

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

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**DECISIONS OF 109<sup>th</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 20-11-2025 (MANUAL APPLICATION AGENDA PART-II)**

109<sup>th</sup> meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 20<sup>th</sup> November, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr M Salik Zahid, Chief Drugs Inspector, Nominee of DGHS Baluchistan	Member (attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
4.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member (attended meeting through videolink)
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
9.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
10.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Ammar Ashraf Awan	Deputy Director
10.	Mr. Hanif Ullah	Deputy Director

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**

**DEPUTY DIRECTOR-IX (MR. MUHAMMAD AMIN)**

**(FRESH CASES-ELI)**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s AF Solutions Pakistan  Office and Godown: Office No. 516-A, 1 <sup>st</sup> Floor, Jeff Heights, Main Boulevard, Gulberg-III, Lahore	Danish Sarfraz  Pharm D	<b>Approved</b>
2.	M/s Aria Pharma (SMC Pvt) Ltd.,  Office and godown: A-18, Eastern Industrial Zone, Port Qasim Authority, Karachi	Kashif Rehman Khan  Pharm D	<b>Approved</b>
3.	M/s Lepharma & Diagnostic (Private) Limited  Office and Godown: Block-D, Unit 5, 8 <sup>th</sup> Floor, Lakson Square Building-1, Sarwar Shaheed Road, Saddar, South Saddar Town, Karachi	Sadaf Hidayat  Pharm D	<b>Approved</b>
4.	M/s Medical Advantages,  Office and godown:	Hafiz Shaikh Muhammad Shaheryar	<b>Approved</b>

	Plot No. 4-C, Suit No. 02, 20 <sup>th</sup> Commercial Street, Phase II (Extension), DHA, Karachi	BS (Bio Medical Engineer)	
5.	M/s Awais Enterprises  Office : Shop No. 19, Block-A, Malik Syed Akbar Plaza, Bara Bazar, Khyber Bara, Peshawar  Godown: Afridi House Godown No. 2, Chugal Pura Ring Road, Peshawar	Faheem Amad Khan  Microbiology	<b>Approved</b>
6.	M/s Qureshi Trading Agency (Pvt) Ltd.,  Office and Godown: House No. 2632V40, Backside Multan Art Council Al Raheem Colony Nishter, Multan.	Ms. Arwa Shahid  Pharm D	<b>Approved</b>
7.	M/s Gastro specialty care,  Office/Godown: Masood Hospital 99, Garden Block Garden Town, Lahore, Punjab 54600 Lahore		Keeping in view of the statement and recommendations submitted by the inspector, The Board <b>decided to reject</b> the application for establishment license to import medical devices.
8.	M/s Khalil Sons (Private) Limited, A-18, Eastern Industrial Zone, Port Qasim Authority, Karachi		The board considered the report of the inspector and observed the major shortcomings in warehouse. It is further observed that the firm initially applied on Plot No CP 1/21, Port Operation Zone, Port Qasim Authority but later on changed to A-18, Eastern Industrial Zone, Port Qasim Authority, Karachi without intimation of Medical Devices Board. The inspector conducted the inspection of the firm at A-18, Eastern Industrial Zone, Port Qasim Authority, Karachi and reported major shortcomings at the premises. Keeping in view of the above, the board <b>decided to reject</b> the application for establishment license to import medical devices.

**Item No. I(B)::**

**Subject: ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES –  
INSPECTION THEREOF OF M/S MODERN TRADING COMPANY, LAHORE**

It is submitted that an inspection of M/s Modern Trading Company, located at 15-S-256 Al-Faisal Town, Bahar Shah Road, Block-C, Lahore Cantt (near Saka Honda Center), Lahore, was conducted by Mr. Abdul Rashid Shaikh, Additional Director, DRAP Lahore, on 01-08-2025, wherein the storage facility of the firm was recommended.

However, the case of the said firm was discussed in the 89th meeting of the MDB. During the meeting, the firm requested additional time, which was placed before the Board for consideration. The Board, however, rejected the application on the grounds that the firm was still not ready despite having applied for grant of an import licence. The Board decided that the firm may submit a fresh application on the prescribed form, along with the prescribed fee and all required documents.

It is therefore submitted that, as the case was rejected in the 89th meeting, the received inspection report may be treated as null and void.

The case is placed before the MDB for consideration.

**Decision: The board noticed that the establishment license to import medical devices of the firm was rejected in 89<sup>th</sup> meeting of the board. However, the Deputy Director DRAP Lahore inspected the premises inadvertently without knowing decision of the board. Therefore, report was considered null and void and advised the firm to apply afresh for establishment license to import medical devices.**

**Item No. II (a): DEFERRED APPLICATION FOR REGISTRATION / ENLISTMENT OF  
MEDICAL DEVICE FOR IMPORT.**

**DEFERRED CASES MINUTES**

**IHSAN-UL-HAQ ATHAR, DEPUTY DIRECTOR-VIII**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Health Tec,  H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan.  ELI-00046  Date of R&I 22/4/2025	SCW Medicath Ltd,  Address: No. 4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, <b>518116</b> Guangdong, P.R. China.  FSC: China.	<b>Angiographic Catheter</b>  Peripheral angiographic Catheter  Class-C  <b>Shelf life: 12 Months</b>  <b>(Model and specification as per FSC)</b>	Approved in class B.

	<b>Fee Details:</b> <b>Paid Fee:</b> 62,000/-  Fee Challan No: 73333755806	Validity: 25-11-2026. (Apostille)  <b>LOA Validity:</b> 26/08/2029 (copy)  EU Quality Management System Certificate (MDR) validity 26-09-2029. (copy)  <b>ISO Validity:</b> 08-07-2027 (copy)		
2.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b>  <b>R&amp;I Date:</b> 03-06- 2025 <b>Fee:</b> 31000/- <b>Slip #</b> 949961765141	<b>Name of Manufacturer:</b> Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year • <b>FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027  <b>ii. Issued by:</b> AEMPS of Spain <b>Type:</b> Copy <b>Legalization:</b> Legalized <b>Issue Date:</b> 06-11-2019 <b>Validity:</b> N/A  • <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Validity:</b> 26-05-2024	<b>Brand Name:</b> HT-Burette Set <b>Generic Name:</b> Measured Volume Fluid Administration Set <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application Model:</b> FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. <b>Shelf Life:</b> 5 years (Room temperature)	Deferred for submission of: 1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is HT- Burette Set Measured Volume Fluid Administration Set and codes not mentioned in it. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is Ultramed Burette Set Measured Volume Fluid Administration Set-1016. The codes are 1016- 100 and 1016-150. 4. clarify that name & address of the manufacturer declared in FSC, DoC etc is “Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab El Awamer. 5. The fee for the family has not been submitted.
3.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24,	<b>Name of Manufacturer:</b>	<b>Brand Name:</b> HT-Latex Foley Balloon Catheter	Deferred for submission of: 1. Notarized LOA with name, model/sizes of the product.

	<p>Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b></p> <p><b>R&amp;I Date:</b> 03-06-2025 <b>Fee:</b> 31000/- <b>Slip #</b> 638591659997</p>	<p>Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027</p> <p><b>ii. Issued by:</b> AEMPS of Spain <b>Type:</b> Copy <b>Legalization:</b> Legalized <b>Issue Date:</b> 06-11-2019 <b>Validity:</b> N/A</p> <p>• <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Validity:</b> 20-05-2026</p>	<p><b>Generic Name:</b> Indwelling Urinary Catheter <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application Model:</b> Silicon Coated Latex Foley Balloon Catheter 2 way and 3 way</p> <p><b>**FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes.</b> <b>Shelf Life:</b> 5 years (Room temperature)</p>	<p>2. clarification that product name in FSC (Egypt) is Silicon coated Latex Folly Balloon Catheter 2 Way and 3 way Code not mentioned in FSC.</p> <p>3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is Ultramed silicon coated latex <u>Foley</u> balloon catheter 2-way and 3-way-3006. Multiple sizes/types and codes mentioned in it.</p> <p>4. clarify that name &amp; address of the manufacturer declared in FSC, DoC etc is “Ultra for medical products co. ((ULTRAMED))) U.M.I.C) S.A.E, Paret No. (304:310) &amp; Part No. (312 – Industrial Area, Arab El Awamer.</p> <p>5. The fee for the family has not been claimed but fee voucher not attached.</p>
4.	<p>M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b></p> <p><b>R&amp;I Date:</b> 03-06-2025 <b>Fee:</b> 31000/- <b>Slip #</b> 2664028627</p>	<p><b>Name of Manufacturer:</b> Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027</p>	<p><b>Brand Name:</b> HT-Surgical Gloves (Powder free) <b>Generic Name:</b> Surgical Gloves (Powder free) <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application:</b> 6.5, 7.0, 7.5, 8.0, 8.5</p> <p><b>**FSC issued by Egyptian Drug Authority does not declare any Sizes.</b> <b>Shelf Life:</b> 5 years</p>	<p>Deferred for submission of:</p> <p>1. Notarized LOA with name, model/sizes of the product.</p> <p>2. clarification that product name in FSC (Egypt) is Surgical Gloves Powder free and codes not mentioned in it.</p> <p>3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is HT-Surgical Gloves (Powder free) -9013/PF – with multiple codes/sizes mentioned in it.</p> <p>4. clarify that name &amp; address of the manufacturer declared in FSC, DoC etc is “Ultra for medical products co. ((ULTRAMED))) U.M.I.C)</p>

		<b>ii. Issued by:</b> AEMPS of Spain <b>Type:</b> Copy <b>Legalization:</b> Legalized <b>Issue Date:</b> 06-11-2019 <b>Validity:</b> N/A  <b>• ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Validity:</b> 20-05-2026		S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer. 5. The fee for the family has not been submitted.
5.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b>  <b>R&amp;I Date:</b> 03-06-2025 <b>Fee:</b> 31000/- <b>Slip #</b> 2318455592	<b>Name of Manufacturer:</b> Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year <b>• FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027  <b>ii. Issued by:</b> AEMPS of Spain <b>Type:</b> Copy <b>Legalization:</b> Legalized <b>Issue Date:</b> 06-11-2019 <b>Validity:</b> N/A  <b>• ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Validity:</b> 26-05-2024	<b>Brand Name:</b> HT-Blood Administration Set <b>Generic Name:</b> Blood Administration Set <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application Model:</b> FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. <b>Shelf Life:</b> 5 years (Room temperature)	Deferred for submission of: 1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Blood Administration Set. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is Ultramed Blood Transfusion Set, codes is 7007. 4. clarify that name & address of the manufacturer declared in FSC, DoC etc is “Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer. 5. The fee for the family has not been submitted.
6.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24,	<b>Name of Manufacturer:</b>	<b>Brand Name:</b> Silicon Foley Balloon Catheter	Deferred for submission of: 1. Notarized LOA with name, model/sizes of the product.

	<p>Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b></p> <p><b>R&amp;I Date:</b> 03-06-2025 <b>Fee:</b> 31000/- <b>Slip #</b> 450645153</p>	<p>Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027</p> <p><b>ii. Issued by:</b> AEMPS of Spain <b>Type:</b> Copy <b>Legalization:</b> Legalized <b>Issue Date:</b> 06-11-2019 <b>Validity:</b> N/A</p> <p>• <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Validity:</b> 20-05-2026</p>	<p><b>Generic Name:</b> Indwelling Urinary Catheter <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application Model):</b> Silicon Foley Balloon Catheter 2 way and 3 way</p> <p><b>**FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes.</b> <b>Shelf Life:</b> 5 years (Room temperature)</p>	<p>2. clarification that product name in FSC (Egypt) is Silicon Foley Balloon Catheter 2-way/3-Way and codes not mentioned in it.</p> <p>3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is <b>Ultrmed All silicon, Silicon Foley balloon catheter 2-way and 3-way -3007.</b></p> <p>4. clarify that name &amp; address of the manufacturer declared in FSC, DoC etc is “Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) &amp; Part No. (312 – Industrial Area, Arab El Awamer.</p> <p>5. The fee for the family has not been submitted.</p> <p>6. Firm need to apply 2-way and 3-way separately.</p>
7.	<p>M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. <b>(ELI-00046)</b></p> <p><b>R&amp;I Date:</b> 03-06-2025 <b>Fee:</b> 31000/- <b>Slip #</b> 691480401310</p>	<p><b>Name of Manufacturer:</b> Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Legalized <b>Issue Date:</b> 27-03-2025 <b>Validity:</b> 1 year</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>i. Issued By:</b> Egyptian Drug Authority <b>Legalization:</b> Legalized <b>Issue Date:</b> 07-04-2025 <b>Validity:</b> 07-04-2027</p>	<p><b>Brand Name:</b> Ultramed Urine Collection Bag <b>Generic Name:</b> Urine Collection Bag <b>Applied as:</b> Set <b>Class:</b> B <b>Models/Code/sizes (as per FSC &amp; application Capacity):</b> 2000ml</p> <p><b>**FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes.</b> <b>Shelf Life:</b> 5 years (Room temperature)</p>	<p>Deferred for submission of:</p> <p>1. Notarized LOA with name, model/sizes of the product.</p> <p>2. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve.</p> <p>3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine collection bag with non-return valve (push/pull connector)).</p> <p>4. clarify that name &amp; address of the manufacturer declared in FSC, DoC etc is “Ultra for</p>



