

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

DECISIONS OF 108TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)

HELD ON 12-11-2025 (MANUAL APPLICATIONS- PART-II)

108th 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 12th 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 Hospitaol, 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
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SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X
10.	Mr. Hanif Ullah	Deputy Director-XI

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.

(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

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

FRESH ESTABLISHMENT LICENSE TO MANUFACTURE (ELM) CASES:

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Defence Science and Technology Organization Labs, Complex, Biological Research Centre, DESTO, 34-37 PNH, Lines, Karachi.	Dr. Shaukat Ali Bs Hons (Microbiology) Experience as Deputy Chief Manager Desto from 01-09-2021 to 27-1-2023	Ms. Misbah Khadim MSc Biosciences Experience: Incharge QC Desto 15 Years	The board considered the report of the firm and approved following sections for manufacturing of medical devices: <ul style="list-style-type: none"> • Processing Kit Section • Microbiological Diagnostic Section • Immunodiagnostic Section • Sterile filling Section • Biomaterial Production Facility

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

FRESH CASES ELI

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Accumed Supplies, B-16, Hina Palace, Hoshang Road, Civil Lines, Karachi South Saddar Town, Karachi	Engr. Nawab Suhail Imtiaz Bio Medical Engineer	Approved
2.	M/s MCG Healthcare (Private) Limited, Carim House, 6-Davis Road, Lahore	Ms. Qammer Saeed Pharm D	Approved
3.	M/s Universal Enterprises (Medcare), Office: 527-Janiper Block, Bahria Town, Lahore Godown: 1748 Pine Avenue Road Valencia Town, Lahore	Muhammad Tayyab Bs (Hons) Medical Laboratory	Rejected. The board considered the findings of the inspector that the premises was used for residential purpose and no medical device storage facility was available. Therefore board decided to reject ELI application of the firm.
4.	M/s Mays Marketing Enterprises Office: 2 nd Floor, House No. 46/E/2, Block-6, PECHS, Karachi Godown: Room No. G02, Plot No. 42, Darulaman Housing Society Block 7 & 8, Karachi.	Muhammad Fareed Uddin BSC (Pass)	Deferred for appointment of technical staff as per requirement of Medical Devices Rules, 2017.

Deferred Cases for Grant of Establishment License to Import:

Name of Establishment	Name of Person previously applied as Q.P.	Remarks
M/s Advance Medical Devices, Apartment # 1 3rd floor Plaza 01 linear commercial phase 8 Bahria town Rawalpindi.	Mubashar Abbas CNIC37405-3758089-9 BS Computer Science	The board approved Establishment License to Import medical devices as the firm has complied with the requirements of medical devices rules 2017 and appointed a qualified person Muhammad Nawaz Sultan, cnic 1350491691851 Qualification Pharm D as per requirement law.

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

RENEWAL CASES ELI

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Metro Commercial Enterprises, Office/Godown: Suite No. 1, L.G.R., Abrar Business Centre, Wahdat Road, Lahore (ELI-00137)	Usama Bin Sabir Pharm D	Muhammad Jalil Tahir	Approved
2.	M/s Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. Godown 1: M-4 , Asghar Ali Building, Campbell Street , Karachi. Godown 2: 201, Union Chambers, North Napier Road, Karachi	Syed Muhammad Sami Pharm D	Tausif Jamil	Approved
3.	M/s Sultan Sons, 133, Kutchi Gali No.1, Marriot Road, Karachi. Godown 1: M-2, Mez floor, Asghar Ali Building , Karachi Godown: 2nd Floor #29, Sadaf Centre, Serai Road, Karachi Godown 3: 2nd floor 27/28 Sadaf centre, Serai Road, Karachi Godown 4: 2-A Plot # 07/15 N.Napier Road, Karachi	Urooj Fatima Pharm-D	Mohammad Aslam Shakil Ahmed Jamil Sultan	Approved
4.	M/s Wasim Co, Kachi Gali No 1, Marriot Road, Karachi Godown: Sadaf Center SR- -3/22 Serial Road, 2nd Floor No.15 & 26, Karachi.	Humayun Khalid Pharm D	Khalil Ahmed	Approved
5.	M/s Princess Scientific Services, Office/Godown: Office No. 11, 3 rd Floor, Zaraj Centre-II, Bakery Road, Opposite MAG Office Saddar, Rawalpindi (ELI-00215)	Ihsan Ullah MSc. Biochemistry	Abdul Hafeez	Approved
6.	M/s Hospital Supply Corporation,	Muhammad Sohail Arif	M Yahya Feroz Sohail Feroz	Approved

	Office: 42 Darul Aman Housing Society, Block 7 & 8, Karachi Godown 1: 42 Darul Aman Housing Society, Block 7 & 8, Karachi Godown 2: Room No. G01, Ground Floor, Plot No. 167, Sector 23, Korangi Industrail Area, Karachi. ELI-00005	Pharm D	M Yahya Feroz	
7.	M/s 4A International, Office/Godown: Plot 7, street No 11,lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Muhammad Ali Pharm D	Sana Ullah Nasir	Approved

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

Deferred Renewal Cases:

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s B.Braun Pakistan (Pvt) Ltd., Office: The Forum, Suite no. 501, 5 th Floor Khayaban-e-Jami, Clifton Block -9, Karachi (ELI-00006) Godown: Ground Floor, Plot No. C-153, Sector 6F, Mehran Town, Karachi	Umair Saleem Khan Pharm D	Sinon Esermann Muhammad Arqam Ali Jaleel Cristoph Hux	Approved

Item 1(E): Misc Cases

Subject: **CANCELLATION OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES OF M/S ADVANCE SYSTEMS, LAHORE (ELI-00616)**

M/s Advance Systems, Lahore (ELI-00616) was granted Establishment license to Import (ELI) on 14-12-2020 for a period of 5 years. Ms. Zoha Khalid was appointed as qualified person of the firm at the time of grant of license. However, she left the company and the firm did not intimate medical devices board regarding this change. The qualified person Ms. Zoha Khalid has approached Wafaqi Mohtasib (Ombudsman) Secretariat, Lahore and requested for removal her name on the license of M/s Advance Systems, Lahore.

The firm has now submitted a letter in writing that they are going to close the import form their company and close the company due to financial constraints. The have further informed that they have not imported any shipment since long and company is almost closed.

Therefore, they have requested to withdraw the name of qualified person and cancel their license to import medical devices (ELI-00616).

Decision: The board observed that the firm had made a request to cancel ELI of the firm which was considered in 107 MDB meeting. To complete requirements of law, the firm was provided opportunity of personal hearing. However, the applicant did not appear before the board and submitted a written reply reiterating the previous stance for cancellation of license and that they have no objection to the immediate cancellation of license. The board considered this written statement of the firm and decided to cancel ELI-00616 granted to the applicant by MDB. The board further advised that the MIS division shall immediately remove the name of qualified person of the firm Ms. Zoha Khalid from the ELI - 00616 if it is appearing on DRAP website or any other DRAP IT system.

Item No.II. ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Dr. Hanif Ullah (Deputy Director-XI)

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Medifa Enterprises, TF-185, Deans Trade Center Peshawar Cantt. ELI-00756 R&I Date: 22.05.2025 Fee: 31000/- Slip #36376019	Name of Manufacturer: Shezan Biocare Bio-Medical Equipment Co. Ltd., Address: #16-1 Jinhui Road, Jinsha Community Kengzi Sub-District pingshan New District 518122 Shebzhen People's Republic of China LOA Type: Copy Notarization: No Issue date: 31.03.2023 Validity: Dec, 2026 FSC Type: Not submitted	Brand Name: Biocare Generic Name: Digital Electrocardiograph (ECG machine) Applied as: Single Class: B Models/Code/sizes (as per FSC & application: iE101, iE300 and iE6 Shelf Life: NIL	<i>Deferred for:</i> <i>Notarized LOA (mentioning the applied brand name) is required.</i> <i>Legalized FSC in the country of origin issued by the Government of People's Republic of China is required.</i> <i>Legalized FSC in reference country or CE certificate / EU QMS certificate is required.</i> <i>Clarification / selection of the code is required.</i> <i>Declaration of conformity is required.</i> <i>Shelf life verification / stability studies report is required.</i> <i>ISO – Certificate is required.</i>

		<p>Issued By: NIL</p> <p>Legalization: NIL</p> <p>Validity: NIL</p> <p>ISO – Certificate:</p> <p>Type: NIL</p> <p>Notarization NIL</p> <p>Validity: NIL</p>		
2.	<p>Medifa Enterprises, TF-185, Deans Trade Center Peshawar Cantt.</p> <p>ELI-00756</p> <p>R&I Date: 22.05.2025</p> <p>Fee: 31000/-</p> <p>Slip #19257589534</p>	<p>Name of Manufacturer: Shezan Biocare Bio-Medical Equipment Co. Ltd.,</p> <p>Address: #16-1 Jinhui Road, Jinsha Community Kengzi Sub-District pingshan New District 518122 Shebzhzen People's Republic of China</p> <p>LOA</p> <p>Type: Copy</p> <p>Notarization: No</p> <p>Issue date: 31.03.2023</p> <p>Validity: Dec, 2026</p> <p>FSC</p> <p>Type: Not submitted</p> <p>Issued By: NIL</p> <p>Legalization: NIL</p> <p>Validity: NIL</p> <p>ISO – Certificate:</p> <p>Type: NIL</p> <p>Notarization: NIL</p> <p>Validity: NIL</p>	<p>Brand Name: Micomme Medical</p> <p>Generic Name: Heated humidified high flow nasal cannula therapy device (HNFC)</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application: NIL</p> <p>Shelf Life: NIL</p>	<p><i>Deferred for:</i></p> <p><i>Notarized LOA (mentioning the applied brand name) is required.</i></p> <p><i>Legalized FSC in the country of origin issued by the Government of People's Republic of China is required.</i></p> <p><i>Legalized FSC in reference country or CE marking document is required.</i></p> <p><i>Clarification / selection of the code is required.</i></p> <p><i>Declaration of conformity is required.</i></p> <p><i>Shelf life verification / stability studies report is required.</i></p> <p><i>ISO – Certificate is required.</i></p> <p><i>Justification for applying as single, and not as a system.</i></p>
3.	<p>JF International, 4th Floor, 10C, 6th Sunset Commercial Lane, Phase 2</p>	<p>Name of Manufacturer: Bionet Co., Ltd.,</p> <p>Address: 5F, 61, Digital-Ro 31-Gil, Guro-Gu, Seoul</p>	<p>Brand Name: Bionet</p> <p>Generic Name: Electrocardiographic Analyser</p> <p>Applied as: System</p>	<p><i>Deferred for:</i></p> <p><i>Stamp paper shall be issued in the name of the firm / signatory.</i></p>

	<p>Ext, DHA, Karachi</p> <p>ELI-00246</p> <p>R&I Date: 21.05.2025</p> <p>Fee: 31000/-</p> <p>Slip #7997027901</p>	<p>Republic of Korea 08375</p> <p>Sub Assembly unit: Bionet Co., Ltd., #401, 34LS-ro 91 beon-gil, Dongan-gu, Anyang-Si, Gyeonggi-do</p> <p>LOA</p> <p>Type: Original</p> <p>Notarization: yes</p> <p>Validity: 01.01.2030</p> <p>FSC</p> <p>Type: Copy</p> <p>Issued by: National Institute of Medical Devices Safety Information, South Korea</p> <p>Legalization: Apostille</p> <p>Validity: NIL</p> <p>ISO – Certificate:</p> <p>Type: Copy</p> <p>Notarization: Yes</p> <p>Validity: 19.10.2026</p> <p>CE certificate / EU QMS certificate (MDR)</p> <p>Type: Copy</p> <p>Notarization: Yes (apostilled the notarization)</p> <p>Validity: 26.05.2024</p> <p>Extended till 31.12.2028 for class IIa devices.</p>	<p>Class: B</p> <p>Models/Code/sizes (as per FSC & application: Cardio Touch 3000</p> <p>Shelf Life: 10 years</p>	<p><i>Notarized LOA on the letter head of the manufacturer (mentioning the brand name) is required.</i></p> <p><i>Legalized FSC in the country of origin with validity is required.</i></p> <p><i>Shelf life verification / stability studies report is required.</i></p> <p><i>Clarification regarding variation in the address of manufacturer in Form and FSC etc.</i></p>
4.	<p>La Vie Pvt. Ltd., 450 G/3, Gohar Town, Lahore</p> <p>ELI: 00113</p>	<p>Name of Manufacturer: Zhejiang haichuang Medical Device Co., Ltd.</p> <p>Address: #3 Building No. 146, East Chaofeng</p>	<p>Brand Name: Bi-fix</p> <p>Generic Name: Surgical incision closure set</p> <p>Applied as: Set</p> <p>Class: B</p>	<p><i>Deferred for:</i></p> <p><i>The firm has mentioned new application as well as proposed changes in the Form-7A. Clarification is required.</i></p> <p><i>Notarized LOA (both) on the letter head of the manufacturer mentioning the brand</i></p>

