> 03-12-2029  <b>FSC : China</b> Validity:03-11-2026 FSC: Germany Issue date: 30-01-2025  <b>ISO Validity: 31-12-2025</b>  EC Certificate: Validity:14-12-2025	<b>Brand name:</b>  Biossays  Generic Name: Automatic Biochemistry Analyzer  Class-A  <b>Shelf life:</b> <b>10 years</b>  Models/ Specification:	Deffered for following.  Firm shall submit legalized FSC Certificate issued by concerned regulatory authority showing the applied product.  Notarized copy of ISO certificate, LOA letter.  Codes and sizes.
328.	Applicant Name: SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan  (ELI-00582)  Application submitted dated : 27.10.2021  Fee details: Paid Fee: Rs. 5000 Challan No : 426858362712	Name of Manufacturer: ISD Meditech SDN BHD No. 3, Jalan PJS 3/2, Taman Medan, 46000 Petaling Jaya, Selangor, Malaysia  LOA Validity: 01.08.2025  FSC: Malaysia Validity 16.08.2027 copy  ISO Validity: 30.11.2025  CE validity: N/A	Brand Name: SKYGEL  Generic Name: ULTRASOUND GEL  Class : A  Shelf life : 36 months	Deffered for following.  Legalized FSC.  Notarized copy of ISO certificate & LOA letter.  Sizes/codes

	Challan Date: 26.10.2021			
<b>329.</b>	<p>Applicant Name: SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan</p> <p>(ELI-00582)</p> <p>Application submitted dated : 27.10.2021</p> <p>Fee details: Paid Fee: Rs. 5000 Challan No : 572322087803 Challan Date: 26.10.2021</p>	<p>Name of Manufacturer: ISD Meditech SDN BHD No. 3, Jalan PJS 3/2, Taman Medan, 46000 Petaling Jaya, Selangor, Malaysia</p> <p>LOA Validity: 01.08.2025</p> <p>FSC: Malaysia Validity 16.08.2027</p> <p>ISO Validity: 30.11.2025</p> <p>CE validity: N/A</p>	<p>Brand Name: SKYGEL</p> <p>Generic Name: ECG GEL</p> <p>Class : A</p> <p>Shelf life : 36 months</p>	<p>Deffered for following.</p> <p>Legalized FSC.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Sizes/codes</p>
<b>330.</b>	<p>Applicant Name: SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan</p> <p>(ELI-00582)</p> <p>Application submitted dated : 27.10.2021</p> <p>Fee details: Paid Fee: Rs. 5000 Challan No : 0514954303 Challan Date: 26.10.2021</p>	<p>Name of Manufacturer: TELE-PAPER (M) Sdn Bhd, Malaysia</p> <p>LOA Validity: 02.07.2026</p> <p>FSC: Malaysia Validity: 25.08.2026</p> <p>ISO Validity: 10.12.2025</p> <p>EC validity: 31.12.2028</p>	<p>Brand Name: Sonomed</p> <p>Generic Name: ECG Paper</p> <p>Class : A</p> <p>Shelf life : 36 months</p>	<p>Deffered for following.</p> <p>Legalized FSC.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Codes/sizes</p>
<b>331.</b>	<p>Applicant Name: SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan</p> <p>(ELI-00582)</p> <p>Application</p>	<p>Name of Manufacturer: TELE-PAPER (M) Sdn Bhd Malaysia</p> <p>LOA Validity: 02.07.2026</p> <p>FSC: Malaysia Validity: 25.08.2026</p>	<p>Brand Name: Sonomed</p> <p>Generic Name: CTG Paper</p> <p>Class : A</p>	<p>Deffered for following.</p> <p>Legalized FSC.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Codes/sizes</p>

	<p>submitted dated : 27.10.2021</p> <p>Fee details: Paid Fee: Rs. 5000 Challan No : 7878029717 Challan Date: 26.10.2021</p>	<p>ISO Validity: 10.12.2025</p> <p>EC validity: 31.12.2028</p>	<p>Shelf life : 36 months</p>	
<b>332.</b>	<p>Applicant Name: SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan</p> <p>(ELI-00582)</p> <p>Application submitted dated : 27.10.2021</p> <p>Fee details: Paid Fee: Rs. 5000 Challan No : 3309825914 Challan Date: 26.10.2021</p>	<p>Name of Manufacturer: TELE-PAPER (M) Sdn Bhd Malaysia</p> <p>LOA Validity: 02.07.2026</p> <p>FSC: Malaysia Validity: 25.08.2026</p> <p>ISO Validity: 10.12.2025</p> <p>EC validity: 31.12.2028</p>	<p>Brand Name: Sonomed</p> <p>Generic Name: ULTRASOUND THERMAL PAPER FOR VIDEO PRINTER (THERMAL PRINT MEDIA)</p> <p>Class : A</p> <p>Shelf life : 36 months</p>	<p>Deffered for following.</p> <p>Legalized FSC.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Codes/sizes</p>
<b>333.</b>	<p>Applicant Name: MH Pharma, Flat No. 1118, 11<sup>th</sup> Floor, Eden Heights, 6 Main Gulberg, Jail Road, Lahore</p> <p>(ELI-00720)</p> <p>R&amp;I Date : 24-04- 2025</p> <p>Fee details: Paid Fee: Rs. 6000 Challan No : 1617353298</p>	<p>Shanghai Intco Electrode Manufacturing Co., Ltd., No. 1358 Hubin Rd, Fengxian District, Shanghai, 201417, P.R. China</p> <p>LOA Validity: 30-06-2026</p> <p>FSC: China Validity: 19-01-2025</p> <p>FSC: USA Validity: 28-10-2026</p> <p>ISO Validity: 17-11-2025</p>	<p>Brand Name: Intco Med</p> <p>Generic Name: Medical Disposable ECG Electrodes</p> <p>Class-A</p> <p><b>Shelf life: 2 years</b></p> <p>Models/ Specification: 35mm, 50mm, 55mm</p> <p>Prewired Neonatal Electrodes</p>	<p>Deffered for following.</p> <p>Valid Legalized FSC certificate.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Justification regarding applying multiple models in single application.</p>

		EC validity:	Resting Tab Electrodes	
<b>334.</b>	<p>Applicant Name: Bio Links International, 243 Ground Floor Rewaz Garden Lahore, Pakistan.</p> <p>(ELI-00933)</p> <p>R&amp;I Date : 28-04-2025</p> <p>Fee details: Paid Fee: Rs. 6000 Challan No : 20375870286</p>	<p>Eaglenos Sciences, Inc. B2-2, Treehouse Headquarters Cluster, No. 73 Tanmi Road Jiangbei New Area, Nanjing, Jiangsu 210044, China</p> <p>LOA Validity: 20-03-2030</p> <p>FSC: China Validity: 26-05-2026</p> <p>ISO Validity: 25-05-2027</p> <p>EC validity:</p>	<p>Brand Name: Eaglenos</p> <p>Generic Name: Blood Gas Analyzer EN102</p> <p>Class-A</p> <p><b>Shelf life: 2 years</b></p> <p>Models/ Specification: EG-110、 EG-120、 EG-130、 EG-140、 EN102</p>	<p>Deffered for following.</p> <p>Legalized FSC certificate.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Justification regarding applying multiple models in single application</p> <p>Justification of class</p>
<b>335.</b>	<p>Applicant Name: GeenTech International , Mumtaz Centre, Suit No. 03, 2<sup>nd</sup> Floor 15- A Shahrah-e-Fatima, Lahore</p> <p>Godown Address: House No. 04-05, Street No. 01, Hassan Kot, Dubai Town, Raiwind Road, Lahore</p> <p>(ELI-01180)</p> <p>R&amp;I Date : 28-04-2025</p> <p>Fee details: Paid Fee: Rs. 6000 Challan No : 97236861139</p>	<p>Minitube GmbH HauptstraBe 41, 84184 Tiefenbach, Germany</p> <p>LOA Validity: 01-05-2025</p> <p>FSC: Germany Issue date: 09-06-2022</p> <p>ISO Validity:</p> <p>EC validity:</p>	<p>Brand Name: QuickLock AI Gun</p> <p>Generic Name: QuickLock AI Gun</p> <p>Class-A</p> <p><b>Shelf life:</b></p> <p>Models/ Specification:</p>	<p>Deffered for following.</p> <p>Legalized FSC certificate.</p> <p>Valid, Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Shelf life. Generic name Models / codes</p> <p>Brief description</p>