		<p>• <b>ISO – Certificate:</b>  <b>Type:</b> Original  <b>Notarization:</b>  Legalized  <b>Validity:</b> 20-05-2026-</p>		<p>medical products co.  ((ULTRAMED)) U.M.I.C)  S.A.E, Paret No. (304:310) &amp;  Part No. (312 – Industrial  Area, Arab E1 Awamer.  5. The fee for the family has  not been submitted.</p>
8.	<p>M/s Health Solutions.  28-B, Second floor,  Zeenat Medicine  Market, North Napier  Road, Karachi.  <b>(ELI-01153)</b>  D.O.I: 07-09-2023  <b>Dy. No.:</b>  15745 DRAP (R&amp;I)  <b>Dated: 18-09-2024</b>  <b>Fee Challan No.:</b>  07048226510  7  PKR: 50000/-  <b>Dated: 30-07-2024</b></p>	<p><b>Legal Manufacturer:</b>  M/s Shandong Haidike  Medical Products Co.  Ltd.  <b>Manufacturer</b>  <b>Address:</b>  Tianfu Road,  Dongcheng District,  Shan County, 274300,  Heze City, Shandong  Province, China.  ISO 13485 Certificate  validity: 19-04-2026  EC Certificate validity:  09-04-2024  LOA Validity:  30-12-2027  FSC Validity: China  (country of origin):  14-02-2025  <b>FSC (MHRA-UK)</b>  <b>Dated 23-02-2019</b></p>	<p>Suigly Suicon Surgical  Sutures  Polyglycolic Acid Surgical  Suture with Needle (PGA)  USP Suture Size: 12-0, 11-  0, 10-0, 9-0, 8-0, 7-0, 6-0,  5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3,  4, 5.  Needle Shape: Round  Bodied, Straight, Curve,  Cutting, Reverse Cutting,  Taper Cutting, Non cutting.  Needle Curvature: ½  Circle, 3/8 circle, straight &amp;  double spatulated.  Class: D  Shelf life: 05 years</p>	<p>Approved with Brand name  SUICARE.</p>
9.	<p>M/s Health Solutions.  28-B, Second floor,  Zeenat Medicine  Market, North Napier  Road, Karachi.  <b>(ELI-01153)</b>  D.O.I: 07-09-2023  <b>Dy. No.:</b>  15744 DRAP (R&amp;I)  <b>Dated: 18-09-2024</b>  <b>Fee Challan No.:</b>  838593134  PKR: 50000/-  <b>Dated: 30-07-2024</b></p>	<p><b>Legal Manufacturer:</b>  M/s Shandong Haidike  Medical Products Co.  Ltd.  <b>Manufacturer</b>  <b>Address:</b>  Tianfu Road,  Dongcheng District,  Shan County, 274300,  Heze City, Shandong  Province, China.  ISO 13485 Certificate  validity: 19-04-2026  EC Certificate  validity:  09-04-2024  LOA Validity:  30-12-2027  <b>FSC Validity: China</b>  (country of origin):  14-02-2025  <b>FSC (MHRA-UK)</b></p>	<p><b>Suicon Surgical Sutures</b>  <b>Silk Braided Surgical</b>  <b>Suture with needle</b>  <b>USP Suture</b>  <b>Size: 12-0, 11-0, 10-0, 9-0,</b>  <b>8-0, 7-0, 6-0, 5-0, 4-0, 3-0,</b>  <b>2-0, 0, 1, 2, 3, 4, 5.</b>  <b>Needle Shape:</b> Round  Bodied, Straight, Curve,  Cutting, Reverse Cutting.  <b>Needle Curvature:</b> ½  Circle, 3/8 circle, straight.  <b>Class: D</b>  <b>Shelf life: 05 years</b></p>	<p>Approved with Brand name  SUICARE.</p>

		<b>Dated 23-02-2019</b>		
10.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. <b>(ELI-01153)</b> D.O.I: 07-09-2023 <b>Dy. No.:</b> 15747 DRAP (R&I) <b>Dated: 18-09-2024</b> <b>Fee Challan No.:</b> 7798811089 PKR: 50000/- <b>Dated: 09-08-2024</b>	<b>Legal Manufacturer:</b> M/s Shandong Haidike Medical Products Co. Ltd. <b>Manufacturer Address:</b> Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. <b>ISO 13485 Certificate validity:</b> 19-04-2026 <b>EC Certificate validity:</b> 09-04-2024 <b>LOA Validity:</b> 30-12-2027 <b>FSC Validity: China</b> (country of origin): 14-02-2025 <b>FSC (MHRA-UK)</b> <b>Dated 23-02-2019</b>	<b>Suicon Surgical Sutures Suilene</b>  <b>Polypropylene Monofilament Surgical Suture with Needle USP Suture</b> <b>Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5.</b> <b>Needle Shape:</b> Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting and non-cutting. <b>Needle Curvature:</b> ½ Circle, 3/8 circle, straight, Double Needle. <b>Class: D</b> <b>Shelf life:</b> 05 years	Approved with Brand name SUICARE.
11.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. <b>(ELI-01153)</b> D.O.I: 07-09-2023 <b>Dy. No.:</b> 15746 DRAP (R&I) <b>Dated: 18-09-2024</b> <b>Fee Challan No.:</b> 06434554213 PKR: 50000/- <b>Dated: 09-08-2024</b>	<b>Legal Manufacturer:</b> M/s Shandong Haidike Medical Products Co. Ltd. <b>Manufacturer Address:</b> Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. <b>ISO 13485 Certificate validity:</b> 19-04-2026 <b>EC Certificate validity:</b> 09-04-2024 <b>LOA Validity:</b> 30-12-2027 <b>FSC Validity: China</b> (country of origin): 14-02-2025 <b>FSC (MHRA-UK)</b> <b>Dated 23-02-2019.</b>	<b>Suicon Surgical Sutures Suicryl</b>  <b>Polyglactin 910 (PGLA) Surgical Suture with Needle</b> <b>USP Suture Size: 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5.</b> <b>Needle Shape:</b> Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting. <b>Needle Curvature:</b> ½ Circle, 3/8 circle, straight. <b>Class: D</b> <b>Shelf life:</b> 05 years	Approved with Brand name SUICARE.
12.	ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED	<b>LEGAL MANUFACTURER</b> <b>Zybio Inc.</b>	High Density Lipoprotein Cholesterol (HDL-C) Kit (Enzymatic Method)  Codes:	Approved subject to submission of fee for the family.

	<p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 55312531</p>	<p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11- 2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11- 2026</b></p>	<table><tr><th>REF (as per IFU)</th><th>Specificatio n (as per FSC)</th></tr><tr><td>01.09.02. 03.EC.01</td><td>R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09.02. 03.EC.02</td><td>R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specificatio n (as per FSC)	01.09.02. 03.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	01.09.02. 03.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	
REF (as per IFU)	Specificatio n (as per FSC)									
01.09.02. 03.EC.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
01.09.02. 03.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
13.	<p>ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 1668763579</p>	<p><b>LEGAL MANUFACTEURER Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11- 2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p>	<p>Total Bilirubin (TBIL) Kit(Vanadate Oxidation Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specifica tion (as per FSC)</th></tr><tr><td>01.09.00. 21.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.00. 21.EC.03</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p>	REF (as per IFU)	Specifica tion (as per FSC)	01.09.00. 21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.00. 21.EC.03	R1 48 mL × 2 R2 12 mL × 2	<p>Approved subject to submission of fee for the family.</p>
REF (as per IFU)	Specifica tion (as per FSC)									
01.09.00. 21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.00. 21.EC.03	R1 48 mL × 2 R2 12 mL × 2									

		<b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	Class:B							
14.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 83172362105</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>Alanine Aminotransferase (ALT) Kit (Enzymatic Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.00.05.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.00.05.EC.03</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.00.05.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.00.05.EC.03	R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.
REF (as per IFU)	Specification (as per FSC)									
01.09.00.05.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.00.05.EC.03	R1 48 mL × 2 R2 12 mL × 2									
15.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p>	<p>Aspartate Aminotransferase (AST) Kit (Enzymatic Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td></td><td></td></tr></table>	REF (as per IFU)	Specification (as per FSC)			Approved subject to submission of fee for the family.		
REF (as per IFU)	Specification (as per FSC)									

	20/02/2025  <b>Deposit Slip No:</b> 58368205383	<b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b>  <b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	<table><tr><td>01.09.00.16.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.00.16.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table>  Shelf Life: 18 months  Class:B	01.09.00.16.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.00.16.EC.02	R1 48 mL × 2 R2 12 mL × 2			
01.09.00.16.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.00.16.EC.02	R1 48 mL × 2 R2 12 mL × 2									
16.	<b>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</b>  Address of Importer House No 323, street No 66, Sector I8/3, Islamabad  <b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025  <b>Deposit Slip No:</b> 89357770	<b>LEGAL MANUFACTURER Zybio Inc.</b>  <b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China  <b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b>  <b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	Urea (UREA) Kit (Urease-GLDH Method) Codes: <table><tr><td><b>REF (as per IFU)</b></td><td><b>Specification (as per FSC)</b></td></tr><tr><td>01.09.01.06.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.01.06.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table>  Shelf Life: 18 months  Class:B	<b>REF (as per IFU)</b>	<b>Specification (as per FSC)</b>	01.09.01.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.01.06.EC.02	R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.
<b>REF (as per IFU)</b>	<b>Specification (as per FSC)</b>									
01.09.01.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.01.06.EC.02	R1 48 mL × 2 R2 12 mL × 2									
17.	<b>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</b>  Address of Importer	<b>LEGAL MANUFACTURER Zybio Inc.</b>  <b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing,	Alkaline Phosphatase (ALP) Kit (Enzymatic Method) Codes: <table><tr><td><b>REF (as per IFU)</b></td><td><b>Specification (as per FSC)</b></td></tr></table>	<b>REF (as per IFU)</b>	<b>Specification (as per FSC)</b>	Approved subject to submission of fee for the family.				
<b>REF (as per IFU)</b>	<b>Specification (as per FSC)</b>									

	<p>House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p> <p>20/02/2025</p> <p><b>Deposit Slip No:</b> 056101453</p>	<p><b>People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<table><tr><td>01.09.01.0 6.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.01.0 6.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	01.09.01.0 6.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.01.0 6.EC.02	R1 48 mL × 2 R2 12 mL × 2			
01.09.01.0 6.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.01.0 6.EC.02	R1 48 mL × 2 R2 12 mL × 2									
18.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p> <p>20/02/2025</p> <p><b>Deposit Slip No:</b> 056101453</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>Albumin (ALB) Kit (Bromocresol Green Method)</p> <p>Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specificat ion (as per FSC)</th></tr><tr><td>01.09.0 0.04.EC .01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.0 0.04.EC .03</td><td>R 60 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specificat ion (as per FSC)	01.09.0 0.04.EC .01	R 30 mL × 6	01.09.0 0.04.EC .03	R 60 mL × 2	Approved subject to submission of fee for the family.
REF (as per IFU)	Specificat ion (as per FSC)									
01.09.0 0.04.EC .01	R 30 mL × 6									
01.09.0 0.04.EC .03	R 60 mL × 2									
19.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p>	<p>Low Density Lipoprotein Cholesterol (LDL-C) Kit (Enzymatic Method)</p> <p>Codes:</p>	Approved subject to submission of fee for the family.						

	<p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 3632546296</p>	<p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11- 2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11- 2026</b></p>	<table><tr><th>REF (as per IFU)</th><th>Specificatio n (as per FSC)</th></tr><tr><td>01.09.02. 00.EC.01</td><td>R1 30 mL × 3 R2 10 mL ×3  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09.02. 00.EC.02</td><td>R1 45 mL × 2 R2 15 mL × 2  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specificatio n (as per FSC)	01.09.02. 00.EC.01	R1 30 mL × 3 R2 10 mL ×3  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1	01.09.02. 00.EC.02	R1 45 mL × 2 R2 15 mL × 2  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1	
REF (as per IFU)	Specificatio n (as per FSC)									
01.09.02. 00.EC.01	R1 30 mL × 3 R2 10 mL ×3  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1									
01.09.02. 00.EC.02	R1 45 mL × 2 R2 15 mL × 2  Calibrator 1 Level × 1.0 mL × 1  Control 2 Levels × 1.0 mL × 1									
20.	<p>ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 44943347</p>	<p><b>LEGAL MANUFACTEURER Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11- 2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p>	<p>Glycated Hemoglobin A1c (HbA1c) Kit (Immunoturbidimetric Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specificat ion (as per FSC)</th></tr><tr><td>01.09.06.0 3.EC.01</td><td>R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2  Calibrator 5 Levels × 1.0 mL × 1  Control 2 Levels ×</td></tr></table>	REF (as per IFU)	Specificat ion (as per FSC)	01.09.06.0 3.EC.01	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2  Calibrator 5 Levels × 1.0 mL × 1  Control 2 Levels ×	<p>Approved subject to submission of fee for the family.</p>		
REF (as per IFU)	Specificat ion (as per FSC)									
01.09.06.0 3.EC.01	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2  Calibrator 5 Levels × 1.0 mL × 1  Control 2 Levels ×									

		<b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	<table><tr><td></td><td>1.0 mL × 1</td></tr><tr><td>01.09.06.03.EC.02</td><td>R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table> Shelf Life: 18 months  Class:B		1.0 mL × 1	01.09.06.03.EC.02	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1							
	1.0 mL × 1													
01.09.06.03.EC.02	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1													
21.	<b>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</b>  Address of Importer House No 323, street No 66, Sector I8/3, Islamabad  <b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025  <b>Deposit Slip No:</b> 44943347	<b>LEGAL MANUFACTURER Zybio Inc.</b>  <b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China  <b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b>  <b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	<b>Magnesium (Mg) Kit (Xylidyl Blue Method)</b> Codes: <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0C.02.EC.01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.0C.02.EC.02</td><td>R 60 mL × 2</td></tr><tr><td>01.09.0C.02.EC.03</td><td>R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1</td></tr><tr><td>01.09.0C.02.EC.04</td><td>R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1</td></tr></table> Shelf Life: 18 months  Class:B	REF (as per IFU)	Specification (as per FSC)	01.09.0C.02.EC.01	R 30 mL × 6	01.09.0C.02.EC.02	R 60 mL × 2	01.09.0C.02.EC.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1	01.09.0C.02.EC.04	R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1	Approved subject to submission of fee for the family.
REF (as per IFU)	Specification (as per FSC)													
01.09.0C.02.EC.01	R 30 mL × 6													
01.09.0C.02.EC.02	R 60 mL × 2													
01.09.0C.02.EC.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1													
01.09.0C.02.EC.04	R 60 mL × 2 Calibrator 1 Level × 1.0 mL × 1													



22.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 50,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 4635111056</p>	<p><b>LEGAL MANUFACTURER</b> <b>Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>Hematology Analyzer Models: (as per FSC) Z50 Z52 Shelf Life: 18 months</p> <p>Class:B</p>	<p>Approved Hematology Analyzer Models: Z50. The firm will apply Hematology Analyzer Models: Z52 separately through online portal for registration.</p>
23.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 50,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 116164750586</p>	<p><b>LEGAL MANUFACTURER</b> <b>Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System</b></p>	<p>Hematology Analyzer Models: (as per FSC) 1. Z3 2. Z31 3. Z30 4. Z3 CRP 5. Z30 CRP 6. Z31 CRP Shelf Life: 18 months</p> <p>Class:B</p>	<p>Approved Hematology Analyzer Models: Z3. The firm will apply online separately for each model.</p>