	<p>R&I Date: 29.05.2025</p> <p>Fee: 31000/-</p> <p>Slip #77290818984</p>	<p>Road, Linping District, Hangzhou China</p> <p>LOA1: (Zhejiang haichuang Medical Device Co., Ltd.) has authorized Joy Beyond Health Limited, China)</p> <p>Type: copy</p> <p>Notarization: No</p> <p>Issue date: 13.09.2024</p> <p>Validity: 12.09.2027</p> <p>LOA2: (Joy Beyond Health Limited, China has authorized La Vie Pvt. Ltd., 450 G/3, Gohar Town, Lahore)</p> <p>Type: copy</p> <p>Notarization: No</p> <p>Issue date:01.08.2024</p> <p>Validity: 31.08.2027</p> <p>FSC</p> <p>Type: Copy</p> <p>Issued By: Zhejiang Medical Product Administration</p> <p>Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Apostilled the notarization.</p> <p>Validity: 20.09.2025</p> <p>ISO – Certificate:</p> <p>Type: Copy</p> <p>Legalization: Notarized (China council for the Promotion of International Trade China Chamber of</p>	<p>Models/Code/sizes (as per FSC & application:</p> <p>5HWH-2, 5HWH-4, 5HWH-6, 5HWH-8, 5HWH-10, 5HWH-12, 5HWH-16, 5HWH-20, (5HWH-24 applied but not mentioned in FSC)</p> <p>Shelf Life: 36 months</p>	<p><i>name and complete address of the importer is required.</i></p> <p><i>Shelf life verification / stability studies report is required. Merely, sterilization dose setting report does not serve the purpose.</i></p> <p><i>Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc.</i></p> <p><i>Legalized valid FSC in the country of origin is required.</i></p> <p><i>The firm shall apply as family.</i></p> <p><i>Models 5HWH-20 and 5HWH-24 applied but not mentioned in CE certificate.</i></p> <p><i>Model 5HWH-24 applied but not mentioned in FSC.</i></p>
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		<p>International Commerce)</p> <p>Apostilled the notarization.</p> <p>Validity: 10.09.2027</p> <p>CE certificate:</p> <p>Type: Copy</p> <p>Validity: 27.05.2024</p> <p>Extension for IIa class: 31.12.2028</p>		
5.	<p>Bay-G Pharma, House No. 103-A, Block A Satellite Town Rawalpindi</p> <p>ELI-00016</p> <p>R&I Date: 09.07.2025</p> <p>Fee: 62000/-</p> <p>Slip #310027118</p>	<p>Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd.,</p> <p>Address: Baisheng Road No. 1, Yuwell Industrial Park, Dan Yang, Jiangsu Province P.R. China</p> <p>LOA</p> <p>Type: copy of already notarized LOA</p> <p>Notarization:</p> <p>Issue date: 03.06.2025</p> <p>Validity: five years</p> <p>FSC</p> <p>Type: copy of already notarized</p> <p>Issued By: Jiangsu Medical Product Administration</p> <p>Legalization: copy of notarized FSC (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 13.07.2025</p> <p>ISO – Certificate:</p>	<p>Brand Name: Believeia Oxygen Concentrator OXC-05</p> <p>Generic Name: Believeia Oxygen Concentrator OXC-05</p> <p>Applied as: NIL</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application: NIL</p> <p>Shelf Life: 3 years</p>	<p><i>Deferred for:</i></p> <p><i>Original fee challan is required.</i></p> <p><i>Correction of the manufacturer's title and address in Form-7A is required.</i></p> <p><i>Specify the medical device grouping in Form-7A.</i></p> <p><i>Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required.</i></p> <p><i>Legalized valid FSC in the country of origin is required.</i></p> <p><i>Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc.</i></p> <p><i>Clarification / selection of the model is required.</i></p> <p><i>DOC on the letterhead of the firm is required.</i></p> <p><i>Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE certificate / EU QMS certificate is required.</i></p>

		<p>Type: copy of notarized certificate</p> <p>Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 04.01.2027</p> <p>CE certificate / EU QMS certificate (MDR):</p> <p>Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 03.03.2029</p>		
6.	<p>Bay-G Pharma, House No. 103-A, Block A Satellite Town Rawalpindi</p> <p>ELI-00016</p> <p>R&I Date: 09.07.2025</p> <p>Fee: 62000/-</p> <p>Slip #01523899</p>	<p>Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd.,</p> <p>Address: Baisheng Road No. 1, Yuwell Industrial Park, Dan Yang, Jiangsu Province P.R. China</p> <p>LOA</p> <p>Type: copy of already notarized LOA</p> <p>Notarization:</p> <p>Issue date: 03.06.2025</p> <p>Validity: five years</p> <p>FSC</p> <p>Type: copy of already notarized</p>	<p>Brand Name: Believeia Oxygen Concentrator OXC-10</p> <p>Generic Name: Believeia Oxygen Concentrator OXC-10</p> <p>Applied as: NIL</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application: NIL</p> <p>Shelf Life: 3 years</p>	<p><i>Deferred for:</i></p> <p><i>Original fee challan is required.</i></p> <p><i>Correction of the manufacturer's title and address in Form-7A is required.</i></p> <p><i>Specify the medical device grouping in Form-7A.</i></p> <p><i>Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required.</i></p> <p><i>Legalized valid FSC in the country of origin is required.</i></p> <p><i>Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc.</i></p> <p><i>Clarification / selection of the model is required.</i></p> <p><i>DOC on the letterhead of the firm is required.</i></p> <p><i>Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE certificate / EU QMS certificate is required.</i></p>

		<p>Issued By: Jiangsu Medical Product Administration</p> <p>Legalization: copy of notarized FSC (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 13.07.2025</p> <p>ISO – Certificate:</p> <p>Type: copy of notarized certificate</p> <p>Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 04.01.2027</p> <p>CE certificate / EU QMS certificate (MDR):</p> <p>Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)</p> <p>Validity: 03.03.2029</p>		
7.	<p>Bay-G Pharma, House No. 103-A, Block A Satellite Town Rawalpindi</p> <p>ELI-00016</p> <p>R&I Date: 09.07.2025</p>	<p>Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd.,</p> <p>Address: Baisheng Road No. 1, Yuwell Industrial Park, Dan Yang, Jiangsu Province P.R. China</p>	<p>Brand Name: Believia Portable Phlegm Suction Unit SU-10</p> <p>Generic Name: Portable Phlegm Suction Unit SU-10</p> <p>Applied as: NIL</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application:</p>	<p><i>Deferred for:</i></p> <p><i>Original fee challan is required.</i></p> <p><i>Correction of the manufacturer's title and address in Form-7A is required.</i></p> <p><i>Specify the medical device grouping in Form-7A.</i></p> <p><i>Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required.</i></p>

	<p>Fee: 31000/- Slip #76753680</p>	<p>LOA Type: Not attached Notarization: Issue date: Validity: FSC Type: copy of already notarized Issued By: Jiangsu Medical Product Administration Legalization: copy of notarized FSC (China council for the Promotion of International Trade China Chamber of International Commerce) Validity: 13.07.2025 ISO – Certificate: Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce) Validity: 04.01.2027 CE certificate / EU QMS certificate (MDR): Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce) Validity: 03.03.2029</p>	<p>NIL Shelf Life: 5 years</p>	<p><i>Legalized valid FSc in the country of origin is required.</i> <i>Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc.</i> <i>Legalized valid FSC in the country of origin is required.</i> <i>Clarification / selection of the model is required.</i> <i>DOC on the letterhead of the firm is required.</i> <i>Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE certificate / EU QMS certificate is required.</i></p>
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8.	<p>Bay-G Pharma, House No. A 103-A, Block Satellite Town Rawalpindi</p> <p>ELI-00016</p> <p>R&I Date: 11.07.2025</p> <p>Fee: 62000/- Slip #69213969</p>	<p>Name of Manufacturer: Cofee Medical Technology Co., Ltd., Address: 816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, China</p> <p>LOA</p> <p>Type: Copy of notarized LOA</p> <p>Notarization: China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 09.05.2030</p> <p>FSC</p> <p>Type: copy of notarized FSC</p> <p>Issued By: Hunan 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: 26.02.2027</p> <p>ISO – Certificate:</p> <p>Type: copy of notarized certificate</p> <p>Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 12.07.2028</p> <p>CE certificate / EU QMS certificate (MDR):</p>	<p>Brand Name: Believia Blood Glucose Test Strips BG-01 50T</p> <p>Generic Name: Believia Blood Glucose Test Strips BG-01 50T Applied as: NIL</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application: NIL</p> <p>Shelf Life: 5 years</p>	<p><i>Deferred for:</i></p> <p><i>Specify the medical device grouping in Form-7A.</i></p> <p><i>Clarification regarding variation in the address of manufacturer in Form-7A, LOA, QMS certificate and FSC etc.</i></p> <p><i>Clarification / selection of the model is required.</i></p> <p><i>DOC on the letterhead of the firm is required.</i></p> <p><i>Clarification and proof are required about the claimed shelf life.</i></p> <p><i>Valid CE certificate is required.</i></p> <p><i>Specify the model as per FSC.</i></p>
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		Type: copy of notarized certificate Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 26.05.2025		
9.	Bay-G Pharma, House No. 103-A, Block Satellite Town Rawalpindi ELI-00016 R&I Date: 11.07.2025 Fee: 62000/- Slip #726547825	Name of Manufacturer: Cofee Medical Technology Co., Ltd., Address: 816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, China LOA Type: Copy of notarized LOA Notarization: China council for the Promotion of International Trade China Chamber of International Commerce Validity: 09.05.2030 FSC Type: copy of notarized FSC Issued By: Hunan Medical Product Administration Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 26.02.2027 ISO – Certificate Type: copy of notarized certificate	Brand Name: Believeia Blood Glucose Test Strips BG-01 Foil Pack 50T Generic Name: Believeia Blood Glucose Test Strips BG-01 Foil Pack 50T Applied as: NIL Class: C Models/Code/sizes (as per FSC & application: NIL Shelf Life: 5 years	<i>Deferred for:</i> <i>Specify the medical device grouping in Form-7A.</i> <i>Clarification regarding variation in the address of manufacturer in Form-7A, LOA, QMS certificate and FSC etc.</i> <i>Clarification / selection of the model is required.</i> <i>DOC on the letterhead of the firm is required.</i> <i>Clarification and proof are required about the claimed shelf life.</i> <i>Clarification of the term Foil Pack is required.</i> <i>Valid CE certificate is required.</i> <i>Specify the model as per FSC.</i>

		<p>Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 12.07.2028</p> <p>CE certificate / EU QMS certificate (MDR):</p> <p>Type: copy of notarized certificate</p> <p>Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 26.05.2025</p>		
10.	<p>Nextawits Private Limited, Office No. 8, First Floor, Shaheen View, Block-6, P.E.C.H.S, Main Shahrah-e-Faisal, Karachi</p> <p>ELI-01171</p> <p>R&I Date: 30.05.2025</p> <p>Fee: 31000/- Slip #1851937536</p>	<p>Name of Manufacturer: Tianchang City Anrui Medical Equipment Co., Ltd.,</p> <p>Address: Renhe Industrial District, TianChang City, Anhui Province China</p> <p>LOA</p> <p>Type: Original</p> <p>Notarization: China council for the Promotion of International Trade China Chamber of International Commerce</p> <p>Validity: 3 years from 15.08.2024</p> <p>FSC</p> <p>Type: copy</p> <p>Issued By: NIL</p> <p>Legalization: Apostilled the notarization of China council for the</p>	<p>Brand Name: CuraPro Surgical Gloves</p> <p>Generic Name: Sterile Surgical Gloves for Single Use</p> <p>Applied as: Set</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application: 6, 6.5, 7, 7.5, 8, 8.5, 9</p> <p>Shelf Life: 5 years</p>	<p><i>Deferred for:</i></p> <p><i>Stamp paper shall be issued in the name of the firm / signatory.</i></p> <p><i>The fee has been submitted for Curacare respiratory and Anesthesia Product. Clarification is required.</i></p> <p><i>The firm shall apply as family.</i></p> <p><i>English translation of the issuing authority of the FSC is required.</i></p> <p><i>Clarification / selection of the model is required.</i></p>