<b>336.</b>	<p>Applicant Name: Muller &amp; Phipps Pakistan (Pvt) Ltd, uzma Court, Main Clifton Road, Karachi</p> <p>(ELI-00030)</p> <p>R&amp;I Date : 23-04- 2025</p> <p>Fee details: Paid Fee: Rs. 6000 Challan No : 97202620</p>	<p>Twin Catalyst Sdn Bhd, Located at 37 Jalan Dr Wong Soon Kai 96000 Sibu, Sarawak Malaysia</p> <p>LOA Validity: 20-11-2029</p> <p>FSC: Malaysia Validity: 03-10-2026</p> <p>ISO Validity: 21-03-2024</p> <p>EC validity:</p>	<p>Brand Name: Wondaleaf Urifyx</p> <p>Generic Name: External Urinary Catheter</p> <p>Class-A</p> <p><b>Shelf life: 3 Years</b></p> <p>Models/ Specification: R Series U Series</p>	<p>Deffered for following.</p> <p>Legalized FSC certificate.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Justification regarding applying multiple types in single application</p> <p>Justification of class</p> <p>Codes/sizes</p>
<b>337.</b>	<p>Biocare Pharma, B- 175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi (ELI-00634</p> <p>Date of R&amp;I 18-04-2025</p> <p>Fee Details: Paid Fee: 6030/- Fee Challan No: 47520053284</p>	<p>Hefei Jingpu Sensor Technology Co., Ltd, Floor 2- 4, No. 2 Keyna Building, Jinhui Photoelectric Industrial Park, Intersection of Pahie Avenue, and Jixin Road, Economic Development Zone, Fexi County, Hefei, China</p> <p>LOA Validity: Issue date: 14-03-2027 (Copy)</p> <p>FSC: China Validity: 13-08-2025 (Copy)</p> <p>ISO13485: nil</p> <p>EC validity: 25-09-2028 (Copy)</p>	<p>Brand Name:</p> <p>Medical Temperature Sensor</p> <p>Class: A</p> <p>Shelf Life : 5 Years</p> <p>Applied as: Single</p> <p>Models/ Specification</p>	<p>Deffered for following.</p> <p>Legalized FSC certificate.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Codes / sizes.</p>
<b>338.</b>	<p>Health Tec,  H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan.</p> <p>ELI-00046</p> <p>Date of R&amp; I</p>	<p>M/s Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt</p> <p><b>LOA validity:</b> 25-03-2026 (Copy)</p> <p><b>FSC validity (Egypt):</b> 07-04- 2027 (Copy)</p>	<p>HT-Ultraflon I.V. Cannula</p> <p><b>Generic Name:</b> Intravenous Cannula with Injection port</p> <p>Code/Sizes: 14G, 16G, 18G, 20G, 22G, 24G &amp; 26G</p>	<p>Deffered for following.</p> <p>Original Legalized FSC certificate from concerned regulatory authority.</p> <p>Notarized copy of ISO certificate &amp; LOA letter.</p>

	03-06-2025 Fee: PKR 31,000/- Slip # 558915420 Dated: N/A	<b>ISO validity:</b> 20-05-2026 (Copy) <b>EC Validity:</b> 26-05-2024 (Copy)	Class-B  <b>Shelf life:</b> 05 Years	Notarized valid EC certificate.
<b>339.</b>	Mana & Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi  <b>ELI-00098</b>  Date of R& I 05-05-2025  Fee: PKR 31,000/- Slip # 3669816101 <b>Dated:</b> 29-11-2024	M/s Jiangxi Huali Medical Instrument Co., Ltd., Yudu Industrial Zone 342300 Ganzhou, Jingxi China  <b>LOA validity:</b> 30-09-2029  <b>FSC validity (China):</b> 27-10- 2026 (Copy)  <b>ISO validity:</b> 20-04-2026 (Copy)  <b>EC Validity:</b> 26-05-2024	Medicare  I.V. Catheter Injection Port  Code/Sizes: 14G, 16G, 18G, 20G, 22G, 24G & 26G  Class-B  <b>Shelf life:</b> 05 Years	Deffered for following.  Original Legalized FSC certificate from concerned regulatory authority.  Valid, Notarized copy of ISO certificate & LOA letter.  Valid Notarized EC certificate.
<b>340.</b>	Mana & Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi  ELI-00098  Date of R& I 05-05-2025  Fee: PKR 31,000/- Slip # 90727353943 <b>Dated:</b> 29-11-2024	Jiangxi Huali Medical Instrument Co., Ltd., Yudu Industrial Zone 342300 Ganzhou, Jingxi China  <b>LOA validity:</b> 30-09-2029  <b>FSC validity (China):</b> 27-10- 2026 (Copy)  <b>ISO validity:</b> 20-04-2026 (Copy)  <b>EC Validity:</b> 26-05-2024	Medicare  I.V Catheter Wings- Like  Code/Sizes:  14G, 16G, 18G, 20G, 22G, 24G & 26G  Class-B  <b>Shelf life:</b> 05 Years	Deffered for following.  Original Legalized FSC certificate from concerned regulatory authority.  Valid, Notarized copy of ISO certificate & LOA letter.  Valid Notarized EC certificate.
<b>341.</b>	Mana & Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi  ELI-00098  Date of R& I 05-05-2025  Fee: PKR 31,000/- Slip # 645816439751 <b>Dated:</b> 29-11-2024	Jiangxi Huali Medical Instrument Co., Ltd., Yudu Industrial Zone 342300 Ganzhou, Jingxi China  <b>LOA validity:</b> 30-09-2029  <b>FSC validity (China):</b> 27-10- 2026 (Copy)  <b>ISO validity:</b> 20-04-2026 (Copy)  <b>EC Validity:</b> 26-05-2024	Medicare  I.V. Catheter Pan-Like  Code/Sizes:  14G, 16G, 18G, 20G, 22G, 24G & 26G  Class-B  <b>Shelf life:</b> 05 Years	Deffered for following.  Original Legalized FSC certificate from concerned regulatory authority.  Valid, Notarized copy of ISO certificate & LOA letter.  Valid Notarized EC certificate



342.	<p>Mana &amp; Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi</p> <p>ELI-00098</p> <p>Date of R&amp; I 05-04-2025</p> <p>Fee: PKR 15,000/- Slip # 647488886496 <b>Dated:</b> 25-11-2024</p>	<p>Jiangxi Huali Medical Instrument Co., Ltd., Yudu Industrial Zone 342300 Ganzhou, Jingxi China</p> <p><b>LOA validity:</b> 30-09-2029</p> <p><b>FSC validity (China):</b> 27-10-2026 (Copy)</p> <p><b>ISO validity:</b> 20-04-2026 (Copy)</p> <p><b>EC Validity:</b> 26-05-2024</p>	<p>Medicare</p> <p>Sterile I.V. Catheter</p> <p>Code/Sizes:</p> <p>14G, 16G, 18G, 20G, 22G, 24G &amp; 26G</p> <p>Class-B</p> <p><b>Shelf life:</b> 05 Years</p>	<p>Deffered for following.</p> <p>Original Legalized FSC certificate from concerned regulatory authority.</p> <p>Valid, Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Valid Notarized EC certificate</p> <p>Type of canula not mentioned</p>
343.	<p>Endoaid Biomedica, 85-D, DHA EME Sector, Phase XII, Multan Road, Lahore</p> <p>ELI-00169</p> <p>Date of R&amp; I 04-07-2025</p> <p>Fee: PKR 6,000/- (Copy) Slip # 683136821917 <b>Dated:</b> N/A</p>	<p>M/s Hangzhou Yniner Pharmaceutical Co. Ltd., No. 42, Yangcheng Road, Nanyang Street, Xiaoshan, Hangzhou, Zhejiang, China.</p> <p><b>LOA validity:</b> 08-06-2045</p> <p><b>FSC validity (China):</b> 30-10-2025 (Copy)</p> <p><b>ISO validity:</b> 09-12-2025 (Copy)</p> <p><b>EC Validity:</b> N/A</p>	<p>RSKINS</p> <p>IV Cannula Wound Dressing</p> <p>Code/Sizes: 4.4cm x 4.4cm, 5cm x 7cm, 5cm x 7.5cm, 6cm x 7cm, 6cm x 8cm, 9cm x 10cm, 9cm x 15cm, 9cm x 20cm, 9cm x 25cm, 9cm x 30cm, 9cm x 35cm, 10cm x 10cm, 10cm x 12cm, 10cm x 15cm, 10cm x 20cm, 10cm x 25cm, 10cm x 30cm, 10cm x 35cm</p> <p>Class-B</p> <p><b>Shelf life:</b> 05 Years</p>	<p>Deffered for following.</p> <p>Original Legalized FSC certificate from concerned regulatory authority.</p> <p>Valid, Notarized copy of ISO certificate &amp; LOA letter.</p> <p>Valid Notarized EC certificate</p>
344.	<p>M/s Sehat Medical Devices (Pvt.) Limited, Plot No. 473, Sundar Industrial Estate, Lahore</p> <p>Date of R&amp; I 10-07-2025</p> <p>Fee: PKR 31,000/-</p>	<p>M/s Weihai Jierui Medical Products Co. Ltd., No. 6-1 Weigao West Road, Weihai, Torch High-Tech, Science Park 264210 Weihai, Shandong, China.</p> <p><b><u>apostile FSC China chamber of commerce validity:</u></b> <b>12-05-2027</b></p> <p><b><u>FSC China regulatory</u></b></p>	<p>SMD Disposable I.V Catheter</p> <p>Peripheral Intravenous Catheter</p> <p>Code/Sizes: 14G, 16G, 18G, 20G, 22G, 24G &amp; 26G</p>	<p>Approved all types as firm submitted separate application Form and fee. Letter will be issued after submission of FSC from concerned regulatory authority.</p>