		<b>Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>								
24.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p> <p>20/02/2025</p> <p><b>Deposit Slip No:</b> 71809609647</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>Lipase (LPS) Kit (Colorimetric Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specificati on (as per FSC)</th></tr><tr><td>01.09.0B .01.EC.0 1</td><td>R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09.0B .01.EC.0 2</td><td>R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specificati on (as per FSC)	01.09.0B .01.EC.0 1	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	01.09.0B .01.EC.0 2	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Approved subject to submission of fee for the family.
REF (as per IFU)	Specificati on (as per FSC)									
01.09.0B .01.EC.0 1	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
01.09.0B .01.EC.0 2	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
25.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p>	<p>Total Protein (TP) Kit (Biuret Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specificat ion (as per FSC)</th></tr><tr><td>01.09.00.2 3.EC.01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.00.2 3.EC.02</td><td>R 60 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p>	REF (as per IFU)	Specificat ion (as per FSC)	01.09.00.2 3.EC.01	R 30 mL × 6	01.09.00.2 3.EC.02	R 60 mL × 2	Approved subject to submission of fee for the family.
REF (as per IFU)	Specificat ion (as per FSC)									
01.09.00.2 3.EC.01	R 30 mL × 6									
01.09.00.2 3.EC.02	R 60 mL × 2									

	20/02/2025  <b>Deposit Slip No:</b> 71809609647	<b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b>  <b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	Class:B							
26.	<b>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</b>  Address of Importer House No 323, street No 66, Sector I8/3, Islamabad  <b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025  <b>Deposit Slip No:</b> 7380613052	<b>LEGAL MANUFACTURER Zybio Inc.</b>  <b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b>  <b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b>  <b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method) <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.00.0 3.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.00.0 3.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> Shelf Life: 18 months  Class:B	REF (as per IFU)	Specification (as per FSC)	01.09.00.0 3.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.00.0 3.EC.02	R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.
REF (as per IFU)	Specification (as per FSC)									
01.09.00.0 3.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.00.0 3.EC.02	R1 48 mL × 2 R2 12 mL × 2									
27.	<b>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</b>  Address of Importer	<b>LEGAL MANUFACTURER Zybio Inc.</b>  <b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing,</b>	Triglyceride (TG) Kit (Enzymatic Method) <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.02.0 2.EC.01</td><td>R1 30 mL × 3</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	01.09.02.0 2.EC.01	R1 30 mL × 3	Approved subject to submission of fee for the family.		
REF (as per IFU)	Specification (as per FSC)									
01.09.02.0 2.EC.01	R1 30 mL × 3									

	<p>House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-</p> <p>20/02/2025</p> <p><b>Deposit Slip No:</b> 51681194097</p>	<p><b>People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<table><tr><td></td><td>R2 7.5 mL × 3</td></tr><tr><td>01.09.02.02.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>		R2 7.5 mL × 3	01.09.02.02.EC.02	R1 48 mL × 2 R2 12 mL × 2					
	R2 7.5 mL × 3											
01.09.02.02.EC.02	R1 48 mL × 2 R2 12 mL × 2											
28.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 62,000/-</p> <p>20/02/2025</p> <p><b>Deposit Slip No:</b> 699990640</p>	<p><b>LEGAL MANUFACTURER Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</b></p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>C-Reactive Protein Kit (Immunoturbidimetric Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specificati on (as per FSC)</th></tr><tr><td>3011001</td><td>25T : R1 0.4mLx25, R2 1.5mLx1</td></tr><tr><td>3011002</td><td>100T: R1 0.4mLx100, R2 3.0mLx2</td></tr><tr><td>3011003</td><td>25T : R1 0.4mLx25, R2 1.5mLx1 (including Cal 6 levels x1 x 0.5mL, Con 2 levels x1x0.5mL)</td></tr></table>	REF (as per IFU)	Specificati on (as per FSC)	3011001	25T : R1 0.4mLx25, R2 1.5mLx1	3011002	100T: R1 0.4mLx100, R2 3.0mLx2	3011003	25T : R1 0.4mLx25, R2 1.5mLx1 (including Cal 6 levels x1 x 0.5mL, Con 2 levels x1x0.5mL)	<p>Approved C-Reactive Protein (CRP) Kit (Latex Enhanced Immunoturbidimetric Method) subject to submission of fee for the family.</p>
REF (as per IFU)	Specificati on (as per FSC)											
3011001	25T : R1 0.4mLx25, R2 1.5mLx1											
3011002	100T: R1 0.4mLx100, R2 3.0mLx2											
3011003	25T : R1 0.4mLx25, R2 1.5mLx1 (including Cal 6 levels x1 x 0.5mL, Con 2 levels x1x0.5mL)											

			<table><tr><td>3011004</td><td>25T: R1 0.4mLx25, R2 1.5mLx1(i ncluding Con 2 levels x1x0.5mL)</td></tr><tr><td>3011005</td><td>100T: R1 0.4mLx10 0, R2 3mLx2 (including Cal 6 levels x1x1.0mL, Con 2 levels x1x1.0mL)</td></tr><tr><td>3011006</td><td>100T: R1 0.4mLx10 0, R2 3mLx2(inc luding Control 2 levels x1x1.0mL)</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:C</p>	3011004	25T: R1 0.4mLx25, R2 1.5mLx1(i ncluding Con 2 levels x1x0.5mL)	3011005	100T: R1 0.4mLx10 0, R2 3mLx2 (including Cal 6 levels x1x1.0mL, Con 2 levels x1x1.0mL)	3011006	100T: R1 0.4mLx10 0, R2 3mLx2(inc luding Control 2 levels x1x1.0mL)			
3011004	25T: R1 0.4mLx25, R2 1.5mLx1(i ncluding Con 2 levels x1x0.5mL)											
3011005	100T: R1 0.4mLx10 0, R2 3mLx2 (including Cal 6 levels x1x1.0mL, Con 2 levels x1x1.0mL)											
3011006	100T: R1 0.4mLx10 0, R2 3mLx2(inc luding Control 2 levels x1x1.0mL)											
29.	<p>ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 51681194097</p>	<p><b>LEGAL MANUFACTURER</b> <b>Zybio Inc.</b></p> <p><b>Company Address:</b> <b>No. 45, Shilin Avenue,</b> <b>Tiaodeng Town,</b> <b>Dadukou District,</b> <b>400082 Chongqing,</b> <b>People's Republic of</b> <b>China</b></p> <p><b>Marketing</b> <b>Authorization Letter</b> <b>(original):</b> <b>Validity Date: 23-11-</b> <b>2028</b></p> <p><b>FSC: China (Original)</b></p>	<table><tr><td colspan="2">Lactate Dehydrogenase (LDH) Kit (Rate Method))</td></tr><tr><td><b>REF (as per IFU)</b></td><td><b>Specificati on (as per FSC)</b></td></tr><tr><td>01.09.04.0 6.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.04.0 6.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	Lactate Dehydrogenase (LDH) Kit (Rate Method))		<b>REF (as per IFU)</b>	<b>Specificati on (as per FSC)</b>	01.09.04.0 6.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.04.0 6.EC.02	R1 48 mL × 2 R2 12 mL × 2	<p>Approved subject to submission of fee for the family.</p>
Lactate Dehydrogenase (LDH) Kit (Rate Method))												
<b>REF (as per IFU)</b>	<b>Specificati on (as per FSC)</b>											
01.09.04.0 6.EC.01	R1 30 mL × 3 R2 7.5 mL × 3											
01.09.04.0 6.EC.02	R1 48 mL × 2 R2 12 mL × 2											

		<b>Issuance Date:</b> 03-11-2026  <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>								
30.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p> <p><b>Deposit Slip No:</b> 48737124</p>	<p><b>LEGAL MANUFACTURER</b> Zybio Inc.</p> <p><b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p><b>Marketing Authorization Letter (original):</b> <b>Validity Date: 23-11-2028</b></p> <p><b>FSC: China (Original)</b> <b>Issuance Date:</b> 03-11-2026</p> <p><b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b></p>	<p>Total Cholesterol (CHOL) Kit (Enzymatic Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.02.10.EC.01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.02.10.EC.02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.02.10.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.02.10.EC.02	R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.
REF (as per IFU)	Specification (as per FSC)									
01.09.02.10.EC.01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.02.10.EC.02	R1 48 mL × 2 R2 12 mL × 2									
31.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p><b>Fee Amount &amp; Fee Submission Date:</b> Rs. 31,000/-  20/02/2025</p>	<p><b>LEGAL MANUFACTURER</b> Zybio Inc.</p> <p><b>Company Address:</b> No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p><b>Marketing Authorization Letter (original):</b></p>	<p>Glucose (GLU) Kit (Hexokinase Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>1080201</td><td>R1 30 mL × 1 R2 7.5 mL × 1</td></tr><tr><td>1080202</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	1080201	R1 30 mL × 1 R2 7.5 mL × 1	1080202	R1 30 mL × 3 R2 7.5 mL × 3	Approved subject to submission of fee for the family.
REF (as per IFU)	Specification (as per FSC)									
1080201	R1 30 mL × 1 R2 7.5 mL × 1									
1080202	R1 30 mL × 3 R2 7.5 mL × 3									

	<b>Deposit Slip No:</b> 0044365032	<b>Validity Date: 23-11-2028</b>  <b>FSC: China</b> (Original) <b>Issuance Date: 03-11-2026</b> <b>Production Quality Management System Certificate (ISO 13485) (Original)</b> <b>Validity Date: 29-11-2026</b>	<div>1080203</div> <div>R1 48 mL × 2 R2 12 mL × 2</div>	Shelf Life: 18 months  Class:B	
32.	Fabnos Traders Pvt Ltd building 26-c, 3rd floor, Touheed commercial area, street no 26 phase v Dha, Karachi (ELI-00750)	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA  Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islands Baleares, 50 Pol. Ind. Fuente De Jarro, Paterna, Valencia, 46988 Spain.	Zimmer Dental (Abutment) Angled  <b>Applied Codes:</b> <b>A5H20/6 (ABUT 20 DEG 5,7MM IMP HEX-LOCK)</b>  <b>AH20/4 (ABUT 20 DEG SCR-V 3.5 MM IMP)</b>  <b>AH20S (SCR REPLACEMENT SCR-V 20 DEG ABUT INT HEX)</b>  <b>AH20W/5 (ABUT 20DEG SCR-V 4.5MM IMP)</b>	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper.	
33.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi. (ELI-00750)	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA  Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islands Baleares, 50 Pol. Ind. Fuente De Jarro, Paterna, Valencia, 46988 Spain.	Zimmer Dental (Healing Collar)	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification for the name of device as the name of device is Healing collars for taped screw-Vent and Screw-Vent Implants.	
34.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA  Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islands Baleares, 50	Zimmer Dental Abutment (Hex Lock Abutment)	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification is required that The codes HLTS2 and MHLAS does not belong to ABUT HEX-LOCK FLARE.	

	(ELI-00750	Pol. Ind. Fuente De Jarro, Paterna, Valencia, 46988 Spain.		
35.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.  (ELI-00750	Dentis Co., Ltd., Korea  Addresses: 1. HQ: 99 Seongseoseo-ro, Dalseo-gu, Daegu, Republic of Korea.  2. Factory address: 1F, B-dong, 6, Yulam-ro, Dong-gu, Daegu, Republic of Korea  Tel: +82-53-582-2804 Fax. +82-53-583-2806 E-mail: <a href="http://www.dentis.co.kr">http://www.dentis.co.kr</a>  LOA: Issuance date: 01-03-2023 Valid Till: 28-02-2026  Country of Origin (Korea) FSC: Date of Issuance: 13-03-2023  ISO Certificate: Issuance date: 02-04-2022 Valid till: 02-04-2025  CE Certificate: Initial date: 16-07-2019 Valid till: 27-05-2024	Dentis s-Clean Healing Abutment  Codes: • DSH4510 • DSH4515 • DSH4520 • DSH4525 • DSH4535 • DSH4545 • DSH4555 • DSH5510 • DSH5515 • DSH5520 • DSH5525 • DSH5535 • DSH5545 • DSH5555 • DSH6515 • DSH6520 • DSH6525 • DSH6535 • DSH6545 • DSH6555 • DSH7515 • DSH7520 • DSH7525 • DSH7535 • DSH7545 • DSH7555 • DSHS4010 • DSHS4015 • DSHS4020 • DSHS4025 • DSHS4035 • DSHS4045	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification is required as The name of device as per FSC is Implant, endosseous, superstructure.
36.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.  (ELI-00750	Dentis Co., Ltd., Korea  Addresses: 1. HQ: 99 Seongseoseo-ro, Dalseo-gu, Daegu, Republic of Korea.  2. Factory address: 1F, B-dong, 6, Yulam-ro, Dong-gu, Daegu, Republic of Korea  Tel: +82-53-582-2804 Fax. +82-53-583-2806	s-Clean SQ-SL Fixture  Codes: DSSFN3507S DSSFN3508S DSSFN3510S DSSFN3512S DSSFN3514S DSSFR4007S DSSFR4008S DSSFR4010S DSSFR4012S DSSFR4014S DSSFR4507S	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification/justification is required as The name of device as per FSC is Implant, endosseous, fixture and The codes DSSFW6006S DSSFW7006S DSSFW8006S are not present in FSC.