		Promotion of International Trade China Chamber of International Commerce Validity: 15.01.2026 ISO – Certificate Type: copy Legalization: Notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 19.07.2027 CE certificate / EU QMS certificate (MDR): Type: copy of notarized certificate Legalization: Notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 26.05.2024 Extended till 31.12.2028 for Class IIa devices		
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Item No. III

DEFERRED APPLICATIONS FOR REGISTRATION /

EVALUATOR: RANA IHSAN UL HAQ ATHAR DEPUTY DIRECTOR

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Hoora Pharma(Pvt) Ltd. WH-01-20-A7-A8, Korangi Creek	Fujifil Healthcare Corporation Medical Syste Operatin Group, Kashiwa 1, Shintoyofuta, Kashiwa-	whole body X-ray Ct System	Deferred for (Final Opportunity) for:

	Industrial Park, Karachi (ELI-00037)	shi, Chiba, 277-0804 Japan FSC Japan		1. clarification that name of device as per FSC is Whole Body X-ray CT system SCENARIA View. 2. Submission of valid LOA. 3. submission of Form 7A along with annexures and undertaking on stamp paper.
2.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden, Lahore ELI-00356	(Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas Anti-Human Globulin kit	Deferred (Final Opportunity) for: 1. The submission of valid notarized LOA with device name mentioned in it. 2. clarification that device name as per FSC is Atlas Anti-Human Globulin Reagent 10ml/vial.
3.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden, Lahore	Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas CRP Latex Test Kit	Deferred (Final Opportunity) for: 1. The submission of valid notarized LOA with device name mentioned in it.
4.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden, Lahore	Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D-15827 Blankenfelde-Mahlow, Germany Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	Atlas Bovine Albumin	Deferred (Final Opportunity) for: 1. The submission of valid notarized LOA with device name mentioned in it. 2. clarification that device name as per FSC is Atlas Bovine Albumin Reagent (22%) 10ml/vial and LOA is Bovine Albumin 22% - 10ml.
5.	M/s Moon Enterprises Address of	(Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D-	Atlas D-Dimer Latex Test Kit	Deferred (Final Opportunity) for:

	<p>Importer 324 Rewaz Garden, Lahore</p>	<p>15827 Blankenfelde- Mahlow, Germany</p> <p>Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan</p>		<p>1. The submission of valid notarized LOA with device name mentioned in it.</p>
6.	<p>Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) [883-6L] R & I Dy.No. 10712 dated 25-04-2025.</p>	<p>MedPro Flex Cystoscopy Drape Pack</p> <p>Class: A</p> <p>Shelf Life: 3 Years</p> <p>Fee: 6000 Fee Slip No. 2765736166</p> <p>Reference Code:</p> <ul style="list-style-type: none"> 7012 	<p>A cystoscopy drape is a specialized surgical drape designed to provide a sterile working surface and fluid control during cystoscopy procedures. Flex Cystoscopy Drape sheets made up of non-woven SMS/SMMS/SMMMS/ PE fabric laminated with thin layer of PE film through adhesive lamination process.</p>	<p>Deferred (last opportunity) the case for submission of following:</p> <ol style="list-style-type: none"> 1. Clarification whether the towels are manufactured by a medical device manufacturer. Submit ISO13485 and FSC as evidence. 2. Clarification that Surge Gauze will be procured from market or through out-sourcing. 3. submission of evidence from RRA that applied product is a medical device. 4. submission of size of each device included in set and its use. 5. Following panel is constituted for verification of manufacturing facility: <ol style="list-style-type: none"> 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID <p>Area FID will coordinate and submit the inspection report.</p>
7.	<p>Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) [884-6L] R & I Dy.No. 10713 dated 25-04-2025.</p>	<p>MedPro Eye Drape</p> <p>Class: A</p> <p>Storage conditions: Temp: 25°C ± 5°C Humidity: NMT 60%</p> <p>Fee: 6000/- Fee Slip No. 066065472</p> <p>Reference codes:</p> <ul style="list-style-type: none"> • 2060 (60cm × 60cm) • 2100 (100cm × 100cm) • 2150 (100cm × 150cm) 	<p>Eye drapes are disposable sterile sheets that are used to separate and safeguard the eye or ocular area throughout medical tests and surgical operations. They are made up of non-woven SMS/SMMS/SMMMS/ PE fabrics that are impervious to bacteria, fluids, and fragments, which make them</p>	<p>Deferred for the verification of the facility by the following panel</p> <ol style="list-style-type: none"> 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID <p>Area FID will coordinate and submit the inspection report.</p>

			perfect for preserving a sterile environment.	
8.	<p>M/S Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]</p> <p>Approved Section: Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section Arsotulle/Arsotin Section (Sterile) Medi-Swab Section Crepe Bandage</p>	<p>Belladerma Fast Plaster (Diclofenac Diethylamine....2%) Class-B 5 years Sizes: 12cm x 14.5cm 12cm x 15.5cm 12cm x 16.5cm Pack Size 24 Plasters, (Patch) 20 Plasters Fee Challan No 4743893904 Rs. 20000/- Date 20-07-2023 08-08-2023</p>	<p>Belladerma Fast Plaster (Diclofenac Diethylamine ...2%) To treat muscle and joint pain due to sprains, bruises, etc. (including ligaments and tendons – structures that strengthen the joints) – for both pain at rest, pain on movement Swelling around the joints</p>	<p>Rejected due to following reasons:</p> <ol style="list-style-type: none"> 1. Firm has not provided any evidence that applied product is registered as medical device in any reference regulatory authorities. 2. Firm has changed the name from Belladerma Fast Plaster to Voltrex Plaster but has not provided revised application Form. 3. Firm stated that online application has been submitted to PE&R and approval is awaited. 4. Firm has submitted scientifically false statement that Diclofenac Diethylamine patch absorbs the pain only nor does it release any pharmacological drug into the skin.
9.	<p>Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [727-L]</p>	<p>AR Cotton Roll 100% Absorbent Cotton Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 7690445907</p>	<p>100% Absorbent Cotton: Surgical Cotton Roll is also called cotton wool or absorbent cotton. It is essential in the medical field. It is made of 100% cotton, which provides softness and absorbency. The cotton rolls are highly used in wound cleaning, dressing, and cushioning.</p>	<p>Rejected as the MDB does not permit the manufacture of absorbent cotton under the First Aid Bandage section.</p>
10.	<p>Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [728-L]</p>	<p>AR Wove Bandage 100% Cotton (BP Type 2) Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 503737508</p>	<p>A lightweight cotton bandage is used to hold a dressing in place, the Bandages is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the</p>	<p>Deferred for the verification of the facility by the following panel</p> <ol style="list-style-type: none"> 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID

			body, or to secure objects to the skin	Area FID will coordinate and submit the inspection report.
11.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [878-7L]	Care Gauze Sterile X-Ray Detectable woven Gauze/cloth Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 9430238935 Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,	Sterile X-ray abdominal compresses are used in surgical procedures for the absorption of fluid. The dressing has an X-Ray thread which allows the product to be located using X-rays. Intended Use Used During Surgery to absorb blood & exudates. Clean wounds & prevent wounds from being infected.	Deferred for the verification of the facility by the following panel 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID Area FID will coordinate and submit the inspection report.
12.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [879-7L]	X-Ray Lap Sponges X-Ray Detectable Open Wove Bandage Abdominal Cloth Class: B Shelf Life: 3 years Fee: 25000 Fee Slip No. 2270953395 Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,	Sterile X-ray abdominal compresses are used in surgical procedures for the absorption of fluid. The dressing has an X-Ray thread which allows the product to be located using X-rays. Available in different sizes. The compresses have stitched edges and are available with and without loop. Intended Use Used During Surgery to absorb blood & exudates. Clean wounds & prevent wounds from being infected.	Deferred for the verification of the facility by the following panel 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID Area FID will coordinate and submit the inspection report.
13.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [880-7L]	ARSO-MAX Combine Dressing X-Ray Detectable Non-Woven Gauze Cloth Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 2751421858 Sizes: (cm) 10x10, 15x20,	Medical Arso-Max Combine Dressing Non-Woven is a sterile, absorbent, non-adherent dressing designed for use on wounds. It is composed of a non-woven pad, a polyurethane film, and a silicone adhesive intended use	Deferred for the verification of the facility by the following panel 1. Prof. Dr. Mehmood Ahmad-Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID Area FID will coordinate and submit the inspection report.

			<p>A highly absorbent dressing providing cushioned protection.</p> <p>Designed for use directly over wounds and primarily for initial injury and controlling blood loss</p>																			
14.	<p>Applicant Name:</p> <p>M/s A.M. Distributors</p> <p>Address: 4th Floor, Plot 37-C, Bukhari Commercial Lane 8, Phase VI, D.H.A, Karachi, Pakistan 75500</p> <p>ELI-00248</p> <p>Date of Receiving: 13-March-2025</p> <p>Fee: PKR 19,000/- + 6,000/-</p> <p>Slip: 63367766560 & 95417733</p>	<p>Legal Manufacturer:</p> <p>M/s ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD</p> <p>Address: No. 29 of Chaoyang Road, Yixiu District 246003 Anqing City, Anqing Province - China</p> <p>FSC (China)</p> <p>Validity: 27-02-2027</p> <p>LOA Validity: 20-June-2027</p>	<p>Brand Name:</p> <p>Medical Sterilization Indicators</p> <p>Class A</p> <p>Shelf life: 2 Years</p> <table><tr><th>S #</th><th>Codes</th></tr><tr><td>1</td><td>Steam Indicator Strips Class 4</td></tr><tr><td>2</td><td>Steam Indicator Strips Class 5</td></tr><tr><td>3</td><td>Steam Indicator Strips Class 6</td></tr><tr><td>4</td><td>Formaldehyde Indicator Strips Class 4</td></tr><tr><td>5</td><td>Plasma Chemical Indicator Strips</td></tr><tr><td>6</td><td>Plasma sterilization Biological Indicator</td></tr><tr><td>7</td><td>Plasma sterilization Biological Indicator 0.5h</td></tr><tr><td>8</td><td>Steam Sterilization Biological Indicator</td></tr></table>	S #	Codes	1	Steam Indicator Strips Class 4	2	Steam Indicator Strips Class 5	3	Steam Indicator Strips Class 6	4	Formaldehyde Indicator Strips Class 4	5	Plasma Chemical Indicator Strips	6	Plasma sterilization Biological Indicator	7	Plasma sterilization Biological Indicator 0.5h	8	Steam Sterilization Biological Indicator	<p>Deferred with final opportunity to submit the following:</p> <p>1. the brand name of the applied medical device.</p> <p>2. the type of the medical device to be considered in this application as multiple products has been applied in single application.</p>
S #	Codes																					
1	Steam Indicator Strips Class 4																					
2	Steam Indicator Strips Class 5																					
3	Steam Indicator Strips Class 6																					
4	Formaldehyde Indicator Strips Class 4																					
5	Plasma Chemical Indicator Strips																					
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8	Steam Sterilization Biological Indicator																					

			<table><tr><td>9</td><td>Steam sterilization Biological Indicator 0.5h</td></tr><tr><td>10</td><td>ETO sterilization Biological Indicator 24h</td></tr><tr><td>11</td><td>Bowie & Dick Test Sheet</td></tr><tr><td>12</td><td>Plasma Tape 19mm x 50m</td></tr><tr><td>13</td><td>Autoclave Tape (Steam)</td></tr><tr><td>14</td><td>Bowie & Dick Test Pack</td></tr><tr><td>15</td><td>EO Tape</td></tr><tr><td>16</td><td>EO indicator strip class 4</td></tr></table>	9	Steam sterilization Biological Indicator 0.5h	10	ETO sterilization Biological Indicator 24h	11	Bowie & Dick Test Sheet	12	Plasma Tape 19mm x 50m	13	Autoclave Tape (Steam)	14	Bowie & Dick Test Pack	15	EO Tape	16	EO indicator strip class 4	
9	Steam sterilization Biological Indicator 0.5h																			
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14	Bowie & Dick Test Pack																			
15	EO Tape																			
16	EO indicator strip class 4																			
15.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden, Lahore	Legal Manufacturer) Guangzhou iCare Medical Technology Co., Ltd., Address: First Floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area, China	ICARE Blood Lancet	Rejected the application due to following reasons: 1. the name of the device on LOA is iCare (ImuMed) Blood Safety Lancet. 2. FSC China valid till 27.06.2025 and device name in it is Alcohol Pads for Single Use. 3. copy of the FSC Germany issue date 08.01.2020. The name of device is safety lancet. 4. copy of the FSC Spain valid till 13.07.2020. The device name is iCare Twisted Safety Lancet. 5. Firm has not submitted the codes of the product.																