	Slip # 46035652390 <b>Dated:</b> 25-06-2025	<b><u>authority validity copy:</u></b> <b>11-11-2026</b>  <b><u>ISO 13485 VALIDITY</u></b> <b><u>Notrized:</u></b> <b>06-05-2028</b>  <b><u>LOA VALIDITY nortized:</u></b> <b>27-05-2030</b>  <b><u>EC CERTIFICATE</u></b> <b><u>VALIDITY notrized:</u></b> <b>31-12-2028</b>	Needle Lengths 19mm, 25mm, 29mm, 32mm & 38mm  Class-B  <b>Shelf life:</b> 03 Years	
<b>345.</b>	M/s United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi  (ELI-00293)  Date of R& I 22-05-2025  Fee: PKR 31,000/- Slip # 76300673917 <b>Dated:</b> 19-05-2025	M/s Jiangsu Webest Medical Prouduct Co., Ltd. No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu, People's Republic of China  <b>LOA validity:</b> 15-12-2029  <b>FSC issuance (EU):</b> 17-09-2023  <b>ISO validity:</b> 31-05-2026 (Copy)  <b>EC Validity:</b> N/A	Starmed I.V. Cannula for Single Use (with Injection Port & Wings)  Code/Sizes: 16-480 (UMDN)  26G 0.6x19\ 24G 0.7x19\ 22G 0.9x25\ 20G 1.1 x 32\ 18G 1.3 x 32\ 18G 1.3x45\ 16G 1.7 x 51\ 14G 2.1 x 51  Class-B  <b>Shelf life: 5 Years</b>	Deffered for following.  Original Legalized FSC certificate from concerned regulatory authority.  Notarized copy of ISO certificate & LOA letter.  Notarized EC certificate
<b>346.</b>	Biomed Solution, House NO. 221-H, Ist Floor Block 2, P.E.C.H.S, Karachi  ELI-01306  Date of R& I 30-05-2025  Fee: PKR 31,000/- Slip # 343729908517 <b>Dated:</b> 19-05-2025	M/s JMI Syringes & Medical Devices Ltd., Noapara, Chaudogram Cumilla, Bangladesh  <b>LOA validity:</b> 31-06-2029  <b>FSC issuance (Bangladesh):</b> 18-12-2023  <b>ISO validity:</b> 22-10-2025  <b>EC Validity:</b> N/A	MI IV Cannula (with Wings and injection Port)  IV Cannula (with wings and injection port)  Code/Sizes: [18G, 20G, 22G, 24G]  Class-B  <b>Shelf life:</b>	Deffered for following.  Original Legalized FSC certificate from concerned regulatory authority.  Valid, Notarized copy of ISO certificate & LOA letter.  Notarized EC certificate  Shelf life.
<b>347.</b>	Absolute Health Care Systems (SMC-Pvt) Ltd., Unit 6, 2F Khyber 3 G-15 Markaz Islambad	<b><u>Legal Manufacturer:</u></b> Ultra For Medical Products Co., (Ultramed), Head Office: 64 Nakhla EL	UltraFlowin  I.V Cannula with Luer Lock & Injection Port	Approved.

	<p>ELI-01457  DRAP Application  Submission Date:  30-05-2025  DRAP Fees:  Rs: 31,000/-  Challan No.  5073330900  Dated: N/A</p>	<p>Motaiy St, Triumph Square,  Cairo, Egypt</p> <p>Factory : Arab El-Awamer  Industrial Zone, Abnoub,  Assiut, Egypt.</p> <p><b>FSC validity (Egypt)</b>  09-01-2027</p> <p><b>EC validity:</b>  <b>31-12-2028</b></p> <p><b>ISO validity:</b>  20-05-2026</p>	<p>Class: B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Code:  6,6.5,7,7.5,8.0,  8.5 &amp; 9.0</p> <p>14G, 16G, 18G, 20G,  22G, 24G, 26G</p>	
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**Item No. IV: DEFERRED APPLICATION FOR REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<p>M/s  MOODY GLOBAL SERVICES  Address:Office No.  14,2ndFloor,  Mujahid Plaza, Blue  area, Islamabad.  License No.  ELI-00926  FEE Receipt No.  25000 18.8.22  R&amp;I 19.8.22  8Z1-PSH-8YWZ</p>	<p>Name:  BMC Medical  Co.,Ltd.,China Room110  Tower AFengyu  Building,No.115  Fucheng Road Haidian,  100036 Beijing,  People's Republic of  China.  FSC Country of origin:  China  Validity:01-01-2024</p> <p>LOA validity:  02-03-2027</p> <p>ISO 13485 VALIDITY  01.03.23</p>	<p>Brand name:  BMC  Generic name:  RESmart GII  Auto CPAP  System  Size/specification:  E-20A-H-O  E-20-AJ-H-O</p> <p>Class: B</p> <p>Shelf life:  5Years</p>	Approved E-20A-H-O
2.	<p>MOODY Global  Services</p> <p>Office address:  Office No. 14,  2nd Floor,  Mujahid Plaza,  Blue area,  Islamabad</p> <p>Licence No. ELI-</p>	<p>Etiometry Inc.,  Address: 280 Summer Street,  Fourth  Floor Boston, MA, USA</p> <p>FSC: UK  Validity: 28-02-2028</p> <p>LOA Validity:  30-06-2029</p>	<p>Etiometry Platform  software</p> <p>Generic Name;  Clinical Decision  Support Software</p> <p>Class A</p> <p>Shelf Life: NA.  Stability studies do not</p>	Deffered for submission of revised application Form and fee for Class-B.

	00926 Date of issue: 17-05-2022	ISO 13485 Validity: 28-02-2027.	apply to software because software does not degrade over time like physical products.  Model name and its version: (As per FSC) T3 Platform Software: DAV5.4 RAE 10.0	
3.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: HE4 human epididymal protein 4 (HE4) reagent Kit and HE4 Control Class-C Shelf life: 18 Months  Codes: 50 tests, 100 tests, 2x 50 tests, 2x 100 tests.	Deffered submission for of verifiable fee.
4.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Maccura Product Name: Anti-Treponema pallidum CLIA Kit and Anti- TP Control Class-C Shelf life: 18 Months  Codes: Kit- 50 tests, 100 tests, 2*50 tests, 2*100 tests. Control-1-2: 1.0ml*2	Deffered submission for of verifiable fee.
5.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: TOXO IgM Antibody Chemiluminescent Immunoassay Kit Class-C Shelf life: 12 Months  Codes/sizes: 50 tests, 2x100 tests	Deffered submission for of verifiable fee.
6.	Name Moody Global Services Address of Importer	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co.,</u>	Brand Name: Maccura Product Name: Cardiac Markers Control Plus	Deffered submission for of verifiable fee.

	No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	<u>Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Level 1, level 2, level 3  Class-C  Shelf life: 12 Months  Codes/sizes: Level 1: 3.0ml*1 Level 1: 3.0ml*3 Level 2: 3.0ml*1 Level 2: 3.0ml*3 Level 3: 3.0ml*1 Level 3: 3.0ml*3	
7.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Herpes simplex virus-2 IgG Antibody Chemiluminescent Immunoassay Kit  Class-C  Shelf life: 13 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests (Control included in all)	Deffered submission verifiable fee. for of
8.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Cancer Antigen CA 19-9 (CLIA)  Class-C  Shelf life: 18 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission verifiable fee. for of
9.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Herpes simplex virus-1 IgG Antibody Chemiluminescent Immunoassay Kit  Class-C  Shelf life: 12 Months  Codes/sizes:	Deffered submission verifiable fee. for of

			50 tests, 100 tests, 2x50 tests, 2x100 tests (Control included in all)	
10.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	<b>Brand Name:</b> Maccura <b>Product Name:</b> Chemiluminescence Immunoassay multianalytes Control Level 1,2  Class-C  Shelf life: 18 Months  Codes/sizes: Level 1: 5.0mL x 1 Level 1: 5.0mL x 6 Level 1: 5.0mL x 12 Level 2: 5.0mL x 1 Level 2: 5.0mL x 6 Level 2: 5.0mL x 12 Level 3: 5.0mL x 1 Level 3: 5.0mL x 6 Level 3: 5.0mL x 12	Deffered submission for verifiable fee. of
11.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	<b>Brand Name:</b> Maccura <b>Product Name:</b> Herpes simplex virus-1 IgM Antibody Chemiluminescent Immunoassay Kit  Class-C  Shelf life: 15 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission for verifiable fee. of
12.	Name Moody Global Services	(LEGAL MANUFACTURER)	Maccura Myoglobin CLIA Kit (CLIA)	Deffered submission for of

	Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan ELI-00926	Maccura Biotechnology Co., Ltd., China  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Class-C  Shelf life: 12 Months  Codes/sizes: 25 tests, 50 tests, 100 tests, 200 tests, 2x25 tests, 2x50 tests, 2x100 tests 2x200 tests	verifiable fee.
13.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) Maccura Biotechnology Co., Ltd., China  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Maccura Generic Name: total PSA CLIA (Total Prostate Specific Antigen PSA (CLIA)  Class-C  Shelf life: 12 Months  Codes/sizes: 50 tests, 100 tests, 200 tests, 2x50 tests, 2x100 tests 2x200 tests	Deffered submission for verifiable fee. of
14.	M/s MOODY GLOBAL SERVICES Address:Office No. 14,2ndFloor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 3764194098 25000 18.8.22  R&I 19.8.22	Name:BMC Medical Co.,Ltd.,China Address:Room110 Tower AFengyu Building,No.115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity:01-01-2024  (Spain) Validity:19-11-2021  LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	Brand name: BMC Generic name: RE Smart GII BPAP System Size/specification: <input type="checkbox"/> T-20S <input type="checkbox"/> T-20A <input type="checkbox"/> T-20T <input type="checkbox"/> T-25S <input type="checkbox"/> T-25A <input type="checkbox"/> T-25T <input type="checkbox"/> T-30T Class: B  Shelf life: 5Years	Deffered for FRESH Original valid LOA.
15.	M/s MOODY GLOBAL SERVICES Address:Office No.	Name:BMC Medical Co.,Ltd.,China Address:Room110 Tower AFengyu	Brand name: BMC Generic name: RE Smart GIIBPAP System	Deferred for the provision of original, valid and notarized LOA.