		<p>E-mail: http://www.dentis.co.kr</p> <p>LOA: Issuance date: 01-03-2023 Valid Till: 28-02-2026</p> <p>Country of Origin (Korea) FSC: Date of Issuance: 13-03-2023</p> <p>ISO Certificate: Issuance date: 02-04-2022 Valid till: 02-04-2025</p> <p>CE Certificate: Initial date: 16-07-2019 Valid till: 27-05-2024</p>	<p>DSSFR4508S DSSFR4510S DSSFR4512S DSSFR4514S DSSFR5007S DSSFR5008S DSSFR5010S DSSFR5012S DSSFR5014S DSSFW6007S DSSFW6008S DSSFW6010S DSSFW6012S DSSFW7007S DSSFW7008S DSSFW7010S DSSFW7012S DSSFW8007S DSSFW8008S DSSFW8010S DSSFW8012S <del>DSSFW6006S</del> <del>DSSFW7006S</del> <del>DSSFW8006S</del></p>	
37.	<p>Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.  (ELI-00750</p>	<p>Dentis Co., Ltd., Korea</p> <p>Addresses: 1. HQ: 99 Seongseoseo-ro, Dalseo-gu, Daegu, Republic of Korea.  2. Factory address: 1F, B-dong, 6, Yulam-ro, Dong-gu, Daegu, Republic of Korea</p> <p>Tel: +82-53-582-2804 Fax. +82-53-583-2806 E-mail: http://www.dentis.co.kr</p> <p>LOA: Issuance date: 01-03-2023 Valid Till: 28-02-2026</p> <p>Country of Origin (Korea) FSC: Date of Issuance: 13-03-2023</p> <p>ISO Certificate: Issuance date: 02-04-</p>	<p>Dentis s-Clean TiN Partial Coating Couple Abutment</p> <p>Model no: DSCA4510HPCTS DSCA4510NPCTS DSCA4510H7PCTS DSCA4510N7PCTS DSCA4515HPCTS DSCA4515NPCTS DSCA4515H7PCTS DSCA4515N7PCTS DSCA4520HPCTS DSCA4520NPCTS DSCA4520H7PCTS DSCA4520N7PCTS DSCA4525HPCTS DSCA4525NPCTS DSCA4525H7PCTS DSCA4525N7PCTS DSCA4535HPCTS DSCA4535NPCTS DSCA4535H7PCTS DSCA4535N7PCTS DSCA4545HPCTS DSCA4545NPCTS DSCA4545H7PCTS DSCA4545N7PCTS DSCA4555HPCTS</p>	<p>Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification/justification is required as The name of device as per FSC is Implant, endosseous, superstructure.</p>

		2022 Validi till: 02-04-2025  CE Certificate: Initial date: 16-07-2019 Validi till: 27-05-2024	DSCA4555NPCTS DSCA4555H7PCTS DSCA4555N7PCTS DSCA5510HPCTS DSCA5510NPCTS DSCA5510H7PCTS DSCA5510N7PCTS DSCA5515HPCTS DSCA5515NPCTS DSCA5515H7PCTS DSCA5515N7PCTS DSCA5520HPCTS DSCA5520NPCTS DSCA5520H7PCTS DSCA5520N7PCTS DSCA5525HPCTS DSCA5525NPCTS DSCA5525H7PCTS DSCA5525N7PCTS DSCA5535HPCTS DSCA5535NPCTS DSCA5535H7PCTS DSCA5535N7PCTS DSCA5545HPCTS DSCA5545NPCTS DSCA5545H7PCTS DSCA5545N7PCTS DSCA5555HPCTS DSCA5555NPCTS DSCA5555H7PCTS DSCA5555N7PCTS DSCA6515HPCTS DSCA6515NPCTS DSCA6515H7PCTS DSCA6515N7PCTS DSCA6520HPCTS DSCA6520NPCTS DSCA6520H7PCTS DSCA6520N7PCTS DSCA6525HPCTS DSCA6525NPCTS DSCA6525H7PCTS DSCA6525N7PCTS DSCA6535HPCTS DSCA6535NPCTS DSCA6535H7PCTS DSCA6535N7PCTS DSCA6545HPCTS DSCA6545NPCTS DSCA6545H7PCTS DSCA6545N7PCTS DSCA6555HPCTS DSCA6555NPCTS	
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38.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.  (ELI-00750	Dentis Co., Ltd., Korea  Addresses: 1. HQ: 99 Seongseoseo-ro, Dalseo-gu, Daegu, Republic of Korea.  2. Factory address: 1F, B-dong, 6, Yulam-ro, Dong-gu, Daegu, Republic of Korea  Tel: +82-53-582-2804 Fax. +82-53-583-2806 E-mail: http://www.dentis.co.kr  LOA: Issuance date: 01-03-2023 Valid Till: 28-02-2026  Country of Origin (Korea) FSC: Date of Issuance: 13-03-2023  ISO Certificate: Issuance date: 02-04-2022 Valid till: 02-04-2025  CE Certificate: Initial date: 16-07-2019 Valid till: 27-05-2024	DENTIS s-Clean TiN Half Coating Angled Abutment  Model no: DSAA45151HCTS DSAA45151NHCTS DSAA45152HCTS DSAA45152NHCTS DSAA45154HCTS DSAA45154NHCTS DSAA55151HCTS DSAA55151NHCTS DSAA55152HCTS DSAA55152NHCTS DSAA55154HCTS DSAA55154NHCTS DSAA65151HCTS DSAA65151NHCTS DSAA65152HCTS DSAA65152NHCTS DSAA65154HCTS DSAA65154NHCTS DSAA45251HCTS DSAA45251NHCTS DSAA45252HCTS DSAA45252NHCTS DSAA45254HCTS DSAA45254NHCTS DSAA55251HCTS DSAA55251NHCTS DSAA55252HCTS DSAA55252NHCTS DSAA55254HCTS DSAA55254NHCTS DSAA65251HCTS DSAA65251NHCTS DSAA65252HCTS DSAA65252NHCTS DSAA65254HCTS DSAA65254NHCTS	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification/justification is required as The name of device as per FSC is Implant, endosseous, superstructure.
39.	Biosorin (Private) Limited,  19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan.	<b><u>Legal Manufacturer &amp; Manufacturing Site:</u></b> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany.	<b>RealStar Filovirus Screen RT-PCR Kit 1.0</b> Filovirus Screen RT-PCR Kit 1.0  <b>Shelf Life:</b> 15 months <b>Class:</b> D	Approved.

	ELI-00186	<b>FSC:</b> Germany Free Sale Certificate (FSC) issued on 22-06-2023.  ISO 13485 validity date: 23-04-2026  LOA valid upto 31-12-2024.	Codes/Sizes: 441013  Fee vide slip No. 887919916.: 62,000/-	
40.	Biosorin (Private) Limited,  19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan.  ELI-00186	<b><u>Legal Manufacturer &amp; Manufacturing Site:</u></b> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany.  <b>FSC:</b> Germany Free Sale Certificate (FSC) issued on 22-06-2023.  ISO 13485 validity date: 23-04-2026  LOA valid upto 31-12-2024.	<b>RealStar Zika Virus RT-PCR Kit 1.0</b> Zika Virus RT-PCR Kit 1.0  <b>Shelf Life:</b> 15 months Class: C  Codes/Sizes: 591013  Fee vide slip No. 50517565737: Rs.62,000/-	Approved
41.	Biosorin (Private) Limited,  19-Usman Block, Main Boulevard New Garden Town Lahore - Pakistan.  ELI-00186	<b><u>Legal Manufacturer &amp; Manufacturing Site:</u></b> Altona Diagnostics GmbH, Bertrand Lecointe Morkenstr.Be 12 22767 Hamburg Germany.  <b>FSC:</b> Germany Free Sale Certificate (FSC) issued on 22-06-2023.  ISO 13485 validity date: 23-04-2026  LOA valid upto 31-12-2024.	<b>RealStar WNV RT-PCR Kit 2.0</b> West Nile virus (WNV) RT-PCR Kit 2.0  <b>Shelf Life:</b> 18 months Class: C  Codes/Sizes: 322013  Fee vide slip No. 56126841590: Rs. 62,000/-	Approved.
42.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New	<b><u>Legal Manufacturer:</u></b> M/s Esco Medical Technologies, UAB, Draugystes g, 19, Kaunas, Lithuania	MIRI IVF incubators (MIRI® TL Family)  (MIRI ® TL6, MIRI ® TL12)	Deferred for following: 1. clarification that the name of the device as per FSC Multiroom IVF.

	Garden Town, Lahore.  ELI: 00186 25,000/-	FSC: Lithuania validity 01-09-2027 LOA issuance 09-01- 2023  ISO 13485 validity 01- 09-2025	Class-B  Shelf Life: N/A	2. submission of original, notarized CE certificate apostille/ legalized FSC of RRA 3. Firm will apply both models separately.
43.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town, Lahore.  ELI: 00186 25,000/-	<b><u>Legal Manufacturer:</u></b> M/s Esco Medical Technologies, UAB, Draugystes g, 19, Kaunas, Lithuania  FSC: Lithuania validity 01-09-2027 LOA issuance 09-01- 2023  ISO 13485 validity 01- 09-2025	Dish for MRI TL® (Culture Coin)  Class-B  Shelf Life: 2 years  Model: Culture Coin	Deferred for the submission of original, notarized CE certificate or apostille/ legalized FSC of RRA
44.	Quality Medical Services, H-49. Gordon College Road Rawalpindi  ELI: 00123	<b><u>Legal Manufacturer:</u></b> CONWELL MEDICAL CO., LTD. 2F, No. 127- 3, 1st Road, Taichung Industrial Park, Situn District, Taichung 407270, Taiwan  FSC: TAIWAN Validity: 31/OCT/2026  LOA Validity: 31/OCT/2024	Conwell Medical –CO Limited Knee, ankle and foot, wrist Series  Class A  Shelf Life: 5 years	Approved only <b>Supper Elastic Knee support.</b>  Firm will apply online separately for each product.
45.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi.  ELI-00694 1121-C 23-12-2022	<b><u>Legal Manufacturer:</u></b> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo (Blood Gas analyzer, reagent pack, Test card and Control)  Class-B  Shelf life: not provided  Codes: FSC is not provided	Deferred with final opportunity for the following: 1. submission of original, notarized LOA with valid dates. 2. Original, valid and attested FSC in any reference country or FQA certificate. 3. Declaration of conformity. 4. Firm will apply Blood Gas Analyzer Reagents Pack, Blood Gas Analyzer Control, Blood Gas Analyzer Test Card and Blood Gas analyzer separately.

46.	<p>Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi.</p> <p>ELI-00694 1688-C 23-12-2022</p>	<p><b>Legal Manufacturer:</b> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.</p>	<p>Wondfo Optical coagulation Analyzer Prothrombin Time kit Activated Partial Thrombin Time Reagent kit Fibrinogen Reagent kit Activated Clotting Time Reagent kit Thrombin Time Reagent kit</p> <p>Class-C</p> <p>Shelf life:</p> <p>Codes: FSC is not provided</p>	<p>Deferred with final opportunity for the following:</p> <ol style="list-style-type: none"> <li>1. submission of original, notarized LOA with valid dates.</li> <li>2. Original, valid and attested FSC in any reference country or FQA certificate.</li> <li>3. Declaration of conformity.</li> <li>4. clarification/ justification that firm has applied Optical coagulation analyzer and multiple kits in single application.</li> </ol>
47.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6075-P 31,000/-</p>	<p><b>Legal Manufacturer:</b> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Belgium. Date of Issuance: 13-05-2022.</p> <p>FSC: Germany. Date of Issuance: 31-08-2022.</p> <p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030</p> <p>ISO 13485 validity 16-03-2026</p> <p>FQA validity 07-04-2025</p>	<p>Orient Gene HCG Pregnancy Rapid Test-Midstream</p> <p>Class-B</p> <p>Shelf Life: 24 Months</p> <p>Code: GAHCG-103a-1T GAHCG-103a-2T GAHCG-103b-1T GAHCG-103b-2T GAHCG-103d-1T GAHCG-103d-2T</p>	<p>Deferred with final opportunity for the following:</p> <ol style="list-style-type: none"> <li>1. clarification that name as per label is BioCheck (for in vitro diagnostic use).</li> <li>2. clarification that label contains "that reagent made in USA".</li> </ol>
48.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p>	<p><b>Legal Manufacturer:</b> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang</p>	<p>HBsAg Rapid Test (Serum / Plasma) (Cassette)</p> <p>Class-D</p>	<p>Rejected due to following:</p> <ol style="list-style-type: none"> <li>1. The product/ device not mentioned in submitted EC Design Examination</li> </ol>

	<p>ELI-00148 6066-P 62,000/-</p>	<p>Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025.</p>	<p>Shelf Life: 24 Months</p>	<p>Certificate, EC FQA and FSC china. 2. Firm has not submitted original documents 3. label contains "that reagent made in USA".</p>
49.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6067-P 62,000/-</p>	<p><b>Legal Manufacturer:</b> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025</p>	<p>HIV 1/2 Human Immunodeficiency Virus Rapid Test Class-D Shelf Life: 24 Months</p> <p>Size: 40 tests/lit GCHIV-302a (Serum / Plasma) GCHIV-402a (whole blood/ Serum / Plasma)</p>	<p>Deferred for the following: 1. The product/ device name is The product name Healgen HIV 1/2 Human Immunodeficiency Virus Rapid Test (Serum/Plasma) in submitted EC Design Examination Certificate, EC FQA and FSC Belgium. 2. label contains "that reagent made in USA". 3. The firm will submit revised application as per brand name mentioned EC Design Examination Certificate, EC FQA and FSC Belgium.</p>
50.	<p>Roys &amp; Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore.</p> <p>ELI-00708 7150-P 31,000/-</p>	<p><b>Legal Manufacturer:</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>Sinocare Blood Glucose Meter Class-B Service Life: 10 Years Model as per FSC</p>	<p>Approved in class B</p>

51.	<p>M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad</p> <p><b>Approved Sections:</b>  1. Assembling Filling Packaging, Labelling &amp; Testing of Reagents Kits  2. Cutting Assembling Packaging Labelling &amp; Testing of Rapid Test Kits  3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump &amp; Pulse Oximeter)</p>	<p><b>Enzymes</b></p> <p><math>\alpha</math>-Amylase (<math>\alpha</math>-AMY) Assay Kit, Creatine Kinase (CK) Assay Kit, Creatine Kinase MB (CK-MB) Assay Kit and Lactate Dehydrogenase (LDH) Assay Kit</p> <p>Shelf Life: <math>\alpha</math>-Amylase (<math>\alpha</math>-AMY) Assay Kit and Creatine Kinase MB (CK-MB) Assay Kit: 12 months  Creatine Kinase (CK) Assay Kit and Lactate Dehydrogenase: 13 months</p> <p>Class: B</p> <p>R &amp; I Details: File submitted on 05/06/2025</p> <p>Rs. 25,000/-</p> <p>Slip No: 3815349909</p> <p>Fee Submitted on: 02/06/2025</p>	<p>Enzymes tests, also known as enzyme marker tests, are used to measure the levels of specific enzymes in the blood, which can provide valuable information about organ function, disease progression, and treatment effectiveness.</p>	<p>Approved as cluster with brand name IVO-CHEM.</p>
52.	<p>M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad</p> <p><b>Approved Sections:</b>  1. Assembling Filling Packaging, Labelling &amp; Testing of Reagents Kits  2. Cutting Assembling Packaging Labelling &amp; Testing of Rapid</p>	<p><b>Liver Function Tests</b></p> <p>Alanine Aminotransferase (ALT) Assay Kit, Aspartate Aminotransferase (AST)/SGOT Assay Kit, Alkaline Phosphatase (ALP) Assay Kit, <math>\gamma</math>-Glutamyltransferase (GGT) Assay Kit, Total Bilirubin (TBIL) Assay Kit, Direct Bilirubin</p>	<p>Liver function tests are intended to assess the overall health of the liver by measuring specific substances in the blood. These tests can help diagnose liver disease, monitor its progression, and assess the effectiveness of treatments.</p>	<p>Approved as cluster with brand name IVO-CHEM.</p>