16.	<p>RMK Bio Private Ltd, 83A, BIII, Gulberg III, MM Alam Road, Near Hussain Chowk, Lahore.</p> <p>ELI-01277 6022-P 31,000/-</p>	<p>Legal Manufacturer: Sonova AG Laubisrutistrasse 28, CH-8712 Stafa, Switzerland. FSC: Switzerland Validity: 09-09-2027.</p> <p>LOA validity issuance 04-02-2024</p> <p>ISO 13485 validity 28-02-2028</p> <p>EU QMS certificate (MDR) validity 21-04-2027</p>	<p>Sonova Phonak Audeo I-Sphere Hearing Aid</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Models: Phonak Audeo ISphere Trial (Atlantic green) Phonak Audeo ISphere Trial (Silver grey)</p>	<p>Deferred with final opportunity for the submission of:</p> <ol style="list-style-type: none"> 1. original legalized FSC, EU QMS certificate. 2. Fee for the family.
17.	<p>Perfect Medical System, D-442, D Block Satellite Town, Rawalpindi.</p> <p>ELI-00964 5705-P 62,000/-</p>	<p>Legal Manufacturer: Spinreact S.A.U CR Santa Coloma No. 7 SantEsteve, Spain.</p> <p>FSC: Spain. Date of Issuance: 29-04-2022.</p> <p>LOA validity 02-03-2026</p> <p>ISO 13485 validity 29-05-2025</p> <p>CE certificate validity 27-05-2025</p>	<p>Spinreact IVD (Coagulation Cluster)</p> <p>Class-C</p> <p>Shelf Life: 2 Years</p> <p>Codes as per FSC</p>	<p>Deferred the application with final opportunity for the submission of:</p> <ol style="list-style-type: none"> 1. that the firm will submit the type of the device to be considered in this application. 2. that the firm will apply remaining devices separately through online MDMC portal.
18.	<p>Perfect Medical System, D-442, D Block Satellite Town, Rawalpindi.</p> <p>ELI-00964 5704-P 62,000/-</p>	<p>Legal Manufacturer: Spinreact S.A.U CR Santa Coloma No. 7 SantEsteve, Spain.</p> <p>FSC: Spain. Date of Issuance: 29-04-2022.</p> <p>LOA validity 02-03-2026</p> <p>ISO 13485 validity 29-05-2025</p> <p>CE certificate validity 27-05-2025</p>	<p>Spinreact IVD (Syphilis Serodiagnostic Cluster)</p> <p>Class-C</p> <p>Shelf Life: 1.5 Years</p> <p>Codes as per FSC</p>	<p>Deferred (last opportunity) the application for:</p> <ol style="list-style-type: none"> 1. that firm will submit the type of the device to be considered in this application. The name of the device should be as per FSC and LOA. Copies of FSC and LOA to be enclosed with reply. 2. that the firm will apply remaining device(s) separately through online MDMC portal.
19.	<p>Noor International</p>	<p>Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan</p>	<p>TOP-5530</p>	<p>Deferred (Last opportunity) for submission of:</p>

	Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory LOA valid till 31.12.2027 FSC Japan Issue date 01.01.2025	Syringe Pump 9018.1900 Class C Shelf life 6 years	1. original legalized FSC confirming the availability of the product in the market. 2. Notarized and valid LOA & ISO 13485.
20.	Hospital Supply corporation 42 Darul Aman Housing Society, Block 7&8, Karachi (ELI-00005	Medkonsult Medical technology s.r.o., Pasteurova 67/15, Klasterni Hradisko, 77900 Olomouc, Czech Republic	MMT Denflow Chord PC	Deferred (Last opportunity) for submission of: 1. valid, notarized LOA. 2. Form 7A with annexures and undertaking on stamp paper.
21.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03- 2024.	Hip Prosthesis System (Acetabular cup Mental cup) Class-D Shelf life: 5years Sizes: 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72	Deferred (Last opportunity) for submission of: 1. Design examination Certificate. 2. Brand name of the medical device. 3. the name of device as per FSC and ISO is Hip Joint Prosthesis (Acetabular Cup).
22.	M/s Safeway Systems Pakistan, Flat No. 4, 2nd Floor, Amna Shopping Centre, Misrial Road, Rawalpindi. (ELI-00308) Evaluator: AD-IV [2739-P]	<u>Legal Manufacturer:</u> M/s CPT Sutures Co., LTD, 83 Hai Ba Trung, Ben Nghe Ward, District 1, Ho Chi Minh City, 700000, Vietnam FSC Vietnam issuance 25-09-2020 valid for 3 years (Original)	Carepace ® Temporary Cardiac Pacing Lead (Wire) Class-D Shelf life: 5 years Codes & Sizes:	Rejected the application due to following reasons; 1. Firm has not submitted the FSC of any reference country. 2. Firm has submitted the certificate of compliance issued by QCC that is non-notified certification body.

23.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400 (ELI-00015) Date of R&I 07-01-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 0603703590 Dated: 08-01-2025	Name of Manufacturer: Gene Proof a.s Manufacturing Site: Videnska 101/119, Dolni Herspice 619 00 Brno. Czech Republic FSC: UK Validity- 31-12-2028 FSC: NA LOA Validity: 31-Dec -2025 EC Certificate Validity: 17-01-2024 extension letter provided ISO 13485 Validity: 26-11-2026	Brand Name: GeneProof™ Hepatitis C Virus (HCV) Diagnostic PCR Kit (Generic name): Hepatitis C Virus (HCV) Diagnostic PCR Kit Class: D Shelf Life: 23 months Codes/Sizes: A58427	Approved Taqpath™ Menu Gene Proof Hepatitis C virus (HCV) Diagnostic PCR Kit Codes/Sizes A58427.
24.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400 (ELI-00015) Date of R&I	Name of Manufacturer: Legal Manufacturer: Gene Proof a.s Manufacturing Site: Videnska 101/119, Dolni Herspice 619 00 Brno. Czech Republic FSC: UK Validity- 31-12-2028 LOA Validity: 31-Dec -2025 EC Certificate Validity: 17-01-2024 extension letter provided ISO 13485	Brand Name: GeneProof™ Hepatitis B Virus (HBV) PCR Kit (Generic name): Hepatitis B Virus (HBV) PCR Kit Class: D Shelf Life: 23 months Codes/Sizes: A58426	Approved Taqpath™ Menu Gene Proof Hepatitis B virus (HBV) Diagnostic PCR Kit Codes/Sizes A58426.

	24-01-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 45051683 Dated: 15-01-2025	Validity: 26-11-2026		
25.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN. ELI-00247 138-C Evaluator: AD-III	<u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. <u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021	Yuwell Infrared Thermometer Ear Class-B Shelf life: 5 years Model: YHT101	Rejected due to the following reasons: 1. Firm has submitted copy of EU quality management System but product not mentioned in it. 2. copy of the ISO 13485 not notarized. 3. copy of the FSC china is valid till 13.07.2025-expired. 4. Firm has not submitted the original documents.
26.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN. ELI-00247 139-C	<u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. <u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone,	Yuwell Mesh Nebulizer Class-B Shelf life: 5 years Model: M102	Rejected due to the following reasons: 1. Firm has submitted copy of EU quality management System but product not mentioned in it. 2. copy of the ISO 13485 not notarized. 3. copy of the FSC china is valid till 13.07.2025. The device name not mentioned in it.

	Evaluator: AD-III	Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11- 08-2021		4. Firm has not submitted the original documents.
27.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN. ELI-00247 142-C Evaluator: AD-III	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11- 08-2021	Yuwell Electronic Blood Pressure Monitor Class-B Shelf life: 5 years Model: YE660D	Rejected due to the following reasons: 1. Firm has submitted copy of EU quality management System but product not mentioned in it. 2. copy of the ISO 13485 not notarized. 3. copy of the FSC china is valid till 13.07.2025. The device name is Yuwell Upper Arm Type Electronic Blood Pressure Monitor. 4. Firm has not submitted the original documents.
28.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane,	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.	Yuwell Oxygen Concentrator Class-B	Rejected due to the following reasons: 1. As per submitted EU quality management System, its class IIb medical device while firm has applied as Class B.

	<p>Phase 2 EXT, DHA, KARACHI, PAKISTAN.</p> <p>ELI-00247 144-C</p> <p>Evaluator: AD-III</p>	<p><u>Manufacturing facilities:</u></p> <p>M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and</p> <p>M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yuyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p> <p>FSC China validity 09-02-2024</p> <p>FSC Germany issued 11-08-2021</p>	<p>Shelf life: 3 years</p> <p>Model: 7F-B5</p>	<p>2. copy of the ISO 13485 not notarized.</p> <p>3. copy of the FSC china is valid till 13.07.2025. The code 7F-B5 not mentioned in it.</p> <p>4. Firm has not submitted the original documents.</p>
29.	<p>M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN.</p> <p>ELI-00247 143-C</p> <p>Evaluator: AD-III</p>	<p><u>Legal Manufacturer:</u></p> <p>M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u></p> <p>M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and</p> <p>M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yuyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p> <p>FSC China validity 09-02-2024</p> <p>FSC Germany issued 11-08-2021</p>	<p>Yuwell Finger Pulse Oximeter</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: YX102</p>	<p>Rejected due to the following reasons:</p> <p>1. ISO 13485 not notarized.</p> <p>2. copy of the FSC China Valid till 13.07.2025.</p>

30.	<p>M/S TRI-TECH INTERNATIONAL</p> <p>10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN.</p> <p>ELI-00247</p> <p>141-C</p> <p>Evaluator: AD-III</p>	<p><u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p> <p>FSC China validity 09-02-2024</p> <p>FSC Germany issued 11-08-2021</p>	<p>Yuwell</p> <p>Portable Phlegm Suction Unit</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: 7E-B5</p>	<p>Rejected due to the following reasons:</p> <ol style="list-style-type: none"> 1. the device name not mentioned in EU QMS certificate. 2. copy of the ISO 13485 not notarized. 3. copy of the FSC china is valid till 13.07.2025. The code 7E-B5 not mentioned in it. 4. Firm has not submitted the original documents.
31.	<p>M/S TRI-TECH INTERNATIONAL</p> <p>10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN.</p> <p>ELI-00247</p> <p>140-C</p> <p>Evaluator: AD-III</p>	<p><u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p>	<p>Yuwell</p> <p>Non-Contact Infrared Thermometer</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: YT-2C</p>	<p>Rejected due to the following reasons:</p> <ol style="list-style-type: none"> 1. the name of device in LOA is Infrared Thermometer. 2. the name of device not mentioned in EU QMS certificate. 3. copy of the ISO 13485 not notarized. 4. copy of the FSC china is valid till 13.07.2025. The code 7E-B5 not mentioned in it. 5. Firm has not submitted the original documents.

		FSC China validity 09-02-2024 FSC Germany issued 11-08-2021		
32.	<p>Name National Enterprises Address of Importer 409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi</p> <p>ELI- 00043</p> <p>R & I 18-10-2024 & 04-12-2024</p>	<p>Legal Manufacturer: Disa Medinotec (Pty) Ltd Manufacturing Site: Stand 171,Northlands Business Park, Bush Telegraph Street , Northriding, Johannesburg, 2169, South Africa</p> <p>FSC: Country of Origin Validity :06-02-2025</p> <p>LOA Validity: 01-01-2027</p>	<p>Brand Name Trachealator Rx Non- Occlusive Airway Dilation Catheter (Generic name) Trachealator Rx Non- Occlusive Airway Dilation Catheter Class A Shelf Life: 03 years Codes/Sizes: TRD1-06030 TRD1- 07030 TRD1-08030 TRD1-09030 TRD1- 10030 TRD1-12040 TRD1-14540 TRD1- 16040 TRD1-18040</p>	<p>Rejected the case due to the following reasons:</p> <ol style="list-style-type: none"> 1. the generic name as per Form 6A is Bronchial Balloon or catheter. 2. The FSC was not valid at the time of submission of reply. 3. the applied codes are mentioned in the FSC. 4. the firm has not submitted fee for the family as per MDB decision.
33.	<p>Quality Medical Services, H-49. Gordon College Road Rawalpindi</p> <p>ELI: 00123</p> <p>1141-P</p> <p>5,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Zhangjiangang Xiehe Medical Apparatus & Instruments Co., Ltd, Zhashang Industrial Zone, Yangshe Town Zhangjiagang City, Jiangsu, China</p> <p>FSC Original China Valid till: 2025-02-24</p> <p>LOA Validity: 30/04/2027</p>	<p>Zhangjiangang Xiehe Medical Apparatus & Instruments Co., Ltd (Emergency Stretcher & Stretcher Accessories)</p> <p>Class-A</p> <p>Shelf Life: 05 years</p> <p>Codes & Sizes: as per FSC</p> <p>STAIR STRETCHER</p> <ul style="list-style-type: none"> ◦ YXH-5A ◦ YXH-5B ◦ YXH-5E ◦ YXH-5F ◦ YXH-5G ◦ YXH-5H ◦ YXH-5L ◦ YXH-5N ◦ YXH-5K ◦ YXH-5M <p>TRANSFER BED</p> <ul style="list-style-type: none"> ◦ YXH-4L ◦ YXH-6L 	<p>Rejected due to following reasons:</p> <ol style="list-style-type: none"> 1. copy of the FSC China valid till 24.02.2025. 2. The FSC is not apostille or legalized. 3. Firm has not justified the grouping of the applied devices. 4. firm has applied multiple products in single application.