	14,2ndFloor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 808484383375 25000 18.8.22  R&I 19.8.22  VVE-YSD-LMNW	Building, No.115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity:01-01-2024  (Spain) Validity:19-11-2021  LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	Size/specification: <input type="checkbox"/> Y-20T <input type="checkbox"/> Y-25T <input type="checkbox"/> Y-30T <input type="checkbox"/> Y-30AT <input type="checkbox"/> U-20T <input type="checkbox"/> U-25T <input type="checkbox"/> U-30T <input type="checkbox"/> U-30AT Class:B Shelf life: 5Years	
16.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) Maccura Biotechnology Co., Ltd., China  <u>16#, Baichuan Road, Hi-tech  zone, 611731 Chengdu,  PEOPLES REPUBLIC OF  CHINA.</u>	Maccura  Generic Name: Reagent kit: B-type natriuretic peptide BNP (CLIA)Kit Controls: B-type natriuretic peptide BNP control  Class-C  Shelf life: 15 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests Level 1: 2.0mLx1 Level 1: 2.2mLx1 Level 1: 3.2mLx1	Deffered submission for verifiable fee. of
17.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co.,  Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech  zone, 611731 Chengdu,  PEOPLES REPUBLIC OF  CHINA.</u>	Brand Name: Maccura Product Name: Cardiac Marker Control Level 1, Level 2 Kit  Class-C  Shelf life: 18 Months  Codes/sizes: Level 1: 2.0mLx1, Level 1: 2.0mLx3,	Deffered submission for verifiable fee. of



			Level 1: 2.0mLx6, Level 2: 2.0mLx1, Level 2: 2.0mLx3 Level 2: 2.0mLx6 Level 1 ~ 2: 2.0mLx2 Level 1 ~ 2: 2.0mLx6	
18.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co.,  Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech  zone, 611731 Chengdu,  PEOPLES REPUBLIC OF  CHINA.</u>	Maccura Product Name: Creatine Kinase MB (CLIA) Reagent Kit  Class-C  Shelf life: 13 Months  Codes/sizes: 25 tests, 50 tests, 100 tests, 200 tests, 2x25 tests, 2x50 tests, 2x100 tests 2x200 tests	Deffered submission for verifiable fee. of
19.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co.,  Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech  zone, 611731 Chengdu,  PEOPLES REPUBLIC OF  CHINA.</u>	Brand Name: Maccura Product Name: Procalcitonin (CLIA) Kit  Class-C  Shelf life: 13 Months  Codes/sizes: 25 tests, 50 tests, 100 tests, 200 tests, 2x25 tests, 2x50 tests, 2x100 tests 2x200 tests	Deffered submission for verifiable fee. of
20.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co.,  Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech  zone, 611731 Chengdu,  PEOPLES REPUBLIC OF  CHINA.</u>	Maccura Product Name: N- terminal pro brain natriuretic peptide (CLIA)( NT-proBNP)  Class-C  Shelf life: 12 Months  Codes/sizes: 25 tests, 50 tests, 100 tests, 200 tests,	Deffered submission for verifiable fee. of

			2x25 tests, 2x50 tests, 2x100 tests 2x200 tests	
21.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: TOXO IgG Antibody Chemiluminescent Immunoassay Kit  Class-C  Shelf life: 12 Months  Codes/sizes: 100 tests, 2x100 tests (Control included)	Deffered submission for verifiable fee. of
22.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: CANCER ANTIGEN CA 15-3 (CLIA)  Class-C  Shelf life: 18 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission for verifiable fee. of
23.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Maccura AFP (CLIA)  Class-C  Shelf life: 18 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission for verifiable fee. of
24.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Maccura Generic Name: Calcitonin (CT) CLIA Kit  Class-C  Shelf life: 12 Months  Codes/sizes: 25 tests, 50 tests, 100 tests, 200 tests, 2x25 tests, 2x50 tests,	Deffered submission for verifiable fee. of

			2x100 tests 2x200 tests	
25.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Neuron Specific Enolase (CLIA) reagent kit  Class-C  Shelf life: 15 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission for of verifiable fee.
26.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Inflammation Control  Class-C  Shelf life: 12 Months  Codes/sizes: Level 1: 3.0mL x 1 Level 2: 3.0mL x 1	Deffered submission for of verifiable fee.
27.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: Carcinoembryonic antigen CEA (CLIA)  Class-C  Shelf life: 12 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered submission for of verifiable fee.
28.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) <u>Maccura Biotechnology Co., Ltd., China</u>  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Brand Name: Maccura Product Name: D-Dimer Chemiluminescent Immunoassay  Class-C  Shelf life: 15 Months  Codes/sizes:	Deffered submission for of verifiable fee.

			50 tests, 100 tests, 2x50 tests, 2x100 tests Level 1: 1.0mL x 1 Level 2: 1.0mL x 1 Level 3: 1.0mL x 1	
29.	Name Moody Global Services Address of Importer No 14, 2 <sup>nd</sup> Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan	(LEGAL MANUFACTURER) Maccura Biotechnology Co., Ltd., China  <u>16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA.</u>	Maccura Product Name: Squamous cell carcinoma CLIA Kit  Class-C  Shelf life: 15 Months  Codes/sizes: 50 tests, 100 tests, 2x50 tests, 2x100 tests	Deffered for submission of verifiable fee.
30.	Applicant:  M/s. Moody Global Services Address:OfficeNo. 14,2ndFloor, Mujahidplaza, JinnahAvenue,Blue area,Islamabad, 44000,Pakistan. LicenseNo. ELI-00926 R&I date: Not clear. Track ID 3UV-2EV-8814 Fee: PKR 5000/- Slip: 363062483 Dated: 08-11-2022.	(Legal Manufacturer) Name: Shenzhen LifotronicTechnology Co.,Ltd Address:UnitA4th floor,Building15, YijingEstate,No1008 Songbairoad,Nanshan District,Shenzhencity, Guangdongprovince, 518055,P.R.China. FSC Countryoforigin (China) Validityperiod:24-09 2022 FSC Referencecountry (Germany) Dateofissuance: 22-06-2021 LOAvalidity: 31-12-2027	Brandname: Lifotronic Genericname:β Thalassaemia& HBA1cReagent Kits(HPLC) Size/specification: 200T/box  Class: A  Shelf life: 24months	Approved
31.	M/s MOODY GLOBAL SERVICES Address:Office No. 14,2ndFloor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 25000 18.8.22	Name:BMC Medical Co.,Ltd.,China Address:Room110 Tower AFengyu Building,No.115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity:01-01-2024	Brand name: BMC Generic name: BPAP System Size/specification: G2S-Series: G2SB20A, G2S B20S, G2SB20T, G2SB25A, G2SB25S, G2SB25T, G2SLAB, G2SB25VT, G2SB30T, G2SB30VT, G2SB30AT	Deferred for provision of valid notarized authorization letter from manufacturer.

	R&I 19.8.22	LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	<b>G3-Series:</b> G3B20A, G3B25S, G3B25A, G3B25VT, G3B30VT, G3B30SV, G3LAB  Class: B  Shelf life: 5Years	
32.	M/s MOODY GLOBAL SERVICES Address:Office No. 14,2ndFloor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 810991193854 25000 18.8.22  R&I 19.8.22  8UY-JWH-3G92	Name: BMC Medical Co. ,Ltd., China Address: Room110 Tower A Fengyu Building,No.115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity:01-01-2024  (Spain) Validity:19-11-2021  LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	Brand name: BMC Generic name: CPAP System Size/specification: CPAP System Models: • G3 C20 • G2S C20  Class: B  Shelf life: 5Years	Deferred for provision of valid notarized authorization letter from manufacturer.
33.	M/s MOODY GLOBAL SERVICES Address:Office No. 14,2ndFloor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 401582193947 25000 18.8.22  R&I 19.8.22  9UW-5WJ-XLEW	Name: BMC Medical Co., Ltd., China Address: Room110 Tower A Fengyu Building, No.115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity:01-01-2024  LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	Brand name: BMC Generic name: NASAL MASK Size/specification: Models: <input type="checkbox"/> N5 <input type="checkbox"/> N5A <input type="checkbox"/> N5B <input type="checkbox"/> N5H <input type="checkbox"/> N5AH <input type="checkbox"/> N5BH Class: B  Shelf life: 5Years	Deferred for provision of valid notarized authorization letter from manufacturer.
34.	M/s	Name: BMC Medical	Brand name: BMC	Deferred for provision

	MOODY GLOBAL SERVICES Address: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad. License No. ELI-00926 FEE Receipt No. 37899622 25000 18.8.22  R&I 19.8.22 Z8V-X7N-M3LX	Co., Ltd., China Address: Room 110 Tower A Fengyu Building, No. 115 Fucheng Road Haidian, 100036 Beijing, People's Republic of China. FSC Country of origin: China Validity: 01-01-2024  (Spain) Validity: 19-11-2021  LOA validity: 02-03-2027  ISO 13485 VALIDITY 01.03.23	Generic name: iVolve F1A Full Face Mask Size/specification: BMC-FM1A Size: All Sizes (small/medium/large) Class: B Shelf life: 5 Years	of valid notarized authorization letter from manufacturer.
35.	M/s Reliable Medical Supply Office No. 204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  Fee Challan No. 38080996 6,000/- 6221-Kpk	<u>Legal Manufacturer:</u> M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd.  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  LOA Validity: 02/04/2030 FSC Validity: 03-09-2026 ISO 13485 validity 16-03-2026	Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A  Shelf Life: 3 Years  Sized: As per FSC	Approved Plain, Clot activator, EDTA K2, EDTA K2/ Sodium, Gel & Clot activator, Heparin Lithium, Heparin Sodium and inhibitor for Glucolysis subject to submission of fee for each.
36.	M/s Reliable Medical Supply Office No. 204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  Fee Challan No. 47363288 6224-Kpk 6,000/-	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd No. 133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China  LOA Validity: 01/03/2030 FSC Validity:	Hematology Analysis Diluent Model: MEK Diluent  Class: A  Shelf Life: 2 Years  Sizes: 1L, 5L, and 20L	Approved
37.	M/s Reliable Medical Supply	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical	Hematology Analysis Lytic Agent	approved

	Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  Fee Challan No. 09159423 6226-Kpk 6,000/-	Technology Co., Ltd Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China  LOA Validity: 1/03/2030 FSC Validity: 18-09-2026 ISO 13485 validity 20-11- 2026	Model: BCII Lyse  Class: A  Shelf Life: 2 Years  Sizes: 500ml, 1L, 5L, and 20L	
38.	M/s Reliable Medical Supply Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  Fee Challan No. 2345846369 6225-P 6,000/-	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China  LOA Validity: 1/03/2030 FSC Validity: 18-09-2026 ISO 13485 validity 20-11- 2026	Cleaning Solution Model: Rinse Cleaning Solution Class: A  Shelf Life: 2 Years  Sizes: 500ml, 1L, 1L x 4, 5L, 5L x 2, 5.5L and 20L	Approved
39.	M/s Reliable Medical Supply  Address: Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  R&I: 17/04/2025  Fee Chalan No. 738123418  Fee Chalan Date: 16/04/2025	<u>Legal Manufacturer:</u> M/s Shenzhen Yurucheng Dental Materials Co., Ltd  Address: 101, 201, 301, Building A, No.35, Zhuqing Rd., Shijing Community, Shijing Street, Pingshan District, Shenzhen, China  LOA Validity: 11/04/2026  FSC Validity:	Yucera (Zirconia Dental Ceramics)  Class: B  Shelf Life: 5 Years  Sizes: As per FSC	Approved
40.	HealthBee Projects Private Limited, E-02, Third floor, Jasim Arcade, Plaza 64-65, Lane 1, Square Commercial, Phase 7, Bahria Town, Islamabad. ELI: 00814	<u>Legal Manufacturer:</u> Maxigen biotech Inc. No. 88, Keji 1 <sup>st</sup> Road., Guishan dist., Taoyuan City 33383, Taiwan R.O.C.  FSC Taiwan issuance 14-06-2022	ArtiAid Intra-articulate Injection  Class-D  Shelf life: 3 years  Models: AA-20 AA-25 AA-27 AA-30	Approved AA-25 model with composition of product instant model.

			AA-35	
41.	M/s Siemens Healthcare (pvt) Ltd., 4 <sup>th</sup> floor, state life building, 15-A, Sir Agha Khan road, Lahore.  ELI: 00146  2186-P	Legal Manufacturer: M/s Siemens Shanghai Medical Equipment ltd. 278 Zhou Zhu road 201318 Shanghai, China. FSC: China expired	Mammomat (Mammographic X-ray System)  Codes & Sizes: As per FSC  Class-  Service Life: 10 years	Approved Mammomat Fusion (Mammographic X-ray System)
42.	<b>Name</b> Aqib Trading Company (Pvt) Limited <b>Address of Importer</b> Main GT Road Adamzai Akora Khattak Distt. Nowshera KPK Pakistan. ELI- 00628  <b>Date of R &amp; I</b> 12 March 2024 <b>Fee</b> Rs. 25,000/ through slip no. 907808576739, dated 15.02.2024	<b>(LEGAL MANUFACTURER)</b> Jiangxi Hongda Medical Equipment Group Ltd. <b>Manufacturing site)</b> NO.39 South Shengli RD. Jinxian county Jiangxi Province, China  <b>Documents submitted:</b>  <b>ISO 13485 certificate validity:</b> 01-12-2027  <b>LOA validity:</b> 31-Dec-2025 <b>Fsc:</b> <b>People Republic of China Site Valid Till 11.01.2026</b>  CE Marked Basis  Marketing Authorization Letter: Loa Valid till 12.01. 2029  <b>Production Quality Management System Certificate ( Iso 13485)</b> Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25  <b>Full Quality Assurance Certificate Or Equivalent:</b> Ce/ Fqas Notifying Body TUV SUD Validity Up To: 26.05.2024	<b>Brand name:</b> <b>AT-INGE</b> Auto Disable Sterile syringe for Single use (with and without needle)  <b>Codes/Sizes:-</b> AD Sterile syringe for Single use(with and without needle) <b>Type:</b> 1 ML, 2ML, 3ML, 5ML, 10ML  <b>Class-B</b>  <b>Shelf life:</b> 5 Years	Approved 0.5ml, 1ml and 10ml sizes. letter of above remaining sizes will be issued with same registration number as for already issued sizes.
43.	Royal Medical Office No. 26th, 3rd	Legal Manufacturer Name: F Care Systems NV	Name of Device : Fistura Catheter	Approved



	Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI-00691)	Complete Address: Uitbreidingstraat 42-46, BE- 2600 Berchem, Belgium Telephone Number: +3234515145 Official Website: <a href="http://www.fcaresystems.com">www.fcaresystems.com</a>  Copy of FSC of Belgium issuance 16.01.2023  Expiry not mentioned  Copy of LOA issued on 4.12.2023  Valid till 4.12.2026	Codes/Models: 6F, 7F, 8F, 9F R&I Date: 7th August 2023 Shelf life 03 years Class C	
44.	Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI-00691)	Legal Manufacturer  Name: Bicakcilar Tibbi Cihazlar Sanayi ve. Tic. A.S. Address: Osmangazi Mah. Gazi Cad. No: 21 Esenyurt 34522, Istanbul – Turkey  copy of FSC issue date 15.09.2023 valid till 14.09.2026  Copy of LOA issue date 28.02.2025	Name of Device: Bicakcilar- Coronary Artery Perfusion Cannula Codes/Models: 330 0461 1 R&I Date: 7th August 2023 Shelf life 05 years  Class D	Deferred for submission of the valid and notarized Design examination certificate. Clarify the brand name applied and in the FSC
45.	Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI-00691)	Legal Manufacturer Name: Bicakcilar Tibbi Cihazlar Sanayi ve. Tic. A.S. Address: Osmangazi Mah. Gazi Cad. No: 21 Esenyurt 34522, Istanbul – Turkey  copy of FSC issue date 15.09.2023 valid till 14.09.2026  Copy of LOA issue date 28.02.2025	Name of Device : Bicakcilar- Aortic Root Cannula/Needle Codes/Models: 330 0111 1 R&I Date: 7th August 2023  Shelf life 05 years  Class D	Deferred for submission of the valid and notarized Design examination certificate. Clarify the brand name applied and in the FSC
46.	BONE MED, OFFICE#	<b>Legal manufacturer:</b>	<b>Brand Name:</b>	Deferred for

44.46.48.50. FIRST FLOOR, MIAN PLAZA, CHANDI CHOWK, RAWALPINDI 46000.  Establishment license No: ELI-01157  Date of issue: 07-09-2023  Renewal Due Date: 06-09-2028	TIPSAN TIBBI ALETLER SAN. VE TiC. A.S Manufacturing Site: Kemalpasa Cad. 7404/1 Sok. No. 3 Pinarbasi / IZMIR Turkiye  Original Legalized Free Sale Certificate (FSC) dated: 19-02-2026  ISO 13485 valid upto. 28 February 2025 FQ/CE Certificate valid upto: 31 December 2027	(T-2 Hip Prosthesis SYSTEM) Class-C  Shelf Life: 05 years  Fee: Rs: 50000/-  Date of Submission: 23-11-2023  Challan No: 907548804	submission of the product catalogue and clarification of the as system.
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#### Codes:

10255022029 T-2 Hip Prosthesis Fixation Bolt Ti6AlVeli/ M6x29 mm, XShort  
10255022035 T-2 Hip Prosthesis Fixation Bolt Ti6AlVeli/M6x35 mm, Short  
10255022045 T-2 Hip Prosthesis Fixation Bolt Ti6AlVeli/M6x45 mm, Medium  
10255022055 T-2 Hip Prosthesis Fixation Bolt Ti6AlVeli/M6x55 mm, Medium  
10258030042 T2 Revision Hip Prosthesis Body with Tendon Holes Ti + HA coated / Ti6Al4Veli/ 42 mm-Xshort  
10258030048 T2 Revision Hip Prosthesis Body with Tendon Holes Ti + HA / Ti6Al4Veli / 48 mm-short Coated  
10258030058 T2 Revision Hip Prosthesis Body with Tendon Holes Ti + HA Coated Ti6AlVeli/58 mm, MEDIUM  
10258030068 T2 Revision Hip Prosthesis Body with Tendon Holes Ti + HA Coated  
10255132142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø13-142 mm  
10258130142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented / Ti6Al4Veli / Ø13-142 mm  
10255132172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø13 X 172 mm  
10258130172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented / Ti6Al4Veli/  
10258130212 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255142142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø14 X 142 mm  
10258140142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255142172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø14 X 172 mm  
10258140172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10258140212 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255152142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø15 X 142 mm  
10258150142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255152172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø15 X 172 mm  
10258150172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10258150212 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255162142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø16 X 142 mm  
10258160142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255162172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø16 X 172 mm  
10258160172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255162212 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/Ø16 X 212 mm  
10258160212 T-2 Revision Hip Prosthesis Stem with Ti + HA Coated-Uncemented  
10255172142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø17 X 142 mm  
10258170142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10255172172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø17 X 172 mm  
10258170172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented  
10258170212 T-2 Revision Hip Prosthesis Stem with Ti + HA Coated-Uncemented  
10255182142 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø18 X 142 mm