	<p>Test Kits 3.Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump &amp; Pulse Oximeter)</p>	<p>(DBIL) Assay Kit Shelf Life: 12 Months Class: B R &amp; I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 69798237</p>		
53.	<p>M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad</p> <p><b>Approved Sections:</b> 1.Assembling Filling Packaging , Labelling &amp; Testing of Reagents Kits 2. Cutting Assembling Packaging Labelling &amp; Testing of Rapid Test Kits 3.Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump &amp; Pulse Oximeter)</p>	<p><b>Serology Tests</b> Antistreptolysin O (ASO) Assay Kit, Rheumatoid Factor (RF) Assay Kit, C-reactive Protein (CRP) Assay Kit Shelf Life: 13 months Class: B R &amp; I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 44445638</p>	<p>Serology tests are used to detect antibodies in the blood, indicating exposure to a specific disease or infection</p>	<p>Approved as cluster with brand name IVO-CHEM.</p>
54.	<p>M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad</p> <p><b>Approved Sections:</b> 1.Assembling Filling</p>	<p><b>Lipid Profile Test</b> Total Cholesterol (CHO) Assay Kit and Triglycerides (TG) Assay Kit</p>	<p>A lipid profile test, also known as a lipid panel, is a blood test used to measure cholesterol and triglyceride levels. It's primarily intended to assess cardiovascular health, identify risk factors for heart disease and stroke,</p>	<p>Approved as cluster with brand name IVO-CHEM.</p>

	Packaging , Labelling & Testing of Reagents Kits 2. Cutting Assembling Packaging Labelling & Testing of Rapid Test Kits 3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	Shelf Life: 12 months  Class: B  R & I Details: File submitted on 05/06/2025  Rs. 25,000/-  Slip No: 863511594841	and monitor treatment effectiveness for high cholesterol	
55.	M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad  <b>Approved Sections:</b> 1. Assembling Filling Packaging , Labelling & Testing of Reagents Kits 2. Cutting Assembling Packaging Labelling & Testing of Rapid Test Kits 3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	<b>Renal Function Tests</b>  Creatinine (CREA-E) Assay Kit, Urea (UREA) Assay Kit, Albumin (ALB) Assay Kit, Total Protein (TP) Assay Kit, Uric Acid (UA) Assay Kit, Urine Microalbumin (UMA) Assay Kit)  Shelf Life: 12 months  Class: B  R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 09464377012	Renal function tests are intended to evaluate the health and function of the kidneys, which play a crucial role in filtering waste and excess fluid from the blood. These tests help diagnose, monitor, and manage various kidney conditions, including chronic kidney disease (CKD).	Approved as cluster with brand name IVO-CHEM.

56.	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055)	<b>B.T Plain Catgut Suture</b> Class: D Shelf Life: 60 Months Fee: 25000 Fee Slip No. 793975159758 Sizes: 0,1,2,2/0,3/0,4/0,	B. T Plain Catgut suture is a natural, absorbable sterile surgical suture that complies with the requirements of the United State pharmacopoeia and European pharmacopoeia. <b>INDICATIONS</b> Plain Catgut suture is indicated for use in general soft tissue approximation and / or ligation especially in General surgery, Gastrointestinal surgery, Gynecology, Obstetrics, Urology, Ophthalmic surgery.	The Board deferred the case for the following: i. List of all materials of animal, human, microbial or recombinant origin used in the applied medical device and in the manufacturing process of the medical device. ii. Detailed information concerning the selection of sources or donors iii. Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances iv. Process full description of the system for record keeping allowing traceability from sources to the finished medical device
57.	Ophth Pharma (Pvt.) Ltd Plot No. 241, Sector 24, Korangi Industrial Area, Karachi Pakistan  License No. ELM-0055  Surgical Suture Section  Ligature section.	<b>Surgimesh</b> Polypropylene Monofilament Knitted non-absorbable mesh undyed  Class: Class D  Shelf-life: 5 years  <b>Sizes:</b> 6 x 11 cm (1 x 3) 15 x 15 cm (1 x 3) 30 x 30 cm (1 x 3)  <b>Fee Challan No.</b> Slip No. 15662641 Dated: 28-12-2022 Rs. .20,000/-	Transparent, Non absorbable, mono-filament polypropylene indicated in Inguinal hernia. Incisional hernia. Reconstruction of chest wall.	Approved

**Item No. II (b):**

**DEFERRED CASES MINUTES**

**MR. KHALID MAHMOOD, DEPUTY DIRECTOR**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<b>Applicant:</b> M/s Safe Health Pakistan Bizcon. Office No. 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi  <b>(ELI- 00275)</b>  <b>Track ID:</b> PDS-58W-A1R8 <b>Fee:</b> PKR 5000/- <b>Slip:</b> 8401979738 <b>Dated:</b> 09-09-2021	<b>(Legal Manufacturer)</b> <b>Name:</b> M/S. Suzhou Yaxin Medical Products Co., Ltd. No. 12, Zhonghua Road, Mudu Town, Suzhou, Peoples Republic of China <b>FSC Validity:</b> 08-10-2025  <b>Letter of  authorization:</b> Issuance date: 25-02- 2024 Expiry date: Not mentioned	<b>Disposable Feeding  Bag Venous™</b> 500ml,1000 ml, 1200 ml & 1500 ml <b>Generic:</b> Enteral Feeding set  <b>Class-A</b>  <b>Shelf life:</b> 05 years <b>Storage Conditions:</b> Room temperature	Deferred with final opportunity for submission of valid FSC, LOA & clarification of class of product as Disposable Feeding Bags are classified as a Class IIa medical device according to the EU Medical Device Regulation (MDR) under Eudamed. Proof of fee submission.
2.	<b>Applicant:</b> M/s Safe Health Pakistan Bizcon. Office No. 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi  <b>(ELI- 00275)</b>  Track ID: PDS-58W-A1R8  <b>Fee:</b> PKR 5000/- <b>Slip:</b> 2043614 <b>Dated:</b> 06-10-2020	<b>(Legal Manufacturer)</b> <b>Name:</b> M/S. Suzhou Yaxin Medical Products Co., Ltd. No. 12, Zhonghua Road, Mudu Town, Suzhou, Peoples Republic of China  <b>FSC Validity:</b> 08-10-2025	<b>Disposable Chest  Drainage Bottle  (System) Single  Chamber, Two  Chambers &amp; Three  Chambers - Venous™</b>  <b>Class-A</b>  <b>Letter of  authorization:</b> Issuance date: 25-02- 2024 Expiry date: Not mentioned  <b>Shelf life:</b> 05 years <b>Storage Conditions:</b> Room temperature	Deferred with final opportunity for final submission of valid FSC, LOA & clarification of class of product as Disposable Feeding Bags are classified as a Class IIb medical device according to the EU Medical Device Regulation (MDR) under Eudamed. Proof of fee submission.
3.	M/S. Safe Health Pakistan Bizcon.	<b>Legal Manufacturer:</b>	Venous Disposable Biopsy Needle.	Deferred with final opportunity for final submission of valid

	<p><b>Address:</b> Office # 25, 2<sup>nd</sup> Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p><b>R&amp;I details</b> 9<sup>th</sup> May 2025</p> <p><b>Fee</b> Rs. 30,000.00 through slip no. 851977932085 Date 12-05-2025</p>	<p>M/S. Chamfond Biotech Co., Ltd. 2/F Building E, Sino Danish Eco Life Science Pak, Jiangbei, New Area, Nanjing Jiangsu, CN 21032, China.</p> <p><b>LOA:</b> Issuance: 01-03-2025</p> <p><b>FSC:</b> Validity: 11-05-2025</p> <p><b>ISO-13485:</b> Validity: 12-07-2027</p>	<p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Sizes: G-8, 9, 11, 13, 15, 16, 18</p> <p>Models: BN, MAB, CF, CB, MA</p>	<p>FSC, LOA &amp; CE regarding subject medical device. The ISO certification validity to be expired on 12-07-2027 may also be provided. Proof of fee submission.</p>
4.	<p>M/S. Safe Health Pakistan Bizcon.</p> <p><b>Address:</b> Office # 25, 2<sup>nd</sup> Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275</p> <p><b>R&amp;I details</b> 20<sup>th</sup> May 2025</p> <p><b>Fee</b> Rs. 30,000.00 through slip no. 8618708376 Date 12-05-2025</p>	<p><b><u>Legal Manufacturer:</u></b> M/S. Jiangsu Jianzhiyuan Medical Instrument Technology Co., Ltd. Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou City. China.</p> <p><b>LOA:</b> Validity: 30-09-2029</p> <p><b>FSC:</b> Validity: 20-09-2025</p> <p><b>ISO-13485:</b> Validity: 20-10-2025</p> <p>CE validity 26-05-2024</p>	<p>Venous Disposable Thoracic Drain Catheter / Chest Drainage Catheter</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Models: WI, WII, WIII, WIV, ZI, ZII, ZIII and ZIV</p> <p>Code/ Sizes: FR-7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39 &amp; 40</p>	<p>Deferred with final opportunity as submitted document is merely a general letter which is ambiguous. <b>No valid CE marked Provided.</b> Medical device Regulation (China). Provision of Valid LOA and FSC of any RRA. Clarification of classification and differential fee required to be paid.</p>
5.	<p>M/S. Safe Health Pakistan Bizcon. Office No. 25, 2<sup>nd</sup> Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)</p>	<p><b><u>Legal Manufacturer:</u></b> M/S. Zheijiang Runqiang Medical Instruments Co., Ltd. Manufacturing Site: No. 618, Dade Road, Jiaying Xiuzhou Distric, 314031 Jianxing City, Peoples Republic of China.</p>	<p>Venous Extension Set (Pressure Tube)</p> <p>Class B (E)</p> <p>Shelf Life: 05 years</p> <p>Codes/Sizes: As per FSC</p>	<p>Deferred with final opportunity as submitted document is merely a general letter instead of provision of Valid LOA and FSC of any RRA. Clarification of classification and differential fee required to be paid. Further the valid FSC, LOA &amp; CE certificate with valid certificate of ISO 13485.</p>

		<u>FSC:</u> _____ <u>Validity:</u> Germany 14-07-2025. <u>LOA</u> <u>Validity:</u> 01-01-2025 <u>EC Certificate</u> <u>Validity:</u> 06-05-2025 <u>ISO 13485</u> <u>Validity:</u> 06-05-2023		
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**Item No. II (c). ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

**Dr. Hanif Ullah (Deputy Director-IX)**

**New application:**

S.#	Name of Firm(s)	Manufacturer's detail	Name of Medical Device	Decision
1.	Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi Peshawar  ELI-00618 R&I Date: 21.05.2025 Fee: 31000/- Slip #10966332402	Manufacturer: Shandong Huge Dental Material Corporation, No. 68 Shanhai Road, Danggang District, Rizhao City, Shandong Province, 276800 P.R. China LOA Type: Copy Notarization: No Validity: 11.05.2028 FSC1 (for zirconia block) Type: Copy Issued by: NIL Legalization: No Validity: 08.10.2026 FSC2 (for zirconia block and coloring liquid) Type: Copy Issued by: NIL Legalization: No Validity: 20.10.2026  ISO – Certificate Type: copy Legalization: No Validity: 20.02.2026 CE certificate / EU QMS certificate (MDR): Type: Copy	Brand Name: Zirking Generic Name: Zirconia Block Applied as: Single Class: B Models/Code/sizes (as per FSC & application: HT Shelf Life: 10 years	Deferred for: English translation of the issuing authority of the FSC is required. There are many shades and specifications of the device in the FSC. The firm has applied as single. Selection / clarification is required. Notarized LOA and ISO certificate are required. Legalized FSC in the country of Origin is required. Notarized CE Certificate / EU QMS certificate (MDR) is required.

		Legalization: No Validity: 26.03.2029		
2.	<p>Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi Peshawar</p> <p>ELI-00618 R&amp;I Date: 21.05.2025 Fee: 31000/- Slip #140095465</p>	<p>Manufacturer: Shandong Huge Dental Material Corporation, No. 68 Shanhai Road, Danggang District, Rizhao City, Shandong Province, 276800 P.R. China</p> <p>LOA Type: Copy Notarization: No Validity: 11.05.2028 FSC1 (for Luting I, Luting II / Lufill HS) Type: Copy Issued by: NIL Legalization: No Validity: 16.05.2026 FSC2 (for Filling I, Filling II) Type: Copy Issued by: NIL Legalization: No Validity: 20.07.2026 ISO – Certificate Type: copy Legalization: No Validity: 20.02.2026 CE certificate / EU QMS certificate (MDR): Type: Copy Legalization: No Validity: 26.03.2029</p>	<p>Brand Name: NIL Generic Name: Glass Ionomer Cement Applied as: Single Class: B Models/Code/sizes (as per FSC &amp; application: Luting I, Luting II / Lufill HS, Filling I, Filling II Shelf Life: NIL</p>	<p>Deferred for: Submission of brand name. English translation of the issuing authority of the FSC is required. There are many codes of the device in the FSC. The firm has applied as single. Selection / clarification is required. Notarized LOA and ISO certificate are required. Legalized FSC in the country of Origin is required. Notarized CE Certificate / EU QMS certificate (MDR) is required. Conclusive report for shelf life verification / stability studies is required.</p>
3.	<p>Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi Peshawar</p> <p>ELI-00618 R&amp;I Date: 21.05.2025 Fee: 62000/- Slip # 2814790550</p>	<p>Name of Manufacturer: Zhejiang QL Biotech Co., Ltd., Address: Room No. 501, Building 1#, 178# Chuangye Rd, Qingshanhu Sub-District, Lin 'an District, Hangzhou, China</p> <p>LOA Type: Copy Notarization: No Validity: 28.04.2030 FSC</p>	<p>Brand Name: NIL Generic Name: Typhoid Ab Rapid Test Applied as: kit Class: C Models/Code/sizes (as per FSC &amp; application: NIL Shelf Life: 2 years</p>	<p>Deferred for: Submission of brand name. Notarized LOA and ISO certificate are required. Legalized FSC in the country of Origin is required. Legalized FSC in reference country or notarized CE Certificate / EU QMS certificate (MDR) is required.</p>

		Type: Copy Issued by: China Chamber of Commerce for Import and Export of Medicines and Health Product Legalization: No Validity: two years from 11.06.2024 ISO – Certificate Type: copy Legalization: No Validity: 30.08.2027 CE certificate / EU QMS certificate (MDR): Type: Not submitted Legalization: NIL Validity: NIL		
4.	Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi Peshawar ELI-00618 R&I Date: 21.05.2025 Fee: 62000/- Slip #34574792560	Name of Manufacturer: Zhejiang QL Biotech Co., Ltd., Address: Room No. 501, Building 1#, 178# Chuangye Rd, Qingshanhu Sub-District, Lin 'an District, Hangzhou, China LOA Type: Copy Notarization: No Validity: 28.04.2030 FSC Type: Copy Issued by: China Chamber of Commerce for Import and Export of Medicines and Health Product Legalization: No Validity: two years from 11.06.2024 ISO – Certificate Type: copy Legalization: No Validity: 30.08.2027 CE certificate / EU QMS certificate (MDR): Type: Not submitted Legalization: NIL Validity: NIL	Brand Name: NIL Generic Name: Malaria pf/pv Rapid Test Applied as: kit Class: C Models/Code/sizes (as per FSC & application): NIL Shelf Life: 2 years	Deferred for: Submission of brand name. Notarized LOA and ISO certificate are required. Legalized FSC in the country of Origin is required. Legalized FSC in reference country or notarized CE Certificate / EU QMS certificate (MDR) is required.