			<p>AMBULANCE STRETCHER</p> <ul style="list-style-type: none"> ◦ YXH-3A ◦ YXH-3F ◦ YXH-3B ◦ YXH-3G ◦ YXH-3A2 ◦ YXH-2A ◦ YXH-3A3 ◦ YXH-2B ◦ YXH-3A5 ◦ YXH- 2C ◦ YXH-3B2 ◦ YXH-3B3 ◦ YXH-3C ◦ YXH-3E2 ◦ YXH-3D ◦ YXH-3K ◦ YXH-3D2 ◦ YXH-3D3 ◦ YXH-3E ◦ YXH-4G ◦ YXH-3E3 <p>TRANSFER BED</p> <ul style="list-style-type: none"> ◦ YXH 2H ◦ YXH-3H ◦ YXH-2H1 ◦ YXH-4H <p>FOLDING STRETCHER</p> <ul style="list-style-type: none"> ◦ 20170191 <p>SCOOP STRETCHER</p> <ul style="list-style-type: none"> ◦ YXH-4A ◦ YXH-4C ◦ YXH-4B ◦ YXH-4D <p>STRETCHER</p> <ul style="list-style-type: none"> ◦ YXH-1A6A ◦ YXH-6C ◦ YXH-1A6B ◦ YXH-6D ◦ YXH-1A6C ◦ YXH-6E ◦ YXH-1A6D ◦ YXH-6F ◦ YXH-1A6E ◦ YXH-7A ◦ YXH-1A6F ◦ YXH-7B(A) ◦ YXH-1A6G ◦ YXH-7B(B) ◦ YXH-1A6K ◦ YXH-7C ◦ YXH-1A6M ◦ YXH-8C 	
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			<ul style="list-style-type: none"> ◦ YXH-1A6N ◦ YXH-8D ◦ YXH-1A6H ◦ YXH-6B ◦ YXH-1A6L ◦ YXH-1A6J ◦ YXH-6A ◦ YXH-1A6P ◦ YXH-1A6A-2 <p>MEDICAL EXTERNAL FIXATOR</p> <ul style="list-style-type: none"> ◦ YXH-7H(A) ◦ XH-17(A) ◦ YXH- 7H(B) ◦ XH-17(B) ◦ XH-16(A) ◦ YXH- 7D ◦ XH-16(B) ◦ YXH-7N ◦ YXH- 8B(A) ◦ XH-15 ◦ YXH-8B(B) ◦ XH-18 ◦ YXH- 9 ◦ YXH-10 <p>EMERGENCY BED</p> <ul style="list-style-type: none"> ◦ YXH-2L2 ◦ YXH-2T2 ◦ YXH-2R2 <p>◦ SAFETY BELTS ◦ S01</p> <p>◦ SPIDER STRAPS ◦ S02</p> <p>◦ 2 HOOKS IV POLE ◦ XH-509</p> <p>◦ 4 HOOKS IV POLE ◦ XH-510</p> <p>◦ XH-511 ◦ XH-512</p> <p>EMERGENCY STRETCHER</p> <ul style="list-style-type: none"> ◦ YXH-1A1 ◦ ATHENA I ◦ YXH-2T2 ◦ YXH-4D ◦ YXH-6D 	
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			<ul style="list-style-type: none"> ◦ YXH-1A2 ◦ YXH-1A6L ◦ YXH-1M ◦ YXH-3A ◦ YXH-5A ◦ YXH-C1 ◦ YXH-1A3 ◦ YXH-1K ◦ ATHENA II ◦ YXH-3A2 ◦ YXH-1A6A ◦ YXH-5B ◦ YXH-C2 ◦ YXH-1L ◦ YXH-3B ◦ YXH-5E ◦ XH-5C ◦ YXH-1B2 ◦ YXH-A2 ◦ YXH-3B2 ◦ YXH-5F ◦ YXH-1B3 ◦ YXH-3B3 ◦ YXH-5K ◦ YXH-1C ◦ YXH-3C ◦ YXH-5N ◦ YXH-5C ◦ YXH-1D ◦ YXH-3D ◦ YXH-1A6B ◦ YXH-1A5 ◦ YXH-1N(A) ◦ YXH-3A3 ◦ ATHENA III ◦ YXH-1A6C 	
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			<ul style="list-style-type: none"> ◦ YXH-1N(C) ◦ YXH-2R2 ◦ YXH-1A6 ◦ YXH-1N(B) ◦ YXH-3A5 ◦ YXH-5D ◦ HERMES I ◦ XH-4C ◦ YXH-1A6N ◦ YXH-1A6M ◦ HEPHAESTUS II ◦ YXH-1B1 ◦ HESTIA III-B ◦ YXH-1F4A ◦ YXH-1A6A-2 ◦ HERMES II ◦ VENUS II ◦ YXH-1E ◦ YXH-1A6D ◦ VENUS III ◦ YXH-1EF ◦ YXH-1A6E ◦ VENUS IV ◦ YXH-1A6G ◦ NEPTUNE ◦ YXH-1A6H ◦ YXH-1F1B ◦ YXH-1A6K ◦ ◦ VENUS I ◦ YXH-1DL ◦ YXH-C3 ◦ HESTIA I ◦ YXH-1F2 ◦ YXH-2L2 ◦ YXH-C4 	
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			<ul style="list-style-type: none"> ◦ YXH-1F3 ◦ YXH-3K ◦ YXH-6A ◦ YXH-1F4 ◦ YXH-4E ◦ YXH-3H ◦ YXH-6B ◦ YXH-7N ◦ YXH-6C ◦ YXH-1G ◦ YXH-2A ◦ YXH-4A ◦ YXH-3D2 ◦ YXH-5H ◦ YXH-3E ◦ YXH-5L ◦ YXH-3E2 ◦ YXH-5M ◦ YXH-50 ◦ YXH-3F ◦ YXH-5P ◦ HESTIA ◦ YXH-1EL ◦ YXH-3E3 ◦ YXH-1F1 ◦ YXH-3GYXH-5G 	
34.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3314-P 18-08-2022</p>	<p><u>Legal Manufacturer:</u> Medivators Inc. 14605 28th Avenue North Minneapolis, MN 55447 USA</p> <p>FSC: U.S.A Valid Till: 04/03/2023</p>	<p>RAPICIDE PA RTU High-Level Disinfectant and Sterilant test strips (Disinfectant for endoscopes)</p> <p>Class-C</p> <p>Shelf Life: N/A</p>	<p>Rejected due to following reasons:</p> <p>1. Firm has submitted manufacturer credentials of M/s Cantel Medical Instead of Medivators Inc. 14605 28th Avenue North Minneapolis, MN 55447 USA.</p> <p>2. copy of LOA issued by Steris Corporation USA. While Steris Corporation is not legal</p>

			<p>Codes:</p> <p>ML02-0117</p> <p>ML02-0116</p> <p>ML02-0115</p> <p>ML02-0118 (Test strips)</p>	<p>manufacturer /distributor as per FSC.</p> <p>3. The applied codes are not mentioned in the FSC.</p> <p>4. End of Shelf life of Rapicide PA Sigle Dose issued by Cantel Medical Italy while name of product in FSC and EU QMS is Rapicide PA High Level Disinfectant.</p> <p>5. firm has not submitted proof of separate applications for the rest of the types (PA RTU Test strips, Rapicide OPA disinfectant, OPA test strips and other types etc.</p>
35.	<p>M/S Ghazali Brothers 1st Floor Azzainab Court Campbell Street, Karachi, Pakistan</p> <p>ELI-00240</p> <p>Fees:</p> <p>Rs 62,030 Paid on 19/05/2025</p> <p>Challan # 66660494286</p> <p>Date of R& I 14th April 2025</p>	<p>Ningbo Yingmed Medical Instruments Co., Ltd</p> <p>Address as per Form-7A:</p> <p>Yingsheng Building, No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China</p> <p>Address as per FSC (MHRA) & DOC:</p> <p>Room 705, Yingsheng Building, No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China.</p> <p>Address as per CE (FQA):</p> <p>Room 1201-9, No.456, Tai'an Middle RD, Yinzhou District, Ningbo, Zhejiang, China.</p> <p>LOA:</p> <p>Agency Agreement (Notarized copy): issued: 25-03-2025. (Validity for ten years)</p> <p>FSC:</p>	<p>Yingmed Non-Absorbable Polypropylene Surgical Suture (with & without needles)</p> <p>Applied as : Single</p> <p>Class C</p> <p>Shelf Life: 5 years</p> <p>Codes/Sizes: (as per dossier but not mentioned in the FSC)</p> <p>PPL201, PPL202</p> <p>PPL203, PPL204</p> <p>PPL205, PPL206</p> <p>PPL207, PPL208</p> <p>PPL209, PPL210</p>	<p>Rejected because firm has not submitted:</p> <p>1. Valid legalized FSC of the RRA or notarized copy of EC certificate (FQA).</p> <p>2. valid notarized ISO 13485.</p> <p>3. legalized FSC of the country of origin mentioning the address of manufacture</p> <p>4. requisite documents, hence correct address of the manufacturer can't be verified.</p> <p>5. Fee for the family.</p>

		<p>MHRA FSC</p> <p>Valid Until: 09/07/2025 (copy)</p> <p><u>FSC:</u></p> <p>China FSC issued on 18-12-2023</p> <p>Valid for two years (Notarized copy)</p> <p><u>ISO:</u></p> <p>ISO 13485:2016) Valid till: 23-11-2026 (Copy)</p> <p>CE (FQA) valid up to 23-11-2028. (Notarized copy)</p>	<p>PPL211, PPL212 PPL213, PPL214 PPL215, PPL216 PPL217, PPL218 PPL219, PPL220 PPL221, PPL222 PPL223</p>	
36.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Date of R&I 14th April 2025</p> <p>Fees: Challan # 19425068411 Rs 31,000.00 submitted on 27/04/2025</p>	<p><u>Legal Manufacturer:</u> M/S JIANGSU WEBEST MEDICAL PRODUCT CO., LTD</p> <p><u>Manufacturing Site:</u> NO. 5 YINGCHUN ROAD INDUSTRIAL PARK, XUYI, JIANGSU, CHINA. Tel: +86-517-88296001 WWW.CNWEBEST.COM</p> <p><u>LOA:</u> Sole Agency Agreement Valid till: 31-12-2029</p> <p><u>FSC:</u> CHINA FSC Validity: 30-06-2025</p> <p><u>ISO:</u> Production Quality Management System Certificate (ISO 13485:2016) Valid till: 2026-05-31</p>	<p>ACCUMAX EXTENSION TUBE</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes: SIZES: 150cm to 210cm, 300cm to 400cm</p>	<p>Rejected because firm has not submitted:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of the RRA or notarized copy of EC certificate (FQA). 2. valid notarized ISO 13485. 3. Fee for the family. 4. The submitted FSC China is not valid (30.06.2025).
37.	<p>Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid</p>	<p>(Legal Manufacturer) Name: M/s Anntom Medical, 5/F, Building A6, Yinlong</p>	<p>Brand Name: Anntommed Balloon Inflation Devices</p>	<p>Deferred (final opportunity) for following:</p>