10258180142 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented				
10255182172 T-2 Hip Prosthesis Stem - Uncemented / Ti6Al4Veli/ Ø18 X 172 mm				
10258180172 T-2 Revision Hip Prosthesis Stem with Ti+ HA Coated-Uncemented				
10258180212 T-2 Revision Hip Prosthesis Stem with Ti + HA Coated-Uncemented				
47.	<p>BONE MED, OFFICE# 44.46.48.50. FIRST FLOOR, MIAN PLAZA, CHANDI CHOWK, RAWALPINDI 46000.</p> <p>Establishment license No: ELI-01157</p> <p>Date of issue: 07-09-2023</p> <p>Renewal Due Date: 06-09-2028</p>	<p>Legal manufacturer: TIPSAN TIBBI ALETLE SAN. VE TiC. A.S</p> <p>Manufacturing Site: Kemalpasa Cad. 7404/1 Sok. No. 3 Pinarbasi / IZMIR Turkiye</p> <p>Original Legalized Free Sale Certificate (FSC) dated: 19-02-2026</p> <p>ISO 13485 valid upto. 28 February 2025</p> <p>FQ/CE Certificate valid upto: 31 December 2027</p>	<p>Brand Name: (Sterile Pressfit Cup, Sterile Ceramic Liner, Sterile PE Liner, Starex Fixation Screw SYSTEM)</p> <p>Class- C</p> <p>Shelf Life: 05 years</p> <p>Fee: Rs: 50000/-</p> <p>Date of Submission: 23-11-2023</p> <p>Challan No: 3516570705.</p>	<p>Deferred for submission of the product catalogue and clarification of the product as system.</p>
<p><b>Code:</b></p> <p>10232010042 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø42 mm</p> <p>10232010044 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø44 mm</p> <p>10232010046 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø46 mm</p> <p>10232010048 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø48 mm</p> <p>10232010050 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø50 mm</p> <p>10232010052 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø52 mm</p> <p>10232010054 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø54 mm</p> <p>10232010056 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø56 mm</p> <p>10232010058 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø58 mm</p> <p>10232010060 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø60 mm</p> <p>10232010062 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø62 mm</p> <p>10232010064 Press fit Cup with Titanium Plasma Spray - HA Coated Ti6AlVeli / Ø64 mm</p> <p>10232177048 Liner for Press fit Cup / PE UHMW Crosslinked / Ø28 - 20°, Ø42-48</p> <p>10232137048 Liner for Press fit Cup / PE UHMW Crosslinked / Ø28 - 10°, Ø42-48</p> <p>10232177052 Liner for Press fit Cup / PE UHMW Crosslinked / Ø28 - 20°, Ø50-52</p> <p>10232127052 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 10°, Ø50-52</p> <p>10232377056 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 20° - Ø54-56</p> <p>10232127056 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 10° - Ø54-56</p> <p>10232377060 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 20° - Ø58-60</p> <p>10232127060 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 10° - Ø58-60</p> <p>10232477064 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 20° - Ø62-64</p> <p>10232127064 Liner for Press fit Cup / PE UHMW Crosslinked / Ø32 - 10° - Ø62-64</p> <p>10802382001 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-15mm</p> <p>10802382002 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-20mm</p> <p>10802382003 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-25mm</p> <p>10802382004 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-30mm</p> <p>10802382005 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-35mm</p> <p>10802382006 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-40mm</p> <p>10802382007 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-45mm</p> <p>10802382008 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-50mm</p> <p>10802382009 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-55mm</p>				

10802382010 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-60mm				
10802382011 Starex Fixation Screw / Ti6Al4Veli / Ø6.5-65mm				
48.	<p>BONE MED,</p> <p>OFFICE# 44.46.48.50.</p> <p>FIRST FLOOR, MIAN PLAZA, CHANDI CHOWK, RAWALPINDI 46000.</p> <p>Establishment license No: ELI-01157</p> <p>Date of issue: 07-09-2023</p> <p>Renewal Due Date: 06-09-2028</p>	<p>Legal manufacturer: TIPSAN TIBBI ALETLER SAN. VE TiC. A.S</p> <p>Manufacturing Site: Kemalpasa Cad. 7404/1 Sok. No. 3 Pinarbasi / IZMIR Turkiye</p> <p>Original Legalized Free Sale Certificate (FSC) dated: 19-02-2026</p> <p>ISO 13485 valid upto. 28 February 2025</p> <p>FQ/CE Certificate valid upto: 31 December</p>	<p>Brand Name: (Prizma Hip SYSTEM) Code:</p> <p>Class- C</p> <p>Shelf Life: 05 years</p> <p>Fee: Rs: 50000/-</p> <p>Date of Submission: 23-11-2023</p> <p>Challan No: 96113581</p>	<p>Deferred for submission of the product catalogue and clarification of the product as system.</p>
<p><b>Codes:</b></p> <p>10284012000 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 0</p> <p>10284012001 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 1</p> <p>10284012002 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 2</p> <p>10284012003 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 3</p> <p>10284012004 Prizma Hip Femoral Stem with HA Coated - Uncemented /Ti6Al4veli/ 4</p> <p>10284012005 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 5</p> <p>10284012006 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 6</p> <p>10284012007 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 7</p> <p>10284012008 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/ 8</p> <p>10284012009 Prizma Hip Femoral Stem with HA Coated - Uncemented / Ti6Al4veli/9</p> <p>10284022000 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 0</p> <p>10284022001 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 1</p> <p>10284022002 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 2</p> <p>10284022003 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 3</p> <p>10284022004 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 4</p> <p>10284022005 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 5</p> <p>10284022006 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 6</p> <p>10284022007 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 7</p> <p>10284022008 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 8</p> <p>10284022009 Prizma Hip Revision Femoral Stem with HA Coated - Uncemented / Ti6Al4Veli/- 9</p>				

49.	<p>BONE MED, OFFICE# 44.46.48.50. FIRST FLOOR, MIAN PLAZA, CHANDI CHOWK, RAWALPINDI 46000.</p> <p>Establishment license No: ELI-01157</p> <p>Date of issue: 07-09-2023</p> <p>Renewal Due Date: 06-09-2028</p>	<p>Legal manufacturer: TIPSAN TIBBI ALETLER SAN. VE TiC. A.S</p> <p>Manufacturing Site: Kemalpaşa Cad. 7404/1 Sok. No. 3 Pınarbaşı / İZMİR Türkiye</p> <p>Original Legalized Free Sale Certificate (FSC) dated: 19-02-2026</p> <p>ISO 13485 valid upto. 28 February 2025</p> <p>FQ/CE Certificate valid upto: 31 December 2027</p>	<p>Brand Name: (CTD Modular Straight Stem Cemented, CTPH Modular Straight Stem Ti+HA Coated Uncemented SYSTEM) Code:</p> <p>Class- C</p> <p>Shelf Life: 05 years</p> <p>Fee: Rs: 50000/-</p> <p>Date of Submission: 23-11-2023</p> <p>Challan No: 95659075</p>	<p>Deferred for submission of the product catalogue and clarification of the product as system.</p>
<p><b>Codes:</b></p> <p>10268022000 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 0-12/14</p> <p>10268022001 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 1-12/14</p> <p>10268022002 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 2-12/14</p> <p>10268022003 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 3-12/14</p> <p>10268022004 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 4-12/14</p> <p>10268022005 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 5-12/14</p> <p>10268022006 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 6-12/14</p> <p>10268022007 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 7-12/14</p> <p>10268022008 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 8-12/14</p> <p>10268022009 CTPH Modular Straight Stem with Ti + HA Coated-Uncemented / Ti6Al4V/ 9-12/14</p> <p>10268123000 CTD Modular Straight Stem, cemented/ CoCr - 0-12/14</p> <p>10268123001 CTD Modular Straight Stem, cemented/ CoCr - 1-12/14</p> <p>10268123002 CTD Modular Straight Stem, cemented/ CoCr - 2-12/14</p> <p>10268123003 CTD Modular Straight Stem, cemented/ CoCr - 3-12/14</p> <p>10268123004 CTD Modular Straight Stem, cemented/ CoCr - 4-12/14</p> <p>10268123005 CTD Modular Straight Stem, cemented/ CoCr - 5-12/14</p> <p>10268123006 CTD Modular Straight Stem, cemented/ CoCr - 6-12/14</p> <p>10268123007 CTD Modular Straight Stem, cemented/ CoCr - 7-12/14</p> <p>10268123008 CTD Modular Straight Stem, cemented/ CoCr - 8-12/14</p> <p>10247007003 Cement Plug PE UHMW Crosslinked/11mm</p> <p>10247007006 Cement Plug PE UHMW Crosslinked/14mm</p> <p>10247007008 Cement Plug PE UHMW Crosslinked/16mm</p> <p>10247007011 Cement Plug PE UHMW Crosslinked/19mm</p> <p>10246007001 Distal Centralizer PE UHMW Crosslinked/ 8mm</p> <p>10246007002 Distal Centralizer PE UHMW Crosslinked/10mm</p> <p>10246007003 Distal Centralizer PE UHMW Crosslinked/12mm</p> <p>10246007004 Distal Centralizer PE UHMW Crosslinked,/14mm</p>				
50.	<p>BONE MED, OFFICE# 44.46.48.50. FIRST FLOOR, MIAN PLAZA, CHANDI CHOWK, RAWALPINDI 46000.</p> <p>Establishment license No: ELI-01157</p>	<p>Legal manufacturer: TIPSAN TIBBI ALETLER SAN. VE TiC. A.S</p> <p>Manufacturing Site: Kemalpaşa Cad. 7404/1 Sok. No. 3 Pınarbaşı / İZMİR Türkiye</p>	<p>Brand Name: (Modular Head SYSTEM)</p> <p>Class- C</p> <p>Shelf Life: 05 years</p> <p>Fee: Rs: 50000/-</p>	<p>Deferred for submission of the product catalogue and clarification of the product as system.</p>