5.	<p>Hi Diagnostic Traders, 21/2 Gulshan-e-Kareem Colony, Jamshaid Tareen Road, Multan</p> <p>ELI-01028</p> <p>R&amp;I Date: 21.05.2025</p> <p>Fee: 62000/-</p> <p>Slip #5229751477</p>	<p>Manufacturer: VivaChek Biotech (HangZhou) Co., Ltd., Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou 311100 Zhejiang P.R. China</p> <p>LOA</p> <p>Type: Copy</p> <p>Notarization: China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 01.12.2029</p> <p>FSC</p> <p>Type: Copy</p> <p>Issued by: Zhejiang Medical Product Administration</p> <p>Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 28.10.2026</p> <p>ISO – Certificate</p> <p>Type: copy</p> <p>Legalization: China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 02.03.2027</p> <p>CE certificate / EU QMS certificate (MDR):</p> <p>Type: Not submitted</p> <p>Legalization: NIL</p> <p>Validity: NIL</p>	<p>Brand Name: Hemoglobin Meter</p> <p>Generic Name: Hemoglobin Meter</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC &amp; application: VOM01</p> <p>Shelf Life: NA</p>	<p>Deferred for: Model has not been mentioned in the FSC. Clarification is required.</p> <p>The firm has applied as single; however, the device is system in the DOC. Clarification is required.</p>
6.	<p>JF International, 4th Floor, 10C, 6th Sunset Commercial Lane, Phase 2 Ext, DHA, Karachi</p> <p>ELI-00246</p>	<p>Name of Manufacturer: Bionet Co., Ltd., Address: 5F, 61, Digital-Ro 31-Gil, Guro-Gu, Seoul Republic of Korea 08375</p> <p>Sub Assembly unit:</p>	<p>Brand Name: Bionet</p> <p>Generic Name: Electrocardiographi c Analyzer</p> <p>Applied as: System</p> <p>Class: B</p>	<p>Deferred for: Stamp paper shall be issued in the name of the firm / signatory. Legalized FSC in the country of origin with validity is required. Shelf life verification / stability studies report is required.</p>

	<p>R&amp;I Date: 21.05.2025 Fee: 31000/- Slip #361428689</p>	<p>Bionet Co., Ltd., #401, 34LS-ro 91 beon-gil, Dongan-gu, Anyang-Si, Gyeonggi-do</p> <p>LOA Type: Copy of notarized LOA submitted for CardioTouch3000 Notarization: No Validity: 01.01.2030 FSC Type: Copy Issued by: National Institute of Medical Devices Safety Information, South Korea Legalization: Apostille Validity: NIL ISO – Certificate: Type: Copy of the notarized certificate submitted for CardioTouch3000 Notarization: No Validity: 19.10.2026 CE certificate / EU QMS certificate (MDR) Type: Copy of notarized certificate submitted for CardioTouch3000 Notarization: No Validity: 26.05.2024 Extended till 31.12.2028 for class IIa devices.</p>	<p>Models/Code/sizes (as per FSC &amp; application: Cardio7 Shelf Life: 10 years</p>	<p>Clarification regarding variation in the address of manufacturer in Form and FSC etc.</p>
7.	<p>BioMax International, P- 150, Street No. 8, Opp. Allied Hospital, Near Daewoo Terminal Akbarabad, Faisalabad</p> <p>ELI-00950 R&amp;I Date: 22.05.2025 Fee: 50000/- Slip #43034064098</p>	<p>Manufacturer: Nanjing Poclight Biotechnology Co., Ltd., South Side, 2nd Floor, Building A02, Biopharmaceutical Valley Accelerator (Phase III), No. 142 Huakang Road, Jiangbei New District, Nanjing City, Jiangsu Province, 210000, P.R. China</p> <p>LOA</p>	<p>Brand Name: CLIA Kits for Poclight 5000 Generic Name: Dry Chemiluminescence Immunoassay analyzer and Test Kit Applied as: Cluster Class: B Models/Code/sizes (as per FSC &amp; application:</p>	<p>Deferred for: Submit properly filled Form- 7A. Blank stamp paper without declaration has been submitted. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name shall be mentioned in the LOA. For class B devices, the firm shall apply in relevant grouping / clusters separately.</p>

		<p>Type: Original Notarization: Apostilled the notarization of CCPIT Validity: 28.02.2028 FSC Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO – Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL</p>	<p><i>Krebs Von den Lungen 6 Test Kit, N-terminal pro-B type Natriuretic Peptide Test Kit, Serum Amyloid A Test Kit, High Sensitive Cardiac Troponin T Test Kit, Free Triiodothyronine Test Kit, C Reactive Protein Test Kit, Heparin Binding Protein Test Kit, Hemoglobin A1c Test Kit, Total Thyroxine Test Kit, Myoglobin Test Kit, Free thyroxine Test Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit</i> Shelf Life: 5 years</p>	<p>Moreover, class C medical devices shall be clustered. Shelf life verification / stability studies report of the kit and not of the analyzer, is required. Legalized FSC in reference country or notarized CE Certificate / EU QMS certificate (MDR) is required.</p>
8.	<p>Koncept Technologies, Ground Floor, A1-198, Block 13-A, Railway Society, Karachi</p> <p>ELI-00767 R&amp;I Date: 26.05.2025 Fee: 31000/- Slip #116729815049</p>	<p>Manufacturer: Shenzhen Sinseng Medical Technology Co., Ltd., Room No. 801, Building C, Guancheng Low Carbon Industrial Park, Shangcun Community, Gongming Street, Guangming District, Shenzhen P.R. China LOA</p>	<p>Brand Name: NIL Generic Name: LH LYSE (HAS 310) LH LYSE (SXHA 610) DIFF LYSE (SXHA 610) Applied as: Cluster Class: B Models/Code/sizes (as per FSC &amp; application:</p>	<p>Deferred for: Submission of brand name. Submit properly filled Form-7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the kits.</p>

		<p>Type: Copy of notarized LOA Apostilled the notarization of CCPIT Validity: 5 years from 01.02.2025 FSC Type: NIL Issued by: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: Copy of notarized Notarization: CCPIT Validity: 29.11.2025 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL</p>	<p>LH LYSE (HAS 310) LH LYSE (SXHA 610) DIFF LYSE (SXHA 610) Shelf Life: 18 months</p>	<p>The firm has submitted FSC of Germany with a different address of the manufacturer, without validity date and without information about the applied kits. Clarification along with FSC legalized in the reference country is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name shall be mentioned in Form-7A. The firm has applied for LH LYSE (HAS 310), which Lyse (HAS 310) in the label. Clarification is required. The requisite fee for cluster shall be submitted. The DOC does not contain the applied devices.</p>
9.	<p>Koncept Technologies, Ground Floor, A1-198, Block 13-A, Railway Society, Karachi</p> <p>ELI-00767 R&amp;I Date: 26.05.2025 Fee: 31000/- Slip #3762065322</p>	<p>Manufacturer: Shenzhen Sinseng Medical Technology Co., Ltd., Room No. 801, Building C, Guancheng Low Carbon Industrial Park, Shangcun Community, Gongming Street, Guangming District, Shenzhen P.R. China LOA Type: Copy of notarized LOA Apostilled the notarization of CCPIT Validity: 5 years from 01.02.2025 FSC Type: NIL Issued by: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: Copy of notarized Notarization: CCPIT Validity: 29.11.2025</p>	<p>Brand Name: NIL Generic Name: Diluent (HAS 310) Diluent (SXHA 610) Applied as: Cluster Class: B Models/Code/sizes (as per FSC &amp; application: Diluent (HAS 310) Diluent (SXHA 610) Shelf Life: 18 months</p>	<p>Deferred for: Submission of brand name. Submit properly filled Form-7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the kits. The firm has submitted FSC of Germany with a different address of the manufacturer, without validity date and without information about the applied kits. Clarification along with FSC legalized in the reference country is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name shall be mentioned in Form-7A.</p>

		CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL		The firm has applied for LH LYSE (HAS 310), which Lyse (HAS 310) in the label. Clarification is required. The requisite fee for cluster shall be submitted. The DOC does not contain the applied devices.
10.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 31.07.2023 Fee: 5,000/- Slip #7130204351 This evaluation is based on the on-line data submitted through E-App. Tracking ID: XL4-4SJ-JURJ	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: Powerhaler Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D05 Shelf Life: 36 months	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. The LOA contains two models ((DI-D04, (DI-D07) other than the applied model (DI-D05). Clarification is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. DOC shall be submitted on the letter head of the manufacturer.
11.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 17.03.2022 Fee: 5,000/- Slip #83059332595 This evaluation is based on the on-line data submitted through E-App.	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC	Brand Name: ROTAFLO Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required.

	Tracking ID: R4V-NYZ-J4QM	Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL		Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name is Free-breath in DOC. Clarification is required.
12.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 10.05.2022 Fee: 5,000/- Slip #7396113710 This evaluation is based on the on-line data submitted through E-App. Tracking ID: MX9-8G7-QJ5W	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: REVOLIZER Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Deferred for: The firm has applied the same model (DL-D07) twice. Clarification is required. The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name is Free-breath in DOC. Clarification is required. DOC shall be submitted on the letter head of the manufacturer.
13.	M/S Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi ELI-00005	Manufacturer: Zhejiang Kindly Medical Devices Co., LTD Address: No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District 325025	Brand Name: YMS Infusion Set Generic Name: Scalp Vein Set Applied as: Single Class: B Models/Code/sizes (as per FSC & application:	Deferred for: The firm shall submit the renewal status of ELI. The firm shall apply as grouping with submission of requisite fee. The fee deposited vide Slip #2045103 Dated 24.06.2025

	<p>R&amp;I Date: 25.06.2020  Fee: 12,500/-  Slip #2045103  Dated 24.06.2025  Diff. Fee: 12,500/-  Slip# 34110862712  Dated: 28.12.2021  This evaluation is based on the on-line data submitted through E-App.  Tracking ID: TRX-1LZ-A145</p>	<p>Wenzhou, Zhejiang  LOA  Type: scanned copy  Notarization: No  Validity: 31.12.2025  FSC  Type: scanned copy  Issued by: Zhejiang Medical Products Administration  Legalization: NIL  Validity: 14.01.2026  ISO – Certificate:  Type: Scanned copy  Notarization: No  Validity: 31.10.2026  CE certificate / EU QMS certificate (MDR)  Type: scanned copy  Notarization: NIL  Validity: 14.04.2026</p>	<p>27G, 26G, 25G.  24G, 23G. 22G, 21G, 20G, 19G, 18G  (With corresponding size / caliber in FSC)  Shelf Life: 36 months</p>	<p>Diff. Fee: 12,500/-  Slip# 34110862712  Dated: 28.12.2021 is meant or renewal of registration (as drug).  Scanned copy of the notarized and ISO certificate and CE certificate are required  Declaration on stamp paper to be issued in the name of the firm / signatory is required.  Valid, legalized FSC of the applied product mentioning the issuing authority in English is required.  Shelf life verification report is required.  The sterilization site has not been mentioned in the ISO certificate and CE certificate.</p>
14.	<p>Global Biotech Medical Devices (Private) Limited.  First Floor of Plot No 35-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi.  ELI-01292  R&amp;I Date: 03.12.2024  Fee: 31,000/-  Slip #594093568  This evaluation is based on the on-line data submitted through E-App.  Tracking ID: 1DG-UEZ-T6M8</p>	<p>Manufacturer: Curatia Medical Limited.  <b>Site 1 (other than sterilization)</b>  No. 198 Xiangjiang Road, New District, Suzhou, China  <b>Site 2 (Sterilization process)</b>  Name: Goals Sterilization Co., Ltd  Address: East of Renkangtang, South of 07 provincial road, Xinfeng Town, Nanhu District  LOA  Type: scanned copy  Notarization: Yes, CCPIT  Validity: 04.07.2026  FSC  Type: scanned copy  Issued by: <b>Jiangsu Medical Products Administration</b>  Legalization: apostilled the notarization of CCPIT  Validity: 03.07.2026  ISO – Certificate:</p>	<p>Brand Name: EXTesia Introducer Sheath Set  Generic Name: Introducer Sheath Set  Applied as: Single  Class: B  Models/Code/sizes (as per FSC &amp; application: (551 codes)  2IS040521PSI, 2IS040525PSI, 2IS040535PSI, 2IS040521PAI, 2IS040525PAI, 2IS040535PAI, 2IS040518SSN, 2IS040521SSN, 2IS040525SSN, 2IS040535SSN, 2IS040518SJJN, 2IS040521SJJN, 2IS040525SJJN, 2IS040535SJJN, 2IS040721PSI, 2IS040725PSI,</p>	<p>Deferred for:  Properly filled application Form shall be submitted.  The sheath and dilators vary in size / caliber. Similarly, the guide wire varies in caliber, type (spring, polymer jacket), and tip shape (straight, J, angled). Likewise, the entry needle varies in type (IV catheter. metallic needle) and size. Moreover, the last 20 codes (from 2IS040500000 to 2IS072500000) does not contain guided wire, entry needle scalpel and syringe. The firm shall apply as grouping with submission of requisite fee.  The application form has been signed by authorized person for Regulatory Affairs.  Authorization letter for the signatory is required.  Declaration on stamp paper to be issued in the name of the firm / signatory is required.</p>