	<p>Amount paid: PKR 25,000/-</p> <p>Paid Slip / challan No.: 9442858643</p>		<p>IS-05 5FX11CM IS-06 65X11CM</p> <p>IS-07 7FX11CM IS-08 8FX11CM</p> <p>IS-09 9FX11CM IS-10 10FX11CM IS-11 11FX11CM IS-14 14FX14CM IS-18 18FX14CM</p> <p>Class-B</p> <p>Shelf life: As per stability studies</p>	<p>4. fee for the family required.</p>
40.	<p>Applicant:</p> <p>4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi.. (ELI- 00290)</p> <p>Fee details:</p> <p>Amount paid: PKR 25,000/-</p> <p>Paid Slip / challan No.: 213944321136</p>	<p>(Legal Manufacturer)</p> <p>Name:</p> <p>M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China</p>	<p>Brand Name:</p> <p>Anntommed</p> <p>Hemostatic Valve Sets</p> <p>Generic:</p> <p>Models / Sizes:</p> <p>(17578)</p> <p>HV-02 7Fr Push/pull</p> <p>HV02 7Fr Push/pull with line HV-01 8Fr Screw HV-01 8Fr Screw with line HV-03 8Fr Push/pull click HV-03 8Fr Push/pull click with line</p> <p>Class-B</p> <p>Shelf life: As per stability studies</p>	<p>Deferred (Final opportunity) for following:</p> <ol style="list-style-type: none"> Both FSC and CE certificate are not apostille and notarized respectively. The manufacturer address in FSC and CE certificate is different from applied manufacturer address. The codes mentioned in the FSC are HV-01, HV-02 and HV-03. fee for the family required.
41.	<p>M/s. TRI TECH INTERNATIONAL 10/C 6 Sunset Comm Line Phase II Defence Housing Authority Karachi. (ELI-00247)</p> <p>Date of R&I</p> <p>07-05-2020</p> <p>Fee: PKR 5000/-</p>	<p>Legal Manufacturer:</p> <p>M/s KLAROMED SP.ZO .O UL .SOBIESKIEGO 123 05 -70 SULEJOWEK POLAND.</p> <p>FSC issuance date:</p> <p>30-01-2020</p>	<p>Brand name:</p> <p>Diagnostic and Examination Lamp</p> <p>Model:</p> <p>PlusLED24 eco</p> <p>PlusLED7 eco</p> <p>Class: A</p> <p>LOA Validity:</p> <p>10/01/2021</p>	<p>Deferred (Final opportunity) for following reasons:</p> <ol style="list-style-type: none"> LOA is not notarized. FSC is nor legalized/apostille. The products PlusLED24 eco PlusLED7 eco Not mentioned in the FSC.

	Slip: 2006260 Dated: 06-05-2020		Shelf life: 05 Years							
42.	<p>ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025</p> <p>Deposit Slip No: 923394298</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p> <p>Full Quality Assurance Certificate or Equivalent (Original): NA Submitted on basis of EU FSC</p>	<p>Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)</p> <p>Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specifica tion (as per FSC)</th></tr><tr><td>01.09.0 0.20.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 0.20.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)	Specifica tion (as per FSC)	01.09.0 0.20.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 0.20.EC .02	R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of the fee for the family.
REF (as per IFU)	Specifica tion (as per FSC)									
01.09.0 0.20.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 0.20.EC .02	R1 48 mL × 2 R2 12 mL × 2									
43.	<p>Merlin International, Office No. 341, 3rd Floor, Land Mark Plaza, Jail Road, Lahore</p> <p>ELI: 00569 5953-P Fee 31,000/- slip no. 962491027856</p>	<p>Legal Manufacturer: Chifeng Tianbo Medical Device Co., Ltd Zhongjing Industrial Park Economic Development Area, Ninhcheng District, Chifeng 024200, Inner Mongolia, P.R China.</p> <p>LOA validity: Not clear</p> <p>FSC validity 14-04-2025</p> <p>ISP 13485 validity 17-02-2025</p>	<p>Well-Flow Infusion Set with Y-Port</p> <p>Class-B</p> <p>Shelf life: Not mentioned</p> <p>Codes/Specifications: As per FSC</p>	<p>Deferred (Last opportunity) for the following:</p> <p>1. The name of the device as per DOC and FSC is Sterile Infusion Sets for single Use with Needles.</p> <p>2. Complete stability study dully signed by authorized person is required.</p> <p>3. fee for the family required, if device has the multiple codes/sizes.</p>						

		Production QA certificate validity 17-02-2027		
44.	Glo-Med Technologies, A-21/2B-1, KDA Scheme 1 (Ext.) National Stadium Road Karachi. (ELI-00712) 4486 02-06-2022	Legal Manufacturer: Urotronic, Inc. 2495 Xenium Lane N Minneapolis, MN 55441 USA FSC: USA Valid Till: 14-12-2023	Optilume Urethral Drug Coated Balloon catheter (Urethral Drug Coated Balloon Catheter) Class-D Shelf life: 12 Months Codes are not provided. per FSC	Approved.
45.	Hospital Supply Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005) Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-	Inciler medikal Saghk Hizmetleri Sanayi Ticaret Limited, Sirketi, Lvedik O.S.B. Mah. Ari S.S 1472. Cad..SK. No.120/, YENIMAHALLE ANKARA, TURKEY	LITHOBOX ZERO intracorporeal Combined Ultrasonic Pneumatic Kidney Stone Crushing Device Class C Shelf life: N/A Storage Condition: -10 to 50° C Codes & Sizes As per FSC MD group: Set LOA Validity: 31-12-2025. FSC (Turkey) (country of origin): Issuance date: 28-11-2022 FQA validity: 27-04-2024 Extension letter attached ISO 13485 validity: 09-04-2026 (Kiwa)	Rejected due to the following reasons: 1. LOA is not notarized and original. 2. The name of the device as per LOA is <u>LITHOBOX ZERO-Intracorporeal Combined Ultrasonic Pneumatic Kidney Stone Crushing Device.</u> 3. The brand name not given in LOA or FSC. 4. Original documents not submitted.
46.	M/s. Hospital Supply Corporation. 42, Darulaman Housing Society Block 7 and 8 Karachi. ELI-00005	Nikkiso Belgium B.V. Industriepark 6, 3300 Tienen, Belgium. FSC Validity: not provided LOA Validity: Dec.2025	Accusol K+0, Accusol K + 2 and Accusol K + 4 Class B,	Rejected due to the following reasons: 1. The FSC Belgium not valid (issue date 19 August 2019). 2. The device as per FSC is of class IIb.

	R&I Details: 14 May 2022	ISO 13485: Validity: July.2026	Shelf life: 24 months.	
47.	Name Hospital Supply Corporation Address of Importer 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan	Name: Zhejiang Kindly Medical Devices Co. Ltd Address: No. 758 5th Binhai Road, Binhai Industrial Park, Longwan Distrit 325025, Wenzhou, Zhejiiang China	YMS disposable Infusion set with Burette	Deferred (last opportunity) for the following. 1. The FSC is neither original not legalized/ apostille. 2. clarification required that as per NB confirmation letter the device is of class IIb.
48.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi ELI-00944 R&I details 27/01/2025 Fee Challan No:7849801972	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd. Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10-2024. Validity 2 years. LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025	Respiratory Filters Shelf Life: 5 Year Class: B	Deferred (last opportunity) for the following: 1. The name has been revised from Respiratory Filters to Heat and Moisture Exchange Filters but application has not been revised. 2. FSC not issued by the relevant Health Regulatory Authority. 3. clarification that Model on FSC is Adult, Child, Infant while as per Brochure is NGM-IM-008. 4. CE marking certificate or FSC of RRA required.
49.	Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E, PIA Housing Society, Johar Town, Lahore. ELI-01265 5980-P 62,000/-	Legal Manufacturer: Dongguan TT Medical, Inc. Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, PR China. FSC: Netherlands. Validity: 31-12-2027.	EverFlow (Paclitaxel Coated PTCA Balloon Catheter) Class-D Shelf life: 2 years	The Board decided to call both the parties as per MDB decision taken in its 89 th meeting.

			Codes as per FSC	
50.	M. Yousaf & Co, 79 M Block Gulberg III Lahore. ELI-00302 1423-P 31,000/-	Legal Manufacturer: Sterilance Medici (SUZHOU) Inc. No. 168, Putuoshan Road, New District 215153, SUZHOU, Jiangsu, Jiangsu, P.R. China. Original FSC: China. Validity: 07-06-2026. LOA validity 08-10-2029 ISO 13485 validity 01-12- 2025 EU QMS certificate (MDR) validity 23-11-2027	SKYMAX Disposable Surgical Blade, carbon steel Class-A Shelf Life: 5 years Codes/sizes as per FSC: 9, 10, 10A, 11, 12, 12B, 12D, 13, 14, 15, 15C, 16, 17 18, 19, 20, 21, 22, 22A, 23, 24, 25, 26, 27, 34, 36, 60, 70, PM40	Approved subject to submission copy of legalized/apostille FSC and verification of fee for the family.
51.	Applicant Name: Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi ELI-00412 Date of R&I 30-05-2025 Fee Details: Paid Fee: 62,000/- 1160861088	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain LOA Validity: 30-11-2026 (Copy) FSC: Spain Issue date: 14-05- 2024(Copy) ISO Validity: 15-03-2027 (Copy) EU QA/ EC Certificate Validity:	Brand name: Inno-Ce Mesha Intense Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml Route of administration: Intradermal injections Class-D Shelf life: 3 Years Models/ Specification	Deferred (final opportunity) for the submission of: 1. submission of original, notarized LOA. 2. clarification that The name of the device as per FSC and LOA and DE certificate is Mesha® Intense while applied name is Inno-Ce Mesha Intense. 3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations. 4. clarification of the difference b/w products having same formulation.
52.	Applicant Name: Zam Zam Corporation, Suit No. 205, 206,	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain	Brand name: Inno-Ce Mesha Essence Generic Name:	Deferred (final opportunity) for the submission of: 1. submission of original, notarized LOA.

	<p>Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- 3180943871</p>	<p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain</p> <p>Issue date: 14-05-2024(Copy)</p> <p>ISO Validity: 15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate Validity:</p>	<p>1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Essence while applied name is Inno-Ce Mesha Essence.</p> <p>3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations.</p> <p>4. clarification of the difference b/w products having same formulation.</p>
53.	<p>Applicant Name: Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- 040092056372</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain</p> <p>Issue date: 14-05-2024(Copy)</p> <p>ISO Validity: 15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate Validity:</p>	<p>Brand name: Inno-Ce Bi-Dens 2.5</p> <p>Generic Name: 1 x 3ml/0.07 fl oz. Sodium Hyaluronate 2.5%</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Deferred (final opportunity) for the submission of:</p> <p>1. submission of original, notarized LOA.</p> <p>2. clarification that The name of the device as per FSC and LOA and DE certificate is Bi-Dense 2.5 while applied name is Inno-Ce Bi-Dens 2.5.</p> <p>3. The brand name not provided in FSC or LOA.</p>
54.	<p>Applicant Name: Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain</p>	<p>Brand name: Brand name: Inno-Ce Mesha Smile</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p>	<p>Deferred (final opportunity) for the submission of:</p> <p>1. submission of original, notarized LOA.</p> <p>2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Smile while applied name is Inno-Ce Mesha Smile.</p> <p>3. applied products Inno-Ce</p>

	<p>ELI-00412</p> <p>Date of R&I 30-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- 42247277229</p>	<p>Issue date: 14-05-2024(Copy)</p> <p>ISO Validity: 15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate Validity:</p>	<p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations.</p> <p>4. clarification of the difference b/w products having same formulation.</p>
55.	<p>Applicant Name:</p> <p>Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- 8174193787</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain</p> <p>Issue date: 14-05-2024(Copy)</p> <p>ISO Validity: 15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate Validity:</p>	<p>Brand name: Inno-Ce Mesha Scars</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Deferred (final opportunity) for the submission of:</p> <p>1. submission of original, notarized LOA.</p> <p>2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Scars while applied name is Inno-Ce Mesha Scars.</p> <p>3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations.</p> <p>4. clarification of the difference b/w products having same formulation.</p>
56.	<p>Applicant Name:</p> <p>Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain</p> <p>Issue date: 14-05-2024(Copy)</p>	<p>Brand name: Inno-Ce Moist 1.5</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml 15mg/ml</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p>	<p>Deferred (final opportunity) for the submission of:</p> <p>1. submission of original, notarized LOA.</p> <p>2. clarification that the name of the device as per FSC and LOA and DE certificate is Moist 1.5 while applied name is Inno-Ce Moist 1.5.</p>