	Date of issue: 07-09-2023  Renewal Due Date: 06-09-2028	Original Legalized Free Sale Certificate (FSC) dated: 19-02-2026  ISO 13485 valid upto. 28 February 2025 FQ/CE Certificate valid upto: 31 December 2027	Date of Submission: 23-11-2023 Challan No 30721983096.	
<b>Codes:</b> 10223013001 Modular Head for Total Hip Prosthesis /CoCrMo / Ø22 - 12*14 Short 10223013002 Modular Head for Total Hip Prosthesis /CoCrMo / Ø22 - 12*14 Medium 10223013003 Modular Head for Total Hip Prosthesis /CoCrMo / Ø22 - 12*14 Long 10236013001 Modular Head for Total Hip Prosthesis /CoCrMo / Ø28 - 12*14 Short 10236013002 Modular Head for Total Hip Prosthesis /CoCrMo / Ø28 - 12*14 Medium 10236013003 Modular Head for Total Hip Prosthesis /CoCrMo / Ø28 - 12*14 Long 10236013004 Modular Head for Total Hip Prosthesis /CoCrMo / Ø28 - 12*14 Xlong 10236013005 Modular Head for Total Hip Prosthesis /CoCrMo / Ø28 - 12*14 XXlong 10236043003 Modular Head for Total Hip Prosthesis /CoCrMo / Ø32 - 12*14 Short 10236043004 Modular Head for Total Hip Prosthesis /CoCrMo / Ø32 - 12*14 Medium 10236043005 Modular Head for Total Hip Prosthesis /CoCrMo / Ø32 - 12*14 Long 10236043006 Modular Head for Total Hip Prosthesis /CoCrMo / Ø32 - 12*14 XLong 10236043007 Modular Head for Total Hip Prosthesis /CoCrMo / Ø32 - 12*14 Xxlong 10236019001 Modular Head for Total Hip Prosthesis / Ceramic / Ø28 - 12*14 Short 10236019002 Modular Head for Total Hip Prosthesis / Ceramic / Ø28 - 12*14 Medium 10236019003 Modular Head for Total Hip Prosthesis / Ceramic / Ø28 - 12*14 Long 10236049001 Modular Head for Total Hip Prosthesis / Ceramic / Ø32 - 12*14 Short 10236049002 Modular Head for Total Hip Prosthesis / Ceramic / Ø32 - 12*14 Medium 10236049003 Modular Head for Total Hip Prosthesis / Ceramic / Ø32 - 12*14 Long 10236049004 Modular Head for Total Hip Prosthesis / Ceramic / Ø32 - 12*14 X long 10236049005 Modular Head for Total Hip Prosthesis / Ceramic / Ø32 - 12*14 XX Long				
51.	M/s Royal Medical  Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi. ELI- 00691 R& I date: 17-05-2024	Chalice Medical Ltd. Address: Manton Wood Enterprise Park, Worksop, Nottinghamshire, S80 2RS, United Kingdom  LOA valid till 30-10-24  FSC Validity: FSCUK Valid till 26-05-2025.  ISO 13485 Validity: Valid till 09-11-2025	Paragon Oxygenator (Paragon Oxygenator MN)  Class: B (Special control) Claimed Shelf Life: 02-years Codes/sizes: XCMOPI300MN, XCMOPI260MN, XCMOPI140MN.	Approved XCMOPI300MN. Firm will apply separately for rest of models.
52.	M/s Saru International, B-194/1 Block-12, Gulistan Johar Karachi.  (ELI-00316)	Legal Manufacturer: Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China.	Healthicon 3L Incise Drape  3L Incise Drape PE/ PU  Class A  Shelf Life: 2 Years Paper	Approved the below mentioned medical device. '3L Incise Drape PE'

		(FSC Valid 22-06-2020)	film Package 5 years in aluminum foil package Sizes & Codes as per FSC	
53.	M/s Saru International, B-194/1 Block-12, Gulistan Johar Karachi.  (ELI-00316)	Legal Manufacturer:  Jiangxi 3L Medical Products Group Co., Ltd, 599, Huoju Street, High-Tech Development Zone, Nanchang, Jiangxi 330096, China  (FSC Valid 04-03-2021)	3L Transparent Surgical Tape (PE)  Surgical Tape  Class A  Shelf Life: 5  Sizes & Codes as per FSC	Approved the below mentioned  '3L Transparent Surgical Tape (PE)'
54.	M/s Saru International, B-194/1 Block-12, Gulistan Johar Karachi.  (ELI-00316)	Legal Manufacturer:  Jiangxi 3L Medical Products Group Co., Ltd, 599, Huoju Street, High-Tech Development Zone, Nanchang, Jiangxi 330096, China  (FSC Valid 22-06-2020)	3L Intravenous (IV) Adhesive Dressing Sterile  Wound Dressing  Class B  Shelf Life: 3 Years  Sizes & Codes as per FSC	Approved the below mentioned  '3L Intravenous (IV) Adhesive Dressing Sterile'
55.	M/s Saru International, B-194/1 Block-12, Gulistan Johar Karachi.  (ELI-00316)	Legal Manufacturer:  Jiangxi 3L Medical Products Group Co., Ltd, 599, Huoju Street, High-Tech Development Zone, Nanchang, Jiangxi 330096, China  (FSC Valid 22-06-2020)	3L Adhesive Wound Dressing Sterile  Wound Dressing  Class B  Shelf Life: 3 Years  Sizes & Codes as per FSC	Approved the below mentioned  '3L Adhesive Wound Dressing Sterile'.
56.	M/s Royal Enterprise. SH5, Karimji Building, Opp HBL North Napier Road, Karachi.  (ELI-00062)  <b>Date of R&amp;I</b> 16-12-2024  <b>Fee:</b> PKR 25000/-	<b>Legal Manufacturer:</b> M/s LONGFIAN SCITECH CO., LTD. <b>Manufacturing Site:</b> 2F&3F, EAST SECTION, BUILDING 12, POWER VALLEY PIONEER PARK, NO.369 HUIYANG STREET, 071051, BAODING, HEBEI PROVINCE, CHINA.	<b>Brand name:</b> WEWELL <b>Generic:</b> Medical Oxygen Concentrator  <b>Model:</b> JAY-5W, JAY-10W, JAY-5, JAY-10, JAY-10D, JAY5AW, JAY-5BW, JAY-5DW, JAY-5CW, JAY-5CW-D,	Approved.

	<b>Slip:</b> 0434728061 <b>Dated:</b> 10-12-2024	<b>FSC Validity:</b> 04-07-2026  <b>ISO 13485 validity:</b> 18-03-2025	JAY-10FW, JAY-10FW-D  <b>Class:</b> B  <b>LOA Validity:</b> 10-11-2034  <b>Shelf life:</b> N/A	
57.	<b>SIND MEDICAL STORES,</b> 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, <b>PAKISTAN</b> Lic. No.ELI-00010	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.  FSC Switzerland Valid Till (18.10.2022)  ISO 13485:2016 Certificate Valid till (30.10.2021)  LOA Valid until (31.12.2020)	ANTIBODY IDENTIFICATION PANEL REAGENT RED BLOOD CELL IVD, KIT, AGGLUTINATION, (FAMILY)  Class – C	DEFERED for clarification which kit to be considered for instant application.
58.	<b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details.</b>	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH,	<b>DIACLON ABD — CONFIRMATION FOR DONORS</b> <b>ITEM NO. 51051</b>  <b>Codes &amp; Sizes:</b> <b>001133 (4x12)</b> <b>001134 (112x12)</b> <b>001135 (60x12)</b> <b>001136 (24x12)</b>  <b>Class:</b> B	Approved in D along with submission of differential fee as per revised SRO..



	<p>Paid Fee PKR: 31,000/- 79701235906 <b>Dated:</b> 10-12-2024</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): Valid till: 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>ISO Certificate validity:</b> 30-10-2027</p>	<p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 12 Months</p>	
59.	<p><b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> Paid Fee PKR: 31,000/- 32704657592 <b>Dated:</b> 10-12-2024</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): Valid till: 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>ISO Certificate validity:</b> 30-10-2027</p>	<p><b>DIACLON ABO/D + REVERSE GROUPING FOR DONORS</b> <b>ITEM No. 51090</b></p> <p><b>Codes &amp; Sizes:</b> <b>001365 (112x12)</b></p> <p><b>Class:</b> B</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 12 Months</p>	<p>Approved in D along with submission of differential fee as per revised SRO..</p>
60.	<p><b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b></p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc.,</p>	<p><b>DIACLON ABO/D + REVERSE GROUPING – ITEM NO. 50092</b></p> <p><b>Codes &amp; Sizes.</b> <b>001234 (4x12)</b> <b>001235 (60x12)</b></p>	<p>Approved in D along with submission of differential fee as per revised SRO..</p>