		<p>Type: Scanned copy  Notarization: Yes, CCPIT  Validity: 31.07.2026  CE certificate / EU QMS certificate (MDR)  Type: scanned copy  Notarization: No  (notarized the statement of manufacturer, not the certificate)  Validity: 26.05.2024  Extended till 31.12.2028</p>	<p>2IS040735PSI,  2IS040721PAI,  2IS040725PAI,  2IS040735PAI,  2IS040718SSN,  2IS040721SSN,  2IS040725SSN,  2IS040735SSN,  2IS040718SJN,  2IS040721SJN,  2IS040725SJN,  2IS040735SJN,  2IS041021PSI,  2IS041025PSI,  2IS041035PSI,  2IS041021PAI,  2IS041025PAI,  2IS041035PAI,  2IS041018SSN,  2IS041021SSN,  2IS041025SSN,  2IS041035SSN,  2IS041018SJN,  2IS041021SJN,  2IS041025SJN,  2IS041035SJN,  2IS041621PSI,  2IS041625PSI,  2IS041635PSI,  2IS041621PAI,  2IS041625PAI,  2IS041635PAI,  2IS041618SSN,  2IS041621SSN,  2IS041625SSN,  2IS041635SSN,  2IS041618SJN,  2IS041621SJN,  2IS041625SJN,  2IS041635SJN,  2IS042521PSI,  2IS042525PSI,  2IS042535PSI,  2IS042521PAI,  2IS042525PAI,  2IS042535PAI,  2IS042518SSN,  2IS042521SSN,  2IS042525SSN,</p>	<p>Scanned copy of the notarized CE certificate are required  Shelf life verification report is required.  The sterilization site has not been mentioned in the ISO certificate and CE certificate.</p>
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			2IS042535SSN, 2IS042518SJN, 2IS042521SJN, 2IS042525SJN, 2IS042535SJN, 2IS050521PSI, 2IS050525PSI, 2IS050535PSI, 2IS050538PSI, 2IS050521PAI, 2IS050525PAI, 2IS050535PAI, 2IS050538PAI, 2IS050518SSN, 2IS050521SSN, 2IS050525SSN, 2IS050535SSN, 2IS050538SSN, 2IS050518SJN, 2IS050521SJN, 2IS050525SJN, 2IS050535SJN, 2IS050538SJN, 2IS050721PSI, 2IS050725PSI, 2IS050735PSI, 2IS050738PSI, 2IS050721PAI, 2IS050725PAI, 2IS050735PAI, 2IS050738PAI, 2IS050718SSN, 2IS050721SSN, 2IS050725SSN, 2IS050735SSN, 2IS050738SSN, 2IS050718SJN, 2IS050721SJN, 2IS050725SJN, 2IS050735SJN, 2IS050738SJN, 2IS051021PSI, 2IS051025PSI, 2IS051035PSI, 2IS051038PSI, 2IS051021PAI, 2IS051025PAI, 2IS051035PAI, 2IS051038PAI,	
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			2IS051018SSN, 2IS051021SSN, 2IS051025SSN, 2IS051035SSN, 2IS051038SSN, 2IS051018SJN, 2IS051021SJN, 2IS051025SJN, 2IS051035SJN, 2IS051038SJN, 2IS051621PSI, 2IS051625PSI, 2IS051635PSI, 2IS051638PSI, 2IS051621PAI, 2IS051625PAI, 2IS051635PAI, 2IS051638PAI, 2IS051618SSN, 2IS051621SSN, 2IS051625SSN, 2IS051635SSN, 2IS051638SSN, 2IS051618SJN, 2IS051621SJN, 2IS051625SJN, 2IS051635SJN, 2IS051638SJN, 2IS052521PSI, 2IS052525PSI, 2IS052535PSI, 2IS052538PSI, 2IS052521PAI, 2IS052525PAI, 2IS052535PAI, 2IS052538PAI, 2IS052518SSN, 2IS052521SSN, 2IS052525SSN, 2IS052535SSN, 2IS052538SSN, 2IS052518SJN, 2IS052521SJN, 2IS052525SJN, 2IS052535SJN, 2IS052538SJN, 2IS060521PSI, 2IS060525PSI, 2IS060535PSI,	
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			2IS060538PSI, 2IS060521PAI, 2IS060525PAI, 2IS060535PAI, 2IS060538PAI, 2IS060518SSN, 2IS060521SSN, 2IS060525SSN, 2IS060535SSN, 2IS060538SSN, 2IS060518SJN, 2IS060521SJN, 2IS060525SJN, 2IS060535SJN, 2IS060538SJN, 2IS060721PSI, 2IS060725PSI, 2IS060735PSI, 2IS060738PSI, 2IS060721PAI, 2IS060725PAI, 2IS060735PAI, 2IS060738PAI, 2IS060718SSN, 2IS060721SSN, 2IS060725SSN, 2IS060735SSN, 2IS060738SSN, 2IS060718SJN, 2IS060721SJN, 2IS060725SJN, 2IS060735SJN, 2IS060738SJN, 2IS061021PSI, 2IS061025PSI, 2IS061035PSI, 2IS061038PSI, 2IS061021PAI, 2IS061025PAI, 2IS061035PAI, 2IS061038PAI, 2IS061018SSN, 2IS061021SSN, 2IS061025SSN, 2IS061035SSN, 2IS061038SSN, 2IS061018SJN, 2IS061021SJN, 2IS061025SJN,	
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			2IS061035SJN, 2IS061038SJN, 2IS061621PSI, 2IS061625PSI, 2IS061635PSI, 2IS061638PSI, 2IS061621PAI, 2IS061625PAI, 2IS061635PAI, 2IS061638PAI, 2IS061618SSN, 2IS061621SSN, 2IS061625SSN, 2IS061635SSN, 2IS061638SSN, 2IS061618SJN, 2IS061621SJN, 2IS061625SJN, 2IS061635SJN, 2IS061638SJN, 2IS062521PSI, 2IS062525PSI, 2IS062535PSI, 2IS062538PSI, 2IS062521PAI, 2IS062525PAI, 2IS062535PAI, 2IS062538PAI, 2IS062518SSN, 2IS062521SSN, 2IS062525SSN, 2IS062535SSN, 2IS062538SSN, 2IS062518SJN, 2IS062521SJN, 2IS062525SJN, 2IS062535SJN, 2IS062538SJN, 2IS070521PSI, 2IS070525PSI, 2IS070535PSI, 2IS070538PSI, 2IS070521PAI, 2IS070525PAI, 2IS070535PAI, 2IS070538PAI, 2IS070518SSN, 2IS070521SSN, 2IS070525SSN,	
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			2IS070535SSN, 2IS070538SSN, 2IS070518SJN, 2IS070521SJN, 2IS070525SJN, 2IS070535SJN, 2IS070538SJN, 2IS070721PSI, 2IS070725PSI, 2IS070735PSI, 2IS070738PSI, 2IS070721PAI, 2IS070725PAI, 2IS070735PAI, 2IS070738PAI, 2IS070718SSN, 2IS070721SSN, 2IS070725SSN, 2IS070735SSN, 2IS070738SSN, 2IS070718SJN, 2IS070721SJN, 2IS070725SJN, 2IS070735SJN, 2IS070738SJN, 2IS071021PSI, 2IS071025PSI, 2IS071035PSI, 2IS071038PSI, 2IS071021PAI, 2IS071025PAI, 2IS071035PAI, 2IS071038PAI, 2IS071018SSN, 2IS071021SSN, 2IS071025SSN, 2IS071035SSN, 2IS071038SSN, 2IS071018SJN, 2IS071021SJN, 2IS071025SJN, 2IS071035SJN, 2IS071038SJN, 2IS071621PSI, 2IS071625PSI, 2IS071635PSI, 2IS071638PSI, 2IS071621PAI, 2IS071625PAI,	
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			2IS071635PAI, 2IS071638PAI, 2IS071618SSN, 2IS071621SSN, 2IS071625SSN, 2IS071635SSN, 2IS071638SSN, 2IS071618SJN, 2IS071621SJN, 2IS071625SJN, 2IS071635SJN, 2IS071638SJN, 2IS072521PSI, 2IS072525PSI, 2IS072535PSI, 2IS072538PSI, 2IS072521PAI, 2IS072525PAI, 2IS072535PAI, 2IS072538PAI, 2IS072518SSN, 2IS072521SSN, 2IS072521SSN, 2IS072535SSN, 2IS072538SSN, 2IS072518SJN, 2IS072521SJN, 2IS072525SJN, 2IS072535SJN, 2IS072538SJN, 2IS072538SJNPAI, 2IS040518SSI, 2IS040521SSI, 2IS040525SSI, 2IS040535SSI, 2IS040518SJI, 2IS040521SJI, 2IS040525SJI, 2IS040535SJI, 2IS040718SSI, 2IS040721SSI, 2IS040725SSI, 2IS040735SSI, 2IS040718SJI, 2IS040721SJI, 2IS040725SJI, 2IS040735SJI, 2IS041018SSI, 2IS041021SSI,	
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			2IS041025SSI, 2IS041035SSI, 2IS041018SJI, 2IS041021SJI, 2IS041025SJI, 2IS041035SJI, 2IS041618SSI, 2IS041621SSI, 2IS041625SSI, 2IS041635SSI, 2IS041618SJI, 2IS041621SJI, 2IS041625SJI, 2IS041635SJI, 2IS042518SSI, 2IS042521SSI, 2IS042525SSI, 2IS042535SSI, 2IS042518SJI, 2IS042521SJI, 2IS042525SJI, 2IS042535SJI, 2IS050518SSI, 2IS050521SSI, 2IS050525SSI, 2IS050535SSI, 2IS050538SSI, 2IS050518SJI, 2IS050521SJI, 2IS050525SJI, 2IS050535SJI, 2IS050538SJI, 2IS050718SSI, 2IS050721SSI, 2IS050725SSI, 2IS050735SSI, 2IS050738SSI, 2IS050718SJI, 2IS050721SJI, 2IS050725SJI, 2IS050735SJI, 2IS050738SJI, 2IS051018SSI, 2IS051021SSI, 2IS051025SSI, 2IS051035SSI, 2IS051038SSI, 2IS051018SJI, 2IS051021SJI,	
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			2IS051025SJI, 2IS051035SJI, 2IS051038SJI, 2IS051618SSI, 2IS051621SSI, 2IS051625SSI, 2IS051635SSI, 2IS051638SSI, 2IS051618SJI, 2IS051621SJI, 2IS051625SJI, 2IS051635SJI, 2IS051638SJI, 2IS052518SSI, 2IS052521SSI, 2IS052525SSI, 2IS052535SSI, 2IS052538SSI, 2IS052518SJI, 2IS052521SJI, 2IS052525SJI, 2IS052535SJI, 2IS052538SJI, 2IS060518SSI, 2IS060521SSI, 2IS060525SSI, 2IS060535SSI, 2IS060538SSI, 2IS060518SJI, 2IS060521SJI, 2IS060525SJI, 2IS060535SJI, 2IS060538SJI, 2IS060718SSI, 2IS060721SSI, 2IS060725SSI, 2IS060735SSI, 2IS060738SSI, 2IS060718SJI, 2IS060721SJI, 2IS060725SJI, 2IS060735SJI, 2IS060738SJI, 2IS061018SSI, 2IS061021SSI, 2IS061025SSI, 2IS061035SSI, 2IS061038SSI, 2IS061018SJI,	
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			2IS061021SJI, 2IS061025SJI, 2IS061035SJI, 2IS061038SJI, 2IS061618SSI, 2IS061621SSI, 2IS061625SSI, 2IS061635SSI, 2IS061638SSI, 2IS061618SJI, 2IS061621SJI, 2IS061625SJI, 2IS061635SJI, 2IS061638SJI, 2IS062518SSI, 2IS062521SSI, 2IS062525SSI, 2IS062535SSI, 2IS062538SSI, 2IS062518SJI, 2IS062521SJI, 2IS062525SJI, 2IS062535SJI, 2IS062538SJI, 2IS070518SSI, 2IS070521SSI, 2IS070525SSI, 2IS070535SSI, 2IS070538SSI, 2IS070518SJI, 2IS070521SJI, 2IS070525SJI, 2IS070535SJI, 2IS070538SJI, 2IS070718SSI, 2IS070721SSI, 2IS070725SSI, 2IS070735SSI, 2IS070738SSI, 2IS070718SJI, 2IS070721SJI, 2IS070725SJI, 2IS070735SJI, 2IS070738SJI, 2IS071018SSI, 2IS071021SSI, 2IS071025SSI, 2IS071035SSI, 2IS071038SSI,	
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			2IS071018SJI, 2IS071021SJI, 2IS071025SJI, 2IS071035SJI, 2IS071038SJI, 2IS071618SSI, 2IS071621SSI, 2IS071625SSI, 2IS071635SSI, 2IS071638SSI, 2IS071618SJI, 2IS071621SJI, 2IS071625SJI, 2IS071635SJI, 2IS071638SJI, 2IS072518SSI, 2IS072521SSI, 2IS072525SSI, 2IS072535SSI, 2IS072538SSI, 2IS072518SJI, 2IS072521SJI, 2IS072525SJI, 2IS072535SJI, 2IS072538SJI, 2IS040500000, 2IS040700000, 2IS041000000, 2IS041600000, 2IS042500000, 2IS050500000, 2IS050700000, 2IS051000000, 2IS051600000, 2IS052500000, 2IS060500000, 2IS060700000, 2IS061000000, 2IS061600000, 2IS062500000, 2IS070500000, 2IS070700000, 2IS071000000, 2IS071600000, 2IS072500000. Shelf Life: 36 months	
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15.	<p>Global Biotech Medical Devices (Private) Limited. First Floor of Plot No 35-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi. ELI-01292 R&amp;I Date: 03.12.2024 Fee: 31,000/- Slip #206211973099 This evaluation is based on the on-line data submitted through E-App. Tracking ID: MUY-P46-TGEL</p>	<p>Manufacturer: Curatia Medical Limited.  <b>Site 1 (other than sterilization)</b>  No. 198 Xiangjiang Road, New District, Suzhou, China  <b>Site 2 (Sterilization process)</b>  Name: Goals Sterilization Co., Ltd  Address: East of Renkangtang, South of 07 provincial road, Xinfeng Town, Nanhu District  LOA  Type: scanned copy  Notarization: Yes, CCPIT  Validity: 04.07.2026  FSC  Type: scanned copy  Issued by: NIL  Legalization: apostilled the notarization of CCPIT  Validity: 15.01.2026  ISO – Certificate:  Type: Scanned copy  Notarization: Yes, CCPIT  Validity: 31.07.2026  CE certificate / EU QMS certificate (MDR)  Type: scanned copy  Notarization: No (notarized the statement of manufacturer, not the certificate)  Validity: 26.05.2024  Extended till 31.12.2028</p>	<p>Brand Name: Navajo PTA Balloon Dilatation Catheter  Generic Name: Balloon Dilatation Catheter  Applied as: Single  Class: B  Models/Code/sizes (as per FSC &amp; application: Catheter Length (80cm)  21005040,  21005060,  21005080,  21006040,  21006060,  21006080,  21007040,  21007060,  21007080,  21008040,  21008060,  21008080,  21009040,  21009060,  21009080,  21010040,  21010060,  21010080.  Catheter Length (100cm)  21205040,  21205060,  21205080,  21206040,  21206060,  21206080,  21207040,  21207060,  21207080,  21208040,  21208060,  21208080,  21209040,  21209060,  21209080,</p>	<p>Deferred for:  Properly filled application Form shall be submitted. English translation of the issuing authority in FSC is required.  The scanned copy of the FSC varies from the attachments and notarization.  The models vary in balloon size (OD x length), catheter length, balloon nominal pressure, rated burst pressure, maximum guide wire lumen and catheter OD. The firm shall apply as grouping with submission of requisite fee.  The application form has been signed by authorized person for Regulatory Affairs.  Authorization letter for the signatory is required.  Declaration on stamp paper to be issued in the name of the firm / signatory is required.  Scanned copy of the notarized CE certificate are required.  The sterilization site has not been mentioned in the ISO certificate and CE certificate.</p>
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			21210040, 21210060, 21210080. Catheter Length (120cm) 21305040, 21305060, 21305080, 21306040, 21306060, 21306080, 21307040, 21307060, 21307080, 21308040, 21308060, 21308080, 21309040, 21309060, 21309080, 21310040, 21310060, 21310080. Catheter Length (130cm) 21105040, 21105060, 21105080, 21106040, 21106060, 21106080, 21107040, 21107060, 21107080, 21108040, 21108060, 21108080, 21109040, 21109060, 21109080, 21110040, 21110060, 21110080. Shelf Life: 2 years	
16.	Global Biotech Medical Devices (Private) Limited.	Manufacturer:	Brand Name: Vela RX PTA Balloon Dilatation Catheter	Deferred for: Properly filled application Form shall be submitted.