	<p>Fee Details:</p> <p>Paid Fee: 62,000/-</p> <p>5143040484</p>	<p>ISO Validity:</p> <p>15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate</p> <p>Validity:</p>	<p>Shelf life: 3 years</p> <p>Models/ Specification</p>	
57.	<p>Applicant Name:</p> <p>Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I</p> <p>30-05-2025</p> <p>Fee Details:</p> <p>Paid Fee: 62,000/-</p> <p>4082100844</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity:</p> <p>30-11-2026 (Copy)</p> <p>FSC: Spain</p> <p>Issue date: 14-05-2024(Copy)</p> <p>ISO Validity:</p> <p>15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate</p> <p>Validity:</p>	<p>Brand name:</p> <p>Inno-Ce Mesha Deep</p> <p>Generic Name:</p> <p>1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p> <p>Route of administration:</p> <p>Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Deferred (final opportunity) for the submission of:</p> <ol style="list-style-type: none"> 1. submission of original, notarized LOA. 2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Deep while applied name is Inno-Ce Mesha Deep. 3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deep etc have the same formulations. 4. clarification of the difference b/w products having same formulation.
58.	<p>Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e-Iqbal, Karachi</p> <p>(ELI-00691)</p> <p>Date of application</p> <p>18.04.2025</p> <p>Fee Rs 62000</p>	<p>Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China</p> <p>Notarized LOA valid till 25.02.2030</p> <p>Copy of Netherlands FSC Valid till: 31.12.2031</p> <p>ISO valid till 19.06.2027</p> <p>Copy of FQA valid till 27.05.2024 and complete extension letter having code not provided</p>	<p>Restenix (Drug (Paclitaxel) Coated Balloon Catheter)</p> <p>Shelf life 02 years</p> <p>Fee 62000/-</p> <p>Challan no 303210117199</p> <p>Class D</p> <p>PCB20010, PCB20014, PCB20018,</p>	<p>Deferred (last opportunity) for the following:</p> <ol style="list-style-type: none"> 1. The name of the device on FSC, CE Certificate and DE certificate is EverFlow® paclitaxel Coated Coronary Balloon Catheter while firm has applied as Restenix (Drug (Paclitaxel) Coated Balloon Catheter). 2. The fee for the family has not been submitted by the firm. 3. clarification that firm has submitted IPO trade mark registry while firm is not manufacturer or researcher of the product. 4. IPO trade mark registry issued to Mrs Anum Ahmed instead of the firm.

		Notarized LOA valid till 25.02.2030	PCB20022, PCB20026, PCB20030,	
		Copy of Design examination 27.05.2024	PCB20034, PCB20038, PCB22510,	
		FSC china Valid till: 08-04-2026	PCB22514, PCB22518, PCB22522, PCB22526, PCB22530, PCB22534, PCB22538, PCB25010, PCB25014, PCB25018, PCB25022, PCB25026, PCB25030, PCB25034, PCB25038, PCB27510, PCB27514, PCB27518, PCB27522, PCB27526, PCB27530, PCB27534, PCB27538, PCB30010, PCB30014, PCB30018, PCB30022, PCB30026, PCB30030, PCB30034, PCB30038, PCB32510, PCB32514,	

			PCB32518, PCB32522, PCB32526, PCB32530, PCB32534, PCB32538, PCB35010, PCB35014, PCB35018, PCB35022, PCB35026, PCB35030, PCB35034, PCB35038, PCB37510, PCB37514, PCB37518, PCB37522, PCB37526, PCB37530, PCB37534, PCB37538, PCB40010, PCB40014, PCB40018, PCB40022, PCB40026, PCB40030, PCB40034, PCB40038 Codes AS per FSC of Netherlands	
59.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e- Iqbal, Karachi (ELI-00691) Date of application 18.04.2025	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi- Tec Industrial Park, Dongguan, Guangdong, PR China apostille china FSC Valid till: 08-04-2026 USFDA FSC Valid till: 03- 04-2026	Valvoflex (Valvuloplasty Balloon Catheter) Shelf life 03 years VBC1540、VBC1840 、VBC2140、 VBC2340、VBC2640 、VBC2940:	Deferred for the following: 1. The registration is being issued on the basis of USFDA CFG, so the brand name in USFDA FSC required. 2. The fee for the family required.

		ISO valid till 19.06.2027 Notarized LOA valid till 25.02.2030	Class D	
60.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e- Iqbal, Karachi (ELI-00691) Date of application 18.04.2025 Fee Rs 62000	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi- Tec Industrial Park, Dongguan, Guangdong, PR China Apostille China FSC Valid till: 08-08-2026 ISO valid till 19.06.2027 FQA valid till 27.05.2024 and having extension letter Design examination 27.05.2024	Angioflex (Semi Compliant Coronary Dilatation Balloon Catheter) Shelf life 2 years Class D Codes SD25010 SD25014 SD25018 SD25022 SD25030 SD30010 SD30014 SD30018 SD30022 SD30026 SD30030 SD35010 SD35014 SD35018 SD35022 SD35026 SD35030 SD40010 SD40014 S040018 S040022 SD25026 SD40026	Deferred (last opportunity) for the following reasons: 1. Firm has not submitted FSC with correct name. 2. Firm has also not submitted the CE FQA and DE certificate. 3. The fee for the family required.

			SD40030	
61.	<p>Applicant: M/s. REAGNCHEM scientific second floor A21- Block 13-D1 Rufi Cottages, Sehba Akhter Road, Gulshan-e-Iqbal, Karachi (ELI: 000345) Fee: Slip: Dated:</p>	<p>Legal Manufacturer: M/s Meizhou Cornley Hi-Tech CO LTD Cornley Hi-Tech Industrial Park, Jincheng Road, Fuda HiTechZone, Meixian, 514700 Meizhou, Guangdong PR China LOA Validity: 02-02-2026</p>	<p>MINI ISE ELECTROLYTE ANALYZER Class A Shelf Life: 05 years Codes / Sizes (if any): K-LITE 8A, K-LITE 8B, K-LITE 8D, K-LITE 8E, K-LITE 8F, K-LITE 8G, K-LITE 8H</p>	<p>Deferred (final opportunity) for the following:</p> <ol style="list-style-type: none"> 1. Brand name with LOA is required. 2. FSC with model Mini ISE required. 3. The supporting document CE certificate and DOC required that support the claimed class of device.
62.	<p>M/s. TRI TECH INTERNATIONAL 10/C 6 Sunset Comm Line Phase II Defence Housing Authority Karachi. (ELI-00247) Date of R&I 07-05-2020 Fee: PKR 5000/- Slip: 2006261 Dated: 06-05-2020</p>	<p>Legal Manufacturer: M/s KLAROMED SP.ZO .O UL .SOBIESKIEGO 123 05 -70 SULEJOWEK POLAND. FSC issuance date: 30-01-2020</p>	<p>Brand name: Surgical Light Model: PlusLED96 eco PlusLED56 eco Class: A LOA Validity: 10/01/2021 Shelf life: 05 Years</p>	<p>Deferred with final opportunity for submission of valid notarized LOA and legalized/ apostille FSC.</p>
63.	<p>Applicant Name: M/s. NI healthcare Products Pvt Ltd. Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I</p>	<p>Legal Manufacturer: Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North, Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China FSC: Validity: 27-12-2026 LOA Validity: 17-12-2027</p>	<p>Brand Name: DYCO Suction Connecting Tube with Yankauer handle Class B Shelf Life: 5 years Codes/Sizes (If any) Sizes: with Yankauer handle 8.2mm</p>	<p>Deferred (final opportunity) for the following:</p> <ol style="list-style-type: none"> 1. The brand name has resemblance to already approved name DYCO. 2. Notarized LOA with brand name required. 3. as per submitted brochure sizes 9.7mm and 10.7mm and Code: A060102 not mentioned. 4. FSC and complete brochure mentioning the sizes and codes required. 5. clarification that name of the firm is Hitec Medical Co mentioned on brochure.

	14-03-2025 Rs.31,000/- Slip# 07733267928	CE Certificate Validity: 08-04-2029 ISO 13485 Validity: 27-02-2027	9.0mm 9.7mm 10.0mm 10.7mm 11.2mm Code: A060102 Surgical Drainage Connection Medical tubes	6. Fee for the family required.
64.	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024 Fee 62000/-	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building No. 5158 Shahe West Road, Xiii, Nanshan, 51 8055 Shenzhen, Guangdong, PEOPLE's REPUBLIC OF CHINA Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted	Patient Monitor PMS 8310/ Vitavue 12 Patient Monitor 9018.1900 33586 Class: C Claimed Shelf Life:10- years	Approved the model/version PMS8310.
65.	NI healthcare	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research	Patient Monitor PMS 8300/ Vitavue 10	Approved the model/version PMS8300.

	<p>Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024</p> <p>Fee 62000/-</p>	<p>Building No. 5158 Shahe West Road, Xiii, Nanshan, 51 8055 Shenzhen, Guangdong, PEOPLE's REPUBLIC OF CHINA</p> <p>Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA</p> <p>Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA</p> <p>FSC not submitted</p> <p>LOA Validity: 16-11s-2027</p> <p>ISO 13485 Validity: 16-02-2026</p> <p>FQA valid till 26.05.2024 extension letter submitted</p>	<p>Patient Monitor</p> <p>9018.1900 33586</p> <p>Class: C Claimed Shelf Life:10- years</p>	
66.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address:</p> <p>Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p> <p>Date of R&I</p>	<p><u>Legal Manufacturer:</u></p> <p>MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.</p> <p>FSC:</p>	<p>Brand Name:</p> <p>Video Laryngoscope Blade</p> <p>Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4</p> <p>Class A</p> <p>Shelf Life: 5 years</p>	<p>Approved subject to submission of fee for the family.</p>

	28-03-2025 Rs. 6000 Slip# 953813925934	Validity: 08-09-2026 LOA Validity: 10-01-2028 CE Certificate Validity: 26-05-2024 with Extension letter Expiry 31- 12-2028 ISO 13485 Validity: 16-06-2025		
67.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi. ELI-01364 Date of R & I 02-06-2025 Fee: 62,000/- Slip # 838569842	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029 • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	Brand name: Xpert Lense 5.25 PMMA Generic Name: PMMA IOL Applied as: Single Class: C Code/sizes (as per DOC & Application): PCC12052CRN Shelf Life: 5 Years	Deferred (last opportunity) due to following reasons: 1. The FSC is not legalized or apostille. 2. The name of device as per FSC is Xpert PMMA Single Piece Intraocular Lens. 3. ISO 13485 not notarized. 4. applied code not mentioned in FSC.
68.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.	Brand name: Xpert Lense PMMA Generic Name: PMMA IOL	Deferred (last opportunity) due to following reasons: 1. The FSC is not legalized or apostille.

	<p>Scheme-42, Gulshan-e-Iqbal, Karachi.</p> <p>ELI-01364</p> <p>Date of R & I 02-06-2025</p> <p>Fee: 62,000/- Slip # 52651769901</p>	<p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029</p> <p>• FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027</p>	<p>Applied as: Single Class: C</p> <p>Code/sizes Application): PJ313565CRO</p> <p>Shelf Life: 5 Years</p>	<p>2. The name of device as per FSC is Xpert PMMA Single Piece Intraocular Lens.</p> <p>3. ISO 13485 not notarized.</p> <p>4. applied code not mentioned in FSC.</p>
69.	<p>M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi.</p> <p>ELI-01364</p> <p>Date of R & I 02-06-2025</p> <p>Fee: 62,000/- Slip # 52651769901</p>	<p>Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029</p> <p>• FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy</p>	<p>Brand name: Mesto Hydrophobic Preloaded Lense</p> <p>Generic Name: Hydrophobic Preloaded IOL</p> <p>Applied as: Single Class: C</p> <p>Code/sizes (as per DOC & Application): FCL113060-CRA-PL</p> <p>Shelf Life: 5 Years</p>	<p>Deferred (last opportunity) due to following reasons:</p> <p>1. The FSC is not legalized or apostille.</p> <p>2. The name of device as per FSC is Mestro, BIOL Hydrophobic Acrylic Foldable IOL</p> <p>3. applied code not mentioned in FSC.</p> <p>4. ISO 13485 not notarized.</p> <p>5. the name of on LOA is Mestro Hydrophobic Intraocular Lens and code not mentioned.</p>

		Notarization: Not Notarized Validity: 17-11-2027		
70.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi. ELI-01364 Date of R & I 02-06-2025 Fee: 62,000/- Slip # 3205927362	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029 • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	Brand name: I-Xpert IOL Generic Name: Hydrophilic Clear Foldable IOL Applied as: Single Class: C Code/sizes (as per FSC & Application): HFL1125606CRA Shelf Life: 5 Years	Deferred (last opportunity) due to following reasons: 1. The FSC is not legalized or apostille. 2. The name of device as per FSC is 1-Xpert, BIOL Hydrophobic Acrylic Foldable IOL 3. applied code not mentioned in FSC. 4. ISO 13485 not notarized. 5. the name of on LOA is X-pert Hydrophobic Intraocular IOL and code not mentioned.
71.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 Fee Challan No. 38080996 6,000/- 6221-Kpk	Legal Manufacturer: M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd. Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone LOA Validity: 02/04/2030	Single-use Container for Human Venous Blood Collection Specimen Collection Class: A Shelf Life: 3 Years Sized: As per FSC	Approved subject to submission of undertaking for every application on stamp paper and original documents.