	<p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> Paid Fee PKR: 25,000/- 2014064 <b>Dated:</b> 23-09-2020</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): Valid till: 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>ISO Certificate validity:</b> 30-10-2027</p>	<p><b>001236 (112x12)</b> <b>001237 (24x12)</b></p> <p><b>Class:</b> B</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 12 Months</p>	
61.	<p><b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> Paid Fee PKR: 31,000/- 77343235 <b>Dated:</b> 10-12-2024</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): Valid till: 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>ISO Certificate validity:</b> 30-10-2027</p>	<p><b>DIACLON ABO/Rh NEWBORNS DVI+ ITEM NO. 50961</b></p> <p><b>Codes &amp; Sizes:</b> <b>001048 (24x12)</b> <b>001047 (4x12)</b> <b>001049 (60x12)</b> <b>001050 (112x12)</b></p> <p><b>Class:</b> B</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 12 Months</p>	Approved in D along with submission of differential fee as per revised SRO..
62.	<b>M/s SIND MEDICAL</b>	DiaMed GmbH	<b>ID-DIACLON ANTI-D</b>	Approved in D along

	<p><b>STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> <b>Paid Fee</b> PKR: 31,000/- 3453001314 <b>Dated:</b> 10-12-2024</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): <i>Valid till:</i> 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>ISO Certificate validity:</b> 30-10-2027</p>	<p><b>ITEM NO.009410</b></p> <p><b>Codes &amp; Sizes:</b> <b>007531 (1x5 ml)</b></p> <p><b>Class:</b> B</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 18 Months</p>	<p>with submission of differential fee as per revised SRO..</p>
63.	<p><b>M/s SIND MEDICAL</b> <b>STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> <b>Paid Fee</b> PKR: 25,000/- 2014066 <b>Dated:</b> 23-09-2020</p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 24-09-2024</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>FSC Switzerland,</b> (country of origin): <i>Valid till:</i> 07-02-2028</p> <p><b>LOA Validity:</b> 31-12-2026</p>	<p><b>ID-Diluent 2</b> <b>ITEM NO. 05761,</b></p> <p><b>Codes &amp; Sizes:</b> <b>009280 (1x500 ml)</b> <b>009290 (10x60x700ul)</b></p> <p><b>Class:</b> B</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 24 Months</p>	<p>Approved</p>

		<b>ISO Certificate validity:</b> 30-10-2027		
64.	<b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details:</b> Paid Fee PKR: 25,000/- 2014067 <b>Dated: 23-09-2020</b>  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated: 24-09-2024</b>	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>FSC Switzerland,</b> <i>(country of origin):</i> Valid till: 07-02-2028  <b>LOA Validity:</b> 31-12-2026  <b>ISO Certificate validity:</b> 30-10-2027	IH-QC Modular System  ITEMS NO. 08710, 08720, 08730, 08740, 08750, 08760, 08770 & 08780.  Codes & Sizes. 009321 (4x6 ml) 009322 (4x6 ml) 009323 (4x6 ml) 009324 (4x6 ml) 009325 (4x6 ml) 009326 (6 ml) 009327 (6 ml) 009328 (6 ml)  Class: B  MD group: Single  Shelf life: 09 Weeks	Approved in D along with submission of differential fee as per revised SRO..
65.	<b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details:</b> Paid Fee PKR: 25,000/- 2014070 <b>Dated: 23-09-2020</b>  <b>Dy. No.: NIL</b> DRAP (R&I)	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b>	ID-DiaCell ABO, ITEM NOS. 45092, 45352 & 06002  Codes & Sizes: 003624 (2x10 ml) 003615 (3x10 ml) 003621 (1x10 ml)  Class: B  MD group: Single  Shelf life: 12 Weeks	Approved in D along with submission of differential fee as per revised SRO..

	<b>Dated:</b> 24-09-2024	(country of origin): Valid till: 07-02-2028  <b>ISO Certificate validity:</b> 30-10-2027		
66.	<b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Challan No.:</b> Paid Fee PKR: 25,000/- 2014071 <b>Dated:</b> 23-09-2020  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated:</b> 24-09-2024	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b> (country of origin): Valid till: 07-02-2028  <b>ISO 13485 Certificate validity:</b> 30-10-2027	<b>NaCl Enzyme test and Cold Agglutination ITEM NO. 50520</b>  <b>Codes &amp; Sizes:</b> <b>005014 (4X12)</b> <b>005015 (112X12)</b> <b>005016 (60X12)</b> <b>005017 (24X12)</b>  <b>Class:</b> B  <b>MD group:</b> Single  <b>Shelf life:</b> 18 Months	Approved in D along with submission of differential fee as per revised SRO..
67.	<b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u>	<b>LISS/COOMBS ITEM NO. 50531</b>  <b>Codes &amp; Sizes:</b> <b>004014 (4x12)</b> <b>004015 (112x12)</b> <b>004016 (60x12)</b> <b>004017 (24x12)</b>  <b>Class:</b> C  <b>MD group:</b> Single	Approved in D along with submission of differential fee as per revised SRO..

	<b>Fee Details:</b> Paid Fee PKR: 62,000/- 271582863260 <b>Dated:</b> 09-12-2024  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated:</b> 24-09-2024	Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b> <i>(country of origin):</i> Valid till: 07-02-2028  <b>ISO 13485 Certificate</b> <b>validity:</b> 30-10-2027	<b>Shelf life:</b> 18 Months	
68.	<b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details:</b> Paid Fee PKR: 31,000/-  <b>Dated:</b>  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated:</b> 24-09-2024	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b> <i>(country of origin):</i> Valid till: 07-02-2028  <b>ISO 13485 Certificate</b> <b>validity:</b> 30-10-2027	<b>DC SCREENING I</b> <b>ITEM NO. 50830</b>  <b>Codes &amp; Sizes:</b> <b>004851 (1x12 Cards)</b>  <b>Class:</b> B  <b>MD group:</b> Single  <b>Shelf life:</b> 12 Months	Approved in D along with submission of differential fee as per revised SRO..
69.	<b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b>	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.	<b>DC SCREENING II</b> <b>ITEM NO. 58560</b>  <b>Codes &amp; Sizes:</b> <b>004831 (1x12 Cards)</b>	Approved in D along with submission of differential fee as per revised SRO..

	<b>PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details:</b> Paid Fee PKR: 31,000/- 7 <b>Dated:</b>  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated:</b> 24-09-2024	<u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b> <i>(country of origin):</i> Valid till: 07-02-2028  <b>ISO 13485 Certificate</b> <b>validity:</b> 30-10-2027	<b>Class:</b> B  <b>MD group:</b> Single  <b>Shelf life:</b> 12 Months	
70.	<b>M/s SIND MEDICAL STORES,</b> <b>13-B, Block 6, PECHS,</b> <b>Shahrah e Faisal,</b> <b>Karachi – 75400,</b> <b>PAKISTAN</b>  <b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023  <b>Fee Details:</b> Paid Fee PKR: 25,000/- <b>Dated:</b>  <b>Dy. No.: NIL</b> DRAP (R&I) <b>Dated:</b> 24-09-2024	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.  <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.  <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland  <b>LOA Validity:</b> 31-12-2026  <b>FSC Switzerland,</b> <i>(country of origin):</i> Valid till: 07-02-2028  <b>ISO 13485 Certificate</b> <b>validity:</b> 30-10-2027	<b>COOMBS Anti-IgG</b> <b>ITEM NO. 50540,</b>  <b>Codes &amp; Sizes.</b> <b>004024</b> (4x12) <b>004025,</b> (60x12) <b>004026</b> (112x12) <b>004027</b> (24x12)  <b>Class:</b> C  <b>MD group:</b> Single  <b>Shelf life:</b> 18 Months	Approved in D along with submission of differential fee as per revised SRO..

71.	<p><b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> Paid Fee PKR: 50,000/- <b>Dated:</b></p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 03-02-2025</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>FSC Switzerland, (country of origin):</b> <i>Valid till:</i> 07-02-2028</p> <p><b>ISO 13485 Certificate validity:</b> 30-10-2027</p>	<p><b>ID-DIACELL I-II-III &amp; ID-DIACELL IP-IIP- IIP ITEM NO. 45184 &amp; 45194</b></p> <p><b>Codes &amp; Sizes.</b> <b>004310</b> (3x10 ml) <b>005310</b> (3x10 ml)</p> <p><b>Class:</b> C</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 10 Weeks</p>	<p><b>Approved Diacell I, II, III (004310) ONLY in D along with submission of differential fee as per revised SRO..</b></p> <p><b>Separate case application shall be submitted for Diacell IP, IIP, IIP (005310)</b></p>
72.	<p><b>M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN</b></p> <p><b>(ELI-00010)</b> D.O.Issue: 03-08-2018 D.O.Renewal: 20-06-2023</p> <p><b>Fee Details:</b> Paid Fee PKR: 50,000/- <b>Dated:</b></p> <p><b>Dy. No.: NIL</b> DRAP (R&amp;I) <b>Dated:</b> 03-02-2025</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland</p> <p><b>LOA Validity:</b> 31-12-2026</p> <p><b>FSC Switzerland, (country of origin):</b> <i>Valid till:</i> 07-02-2028</p>	<p><b>ID-DIAPANEL &amp; ID-DIAPANEL-P ITEM NO. 45161 &amp; 45171</b></p> <p><b>Codes &amp; Sizes.</b> <b>004114</b> (11x4 ml) <b>004214</b> (11x4 ml)</p> <p><b>Class:</b> C</p> <p><b>MD group:</b> Single</p> <p><b>Shelf life:</b> 11 Weeks</p>	<p><b>(Already decided at serial No. 57)</b></p>



		<b>ISO 13485 Certificate</b> <b>validity: 30-10-2027</b>		
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=====END OF DOCUMENT=====

Abdul Qadir  
Assistant Director-I (MIS)  
Thursday, 21 August, 2025, 2:56:59 PM

Abdul Qadir  
Assistant Director-I (MIS)  
Thursday, 21 August, 2025, 2:56:59 PM