<p>First Floor of Plot No 35-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi.          ELI-01292          R&amp;I Date: 03.12.2024          Fee: 31,000/-          Slip #1306741949          This evaluation is based on the on-line data submitted through E-App.          Tracking ID: BUA-Z8Z-9PV3</p>	<p>Curatia Medical Limited.          No. Site 1 (other than sterilization)          198 Xiangjiang Road, New District, Suzhou, China          Site 2 (Sterilization process)          Name: Goals Sterilization Co., Ltd          Address: East of Renkangtang, South of 07 provincial road, Xinfeng Town, Nanhu District          LOA          Type: scanned copy          Notarization: Yes, CCPIT          Validity: 04.07.2026          FSC          Type: scanned copy          Issued by: NIL          Legalization: apostilled the notarization of CCPIT          Validity: 15.01.2026          ISO – Certificate:          Type: Scanned copy          Notarization: Yes, CCPIT          Validity: 31.07.2026          CE certificate / EU QMS certificate (MDR)          Type: scanned copy          Notarization: No (notarized the statement of manufacturer, not the certificate)          Validity: 26.05.2024          Extended till 31.12.2028</p>	<p>Generic Name: Balloon Dilatation Catheter          Applied as: Single          Class: B          Models/Code/sizes (as per FSC &amp; application:          Balloon Length (10mm)          21510140,          22010140,          22510140,          23010140,          23510140,          24010140.          Balloon Length (20mm)          21520140,          22020140,          22520140,          23020140,          23520140,          24020140.          Balloon Length (30mm)          21530140,          22030140,          22530140,          23030140,          23530140,          24030140.          Balloon Length (40mm)          21540140,          22040140,          22540140,          23040140,          23540140,          24040140.          Shelf Life: 2 years</p>	<p>English translation of the issuing authority in FSC is required.          The scanned copy of the FSC varies from the attachments and notarization.          The models vary in balloon Size (OD x Length), rated burst pressure, and catheter OD. The firm shall apply as grouping with submission of requisite fee.          The application form has been signed by authorized person for Regulatory Affairs.          Authorization letter for the signatory is required.          Declaration on stamp paper to be issued in the name of the firm / signatory is required.          Scanned copy of the notarized CE certificate are required.          The sterilization site has not been mentioned in the ISO certificate and CE certificate.</p>
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**ADDITIONAL AGENDA 109<sup>TH</sup> MEETING OF MDB**

**Item No. I(A): APPLICATIONS FOR GRANT OF ADDITIONAL SECTION FOR LOCAL MANUFACTURING (ELM)**

**(Additional Section -ELM)**

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Sayyad Healthcare Limited, Plot No. 37, Allama Iqbal Industrial City, Faisalabad (ELM-0079)	Muhammad Fayyaz	Moshin Ali Altaf	<b>The Board approved the following additional section to manufacture medical devices.</b> <b>1.Disposable Syringes Section</b>

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

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	Electromed Corporation, Office/Godown: 53 Mall Avenue, 54 The Mall, Near Panorama Shopping Center , LAHORE  ELI-00163	Ms. Zartaj  Bs Microbiology	Said Ur Rehman Razi Ur Rehman Zaki Ur Rehman Shoaib Rizwan Usmani	Approved

**Item No. II: CASES OF M/S PERFECT TRADERS (ELI-01394)**

**Muhammad Ashfaq - 0Deputy Director-VI**

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Perfect Traders, 72 Harley Street Lane No.2, Rawalpindi. <b>(ELI-01394)</b>  <b>Date of R&amp; I</b> 11-04-2025  <b>Fee:</b> 6,000/- <b>Slip #</b> 937914403	<b>Name of Manufacturer:</b> Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China	<b>Brand Name:</b> Pro Sun  <b>Generic Name:</b> Prosthetic Knee Joint  <b>Applied as:</b> Single  <b>Class:</b> A	Deferred due to following deficiencies in the application; 1. Copy of filled, signed & stamped application form, has not been submitted. 2. LOA has not been notarized. 3. Validity Period or validity date has not been mentioned on LOA. 4. LOA has been issued by Beijing Chonglang

		<p><b>LOA</b>  <b>Type:</b> Copy  <b>Notarization:</b> Not Notarized  <b>Issue Date:</b> 06-03-2025  <b>Validity:</b> Not mentioned</p> <p>• <b>FSC (UK)</b>  <b>Type:</b> Copy  <b>Issued By:</b> MHRA  <b>Legalization:</b> Not legalized  <b>Validity:</b> 19-06-2029</p> <p>• <b>ISO – Certificate:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Not Notarized  <b>Validity:</b> 22-08-2026</p>	<p><b>Model:</b> X5-T</p> <p><b>Shelf Life:</b> 36 Months</p>	<p>Rehabilitation Accessory Co., Ltd., Room 401, Unit 2, Building 7, Lianhe U valley 4 yard, Renheyuan 2 street, Renhe town, Shunyi District, Beijing, China while manufacturer mentioned on FSC is Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China.</p> <p>5. FSC (UK) has not been legalized.</p> <p>6. ISO certificate submitted has been issued by CAB not found in NANDO data base.</p> <p>7. ISO certificate has not been notarized.</p> <p>8. Stability studies data has not been submitted.</p> <p>9. Undertaking on stamp paper has not been submitted.</p> <p>The Board directed to rectify the above-mentioned deficiencies for further processing the application.</p>
2.	<p>M/s Perfect Traders, 72 Harley Street Lane No.2, Rawalpindi.  <b>(ELI-01394)</b></p> <p><b>Date of R&amp; I</b> 11-04-2025</p> <p><b>Fee:</b> 6,000/-  <b>Slip #</b>  372118529489</p>	<p><b>Name of Manufacturer:</b>  Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China</p> <p><b>LOA</b>  <b>Type:</b> Copy  <b>Notarization:</b> Not Notarized  <b>Issue Date:</b> 06-03-2025  <b>Validity:</b> Not mentioned</p> <p>• <b>FSC (UK)</b>  <b>Type:</b> Copy  <b>Issued By:</b> MHRA  <b>Legalization:</b> Not legalized  <b>Validity:</b> 19-06-2029</p> <p>• <b>ISO – Certificate:</b></p>	<p><b>Brand Name:</b> Pro Sun</p> <p><b>Generic Name:</b> Prosthetic Knee Joint</p> <p><b>Applied as:</b> Single</p> <p><b>Class:</b> A</p> <p><b>Model:</b> X4-T</p> <p><b>Shelf Life:</b> 36 Months</p>	<p>Deferred due to following deficiencies in the application;</p> <p>1. Copy of filled, signed &amp; stamped application form, has not been submitted.</p> <p>2. LOA has not been notarized.</p> <p>3. Validity Period or validity date has not been mentioned on LOA.</p> <p>4. LOA has been issued by Beijing Chonglang Rehabilitation Accessory Co., Ltd., Room 401, Unit 2, Building 7, Lianhe U valley 4 yard, Renheyuan 2 street, Renhe town, Shunyi District, Beijing, China while manufacturer mentioned on FSC is Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China.</p> <p>5. FSC (UK) has not been legalized.</p> <p>6. ISO certificate submitted has been issued by CAB not found in NANDO data base.</p> <p>7. ISO certificate has not been notarized.</p>

		<b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 22-08-2026		8. Stability studies data has not been submitted. 9. Undertaking on stamp paper has not been submitted. The Board directed to rectify the above-mentioned deficiencies for further processing the application.
3.	M/s Perfect Traders, 72 Harley Street Lane No.2, Rawalpindi. <b>(ELI-01394)</b>  <b>Date of R&amp; I</b> 11-04-2025  <b>Fee:</b> 6,000/- <b>Slip #</b> 71013168	<b>Name of Manufacturer:</b> Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Issue Date:</b> 06-03-2025 <b>Validity:</b> Not mentioned  • <b>FSC (UK)</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA <b>Legalization:</b> Not legalized <b>Validity:</b> 19-06-2029  • <b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 22-08-2026	<b>Brand Name:</b> Pro Sun  <b>Generic Name:</b> Prosthetic Knee Joint  <b>Applied as:</b> Single  <b>Class:</b> A  <b>Model:</b> XQ-4  <b>Shelf Life:</b> 36 Months	Deferred due to following deficiencies in the application; 1. Copy of filled, signed & stamped application form, has not been submitted. 2. LOA has not been notarized. 3. Validity Period or validity date has not been mentioned on LOA. 4. LOA has been issued by Beijing Chonglang Rehabilitation Accessory Co., Ltd., Room 401, Unit 2, Building 7, Lianhe U valley 4 yard, Renheyuan 2 street, Renhe town, Shunyi District, Beijing, China while manufacturer mentioned on FSC is Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China. 5. FSC (UK) has not been legalized. 6. ISO certificate submitted has been issued by CAB not found in NANDO data base. 7. ISO certificate has not been notarized. 8. Stability studies data has not been submitted. 9. Undertaking on stamp paper has not been submitted. The Board directed to rectify the above-mentioned deficiencies for further processing the application.
4.	M/s Perfect Traders, 72 Harley Street Lane No.2, Rawalpindi. <b>(ELI-01394)</b>  <b>Date of R&amp; I</b> 11-04-2025  <b>Fee:</b> 6,000/- <b>Slip #</b> 8484982336	<b>Name of Manufacturer:</b> Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China  <b>LOA</b>	<b>Brand Name:</b> Pro Sun  <b>Generic Name:</b> Prosthetic Foot  <b>Applied as:</b> Single  <b>Class:</b> A  <b>Model:</b> J3-M	Deferred due to following deficiencies in the application; 1. Copy of filled, signed & stamped application form, has not been submitted. 2. LOA has not been notarized. 3. Validity Period or validity date has not been mentioned on LOA. 4. LOA has been issued by Beijing Chonglang Rehabilitation Accessory Co., Ltd., Room 401, Unit 2,



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5.	M/s Perfect Traders, 72 Harley Street Lane No.2, Rawalpindi. <b>(ELI-01394)</b>  <b>Date of R&amp; I</b> 11-04-2025  <b>Fee:</b> 6,000/- <b>Slip #</b> 7696282671	<b>Name of Manufacturer:</b> Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Issue Date:</b> 06-03-2025 <b>Validity:</b> Not mentioned  <b>• FSC (UK)</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA <b>Legalization:</b> Not legalized <b>Validity:</b> 19-06-2029  <b>• ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized	<b>Brand Name:</b> Pro Sun  <b>Generic Name:</b> Prosthetic Foot  <b>Applied as:</b> Single  <b>Class:</b> A  <b>Model:</b> J7  <b>Shelf Life:</b> 36 Months	Deferred due to following deficiencies in the application; 1. Copy of filled, signed & stamped application form, has not been submitted. 2. LOA has not been notarized. 3. Validity Period or validity date has not been mentioned on LOA. 4. LOA has been issued by Beijing Chonglang Rehabilitation Accessory Co., Ltd., Room 401, Unit 2, Building 7, Lianhe U valley 4 yard, Renheyuan 2 street, Renhe town, Shunyi District, Beijing, China while manufacturer mentioned on FSC is Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401, Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China. 5. FSC (UK) has not been legalized. <b>6. The Model applied (J7), has not been mentioned in FSC (UK) as well as DOC.</b> 7. ISO certificate submitted has been issued by CAB not found in NANDO data base. 8. ISO certificate has not been notarized.

		<b>Validity:</b> 22-08-2026		<p>9. Stability studies data has not been submitted.</p> <p>10. Undertaking on stamp paper has not been submitted.</p> <p>The Board directed to rectify the above-mentioned deficiencies for further processing the application.</p>
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