		FSC Validity: 03-09-2026 ISO 13485 validity 16-03-2026		
72.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad (ELI-01008	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	DEHYDROEPIANDR OSTERONE SULFATE (CLIA) Class B Shelf life 18 Months Storage condition 2-8 °C	Deferred (last opportunity) for the submission of: 1. Form 7A with annexures and undertaking on stamp paper. 2. FSC of RRA or WHO prequalification or CE certificate. 3. approval of storage condition 2- 8°C.
73.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad (ELI-01008	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	REVERSE TRIIODOTHYRONIN E RT3 Shelf life 18 Months Storage condition 2-8 °C	Deferred (last opportunity) for the submission of: 1. Form 7A with annexures and undertaking on stamp paper. 2. FSC of RRA or WHO prequalification or CE certificate. 3. approval of storage condition 2- 8°C.
74.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad (ELI-01008	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	ANIT - THYROTROPIN RECEPTOR ANTIBODY (TRAB) – CLIA Shelf life 18 Months Storage condition 2-8 °C	Deferred (last opportunity) for the submission of: 1. Form 7A with annexures and undertaking on stamp paper. 2. FSC of RRA or WHO prequalification or CE certificate. 3. approval of storage condition 2- 8°C.
75.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower,	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY	ALDOSTERONE (CLIA)	Deferred (last opportunity) for the submission of:

	Jinnah Avenue, Blue Area, Islamabad (ELI-01008)	BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	Shelf life 18 Months Storage condition 2-8 °C	1. Form 7A with annexures and undertaking on stamp paper. 2. FSC of RRA or WHO prequalification or CE certificate. 3. approval of storage condition 2-8°C.
76.	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 065731143238	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026	Brand name: KMN Gussted Reel Generic Name: Sterillization Gussted Reel Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	Deferred (final opportunity) for the submission of: 1. original, legalized FSC. 2. fee for the family. 3. clarification of the model applied.
77.	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68-Mozang Road, Lahore. (ELI- 01147) R&I detail	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. • LOA Type: Original Attested By: CCPIT Validity: March-2030	Brand name: KMN Sterilization Pouches Generic Name: Sterilization Pouches Class: A	Deferred (final opportunity) for the submission of: 1. original, legalized FSC. 2. fee for the family. 3. clarification of the model applied.

	14-05-2025 Fee: 6,000/- Slip: 28496777	<ul style="list-style-type: none"> • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 	Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	
78.	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68- Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 401295349	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. <ul style="list-style-type: none"> • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026 	Brand name: KMN Flat Reel Generic Name: Sterilization Flat Reel Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	Deferred (final opportunity) for the submission of: 1. original, legalized FSC. 2. fee for the family. 3. clarification of the model applied.
79.	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68- Mozang Road, Lahore.	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District,	Brand name: KMN Steam Indicator Strips	Deferred (final opportunity) for the submission of: 1. original, legalized FSC. 2. fee for the family.

	<p>(ELI- 01147)</p> <p>R&I detail 14-05-2025</p> <p>Fee: 6,000/-</p> <p>Slip: 13361428962</p>	<p>246000 Anqing City, China.</p> <p>• LOA Type: Original Attested By: CCPIT Validity: March-2030</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025</p> <p>• ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026</p>	<p>Generic Name: Steam Indicator Strips</p> <p>Class: A</p> <p>Codes/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>3. clarification of the model applied.</p> <p>4. the name on FSC is Steam Indicator Label and on Covering letter is Steam Indicator Label/Strip Class 5.</p>
80.	<p>M/s. Alam and Sons, 2nd Floor, Asmat Chamber, 68- Mozang Road, Lahore.</p> <p>(ELI- 01147)</p> <p>R&I detail 14-05-2025</p> <p>Fee: 6,000/-</p> <p>Slip: 24181713696</p>	<p>Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <p>• LOA Type: Original Attested By: CCPIT Validity: March-2030</p> <p>• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025</p> <p>• ISO Certificate Type: Original</p>	<p>Brand name: KMN Sterilization Crepe Paper</p> <p>Generic Name: Sterilization Crepe Paper</p> <p>Class: A</p> <p>Codes/Sizes: Not mentioned</p> <p>Applied as: Single</p> <p>Shelf life: Not mentioned</p>	<p>Deferred (final opportunity) for the submission of:</p> <p>1. original, legalized FSC.</p> <p>2. fee for the family.</p> <p>3. clarification of the model applied.</p>

		Attested By: CCPIT Validity: 29-06-2026		
81.	M/s. Alam and Sons, 2 nd Floor, Asmat Chamber, 68- Mozang Road, Lahore. (ELI- 01147) R&I detail 14-05-2025 Fee: 6,000/- Slip: 1435001130	Name of Manufacturer: M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China. • LOA Type: Original Attested By: CCPIT Validity: March-2030 • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025 • ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026	Brand name: KMN Tyvek Reel Generic Name: Tyvek Sterilization Reel Class: A Codes/Sizes: Not mentioned Applied as: Single Shelf life: Not mentioned	Deferred (final opportunity) for the submission of: 1. original, legalized FSC. 2. fee for the family. 3. clarification of the model applied.
82.	Cardio Life, House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3, Rawalpindi. ELI-00984 5465-P 62,000/-	<u>Legal Manufacturer:</u> Delta Med S.P.A, Via Guido Rossa 20, 46019 Viadana (MN) - Italy. Original FSC: Italy. Date of Issuance: 12-08-2024.	Delta Med Arterial Cannula Class-D Shelf Life: 5 Year Codes: 393083103122 (3Fr x 8cm) 394103103222 (4Fr x 10cm)	Deferred (last opportunity) for: 1. clarification of the class of applied device. 2. submission of real time shelf life study of the Delta Med Arterial Cannula.
83.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar	<u>Legal Manufacturer:</u> M/s Zhejiang Bangli Medical Products Co., Ltd Address: No.118, Yuegui South Road, City West New District, 321300 Yongkang	Medical Tape Class: A	Deferred (last opportunity) for submission of: 1. Fee for the family. 2. Brand name mentioned on LOA.

	<p>ELI-00618</p> <p>Fee Challan No. 92530528 6,000/- 6222-Kpk</p>	<p>City, Zhejiang Province, China</p> <p>LOA Validity: 16/03/2035</p> <p>FSC Validity: 10-03-2027</p> <p>ISO 13485 validity 25-11-2026</p>	<p>Shelf Life: 5 Years</p> <p>Sizes: As per FSC</p>	
84.	<p>Zymotic Diagnostics International, 4th Floor Business Center Regency Road new Civil Lines Faisalabad.</p> <p>ELI-00880 7046-P 31,000/-</p>	<p>Legal Manufacturer: GOLDSITE DIAGNOSTICS INC. Goldsite Mansion, No. 9 Rongtian Road, Kengzi, Rongtian Road, Kengzi, Pingshan District, Shenzhen, China, 518122.</p> <p>FSC: China. Date of Validity: 02-01-2026.</p> <p>LOA validity April, 2026</p> <p>ISO 13485 validity 15-10-2027</p>	<p>NEPHSTAR Specific Protein Analyzer</p> <p>Class-B</p> <p>Shelf Life: 1 Year</p> <p>Model: Nephstar</p>	<p>Rejected for the following reasons.:</p> <ol style="list-style-type: none"> 1. FSC is not original. 2. Stability study/Service life not submitted. 3. Class of the device not corrected. 4. firm has not submitted original documents and manufacturer credentials. 5. Firm has not applied separately for all kits depending upon the Class of kit.
85.	<p>M/s Ferozsons Laboratories Limited, P. O. Ferozsons, Amangah, Nowshehra-KPK, Pakistan</p> <p>(ELI-00120)</p> <p>Fee slip#7000318435</p> <p>Dated: 22.04.2025</p> <p>Rs.1,95,000/-</p> <p>R&I 05.05.2025</p> <p>6231-KPK</p>	<p>Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Marlborough MA 01752 USA</p> <p>Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN 55112 USA</p> <p>FSC: US FDA Date of Issuance: 06.12.2023 Validity: 05.12.2025</p>	<p>AMS 700 Inflatable Penile Prosthesis and AMS 700 Accessory Kit</p> <p>Class D</p> <p>Shelf Life: 5-years 2 years</p> <p><u>Codes & Sizes:</u></p> <p>72404010 72404011 72404012 72404013 72404014 72404300 72404301 72404302 72404303</p>	<p>Approved AMS 700 Inflatable Penile Prosthesis CX MS Pump Inhibizone with following codes:</p> <p>72404230 72404231 72404232 72404232-10 72404233 72404233-12 72404234 72404234-14 72404235 72404236 72404237 72404238</p>

			72404305 72404306 72404307 72404308 72404291 72404292 72404293 72404294 72404280 72404281 72404282 72404283 72404284 72404285 72404286 72404287 72404288 72404289 72404282-10 72404283-12 72404284-14 72404271 72404272 72404273 72404274 72404275 72404310 72404161 72404162 720182-01	72404239 subject to verification of the fee.
86.	M/s Maher Apparels, Lahore. ELI-01330 Date of R& I 09-05-2025 Fee: PKR 31,000/- Slip # 5955313212	Name Manufacturer: Changzhou Major Medical Products Co., Ltd.,No. 1, Beiyang Road, Hexi Village, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu, China 213144. LOA: Not Submitted. • FSC Type: Copy of apostilled Issued By: CCCIEMHP Legalization: Apostilled Validity: 02-01-2027	Brand name: Medelast Hydrocolloid Wound Dressing Ultra Thin Generic Name: Hydrocolloid Wound Dressing Class: B Models/Sizes: 5x5cm, 10x10cm, 15x15cm, 20x20cm Shelf Life: 3 Years	Deferred with final opportunity for submission of following: 1. LOA is not original. The date of issuance not mentioned on LOA, hence validity can't be assured. 2. FSC not issued by the relevant Health Regulatory Authority. 3. The device is of class IIb as per EU QMS certificate while firm has applied in class b. 4. The fee for the family not submitted.

		<p>• ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 19-09-2026</p> <p>• EU QMS Certificate: Type: Copy Notarization: By CCPIT Validity: 14-07-2029</p>		
87.	<p>Sonoscape Medical Corporation Pakistan, Office No. FF-21, 1st Floor Hayat Arsallah Heights, Commercial Block, CBR Town Phase 1, Islamabad (ELI-01301)</p> <p>R&I Date: 30-06-2025 Fee: 31,000/- Slip # 4879255436.</p>	<p>Name of Manufacturer: Sonoscape Medical Corporation, Address: Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Sub district, Nanshan District, Shenzhen, 518057, Guangdong P.R. China LOA: Type: Copy Notarization: No Validity: 31-12-2027 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 16-03-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 22-04-2028 Copy of EU Quality Management Certificate submitted.</p>	<p>Brand Name: Digital Color Doppler Ultrasound Diagnostic Machine Generic Name: Model: P10 Applied as: System Class: B Models/Code/sizes (as per FSC & application) P10 Shelf life: --</p>	<p>Deferred (final opportunity) for the following reasons:</p> <ol style="list-style-type: none"> 1. clarification that firm has submitted original documents were submitted 02.06.2025 while application was submitted on 30-06-2025. 2. The name of the device is Digital color Doppler Ultrasound System but fee for the system has not been submitted. 3. Firm has submitted same copy of apostille certificate No.12718950 for all the documents. 4. Firm is once again advised to submit original, notarized/ apostille documents as per MDR 2017.

Abdul Qadir
Assistant Director-I (MIS)
Monday, 08 December, 2025, 9:35:6 AM

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