

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

DCISIONS OF 131ST MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
20th May 2026 (MANUAL APPLICATIONS PART-II)

131st 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 20th May 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S#	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. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
3.	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)
4.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member (attended meeting through videolink)
5.	Dr. Farid Khan, Senior Consultant Neurosurgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
8.	Mr. Wajahat Ali, Biomedical Manager, Biomedical Engineering Department, Darul Sehat Hospital, Street-19, Block-15, KDA Scheme 36, Gulistan-e-Johar, Karachi.	Member (attended meeting through videolink)
9.	Mrs. Tazeen S Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-Opted Expert (attended meeting through videolink)
10.	Ms. Farzana Raja Deputy Director QC on behalf of Director QA< Division	Co-Opted Expert
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

Sr. No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Khalid Mahmood	Deputy Director
10.	Mr. Asif Jalil	Deputy Director

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

EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

Item No. I(A): APPROVAL OF SITES FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

Case. No.1:

M/s World Pack Industries, 725 Sunder Industrial Estate, Sundar Raiwind road, Lahore has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at 725 Sunder Industrial Estate, Sundar Raiwind road, Lahore. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. The site was inspected by Mr. Abdul Rashid Shaikh, Deputy Director, DRAP, Lahore on 25th April, 2026. Recommendations/report of the panel is reproduced as under: -

Location	The proposed site was located at 725-Sunder Industrial Estate, Sundar Raiwind Road, Lahore
Surrounding	• On the front side of the proposed site there was 80 ft wide street. • On the left side the proposed site their was also 40 ft wide road. • On the right side the their was flour mill. • On the back side the proposed site their was open plot.
Size	The size of the plot is about 04-kanl as informed by the management and documents provided by the management are also (copies attached)
Recommendations	It is pertinent to mentioned here that a factory for packing material by the name of World Pack Industries already functional on the ground floor of the premises. However they have constructed an other hall measuring 50 n x 180 ft-9000 sq.ft. constructed only for the purpose of medial devices on their 1 floor of the premises. As per the environment and condition of the surrounding the site is suitable for the manufacturing of medical devices as of today and further submitted for the consideration and decision by the Board

Decision: **The board considered the inspection report for site verification and decided to approve the site for establishment license to manufacture medical devices. This site approval shall remain valid for a period of 03 years; the firm needs to apply for establishment license to manufacture medical devices during the stipulated period failing which a new inspection for site approval shall be conducted.**

Case No. 2

M/s Bridge Surgical, Khan Mehal road, Sialkot has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Khan Mehal road, Sialkot. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. The site was inspected by Mr. Abdul Rashid Shaikh, Deputy Director, DRAP, Lahore on 15th April, 2026. Recommendations/report of the panel are reproduced as under: -

Location	The proposed site was located at Khan Mehal road, Sialkot.
Surrounding	• On the front side of the proposed site there was about 10 ft street in front of the premises their were residential houses as well. • On the left and right sides the proposed site their were hosiery karkhana • On the back side of the site there was warehouse for the storage of Iron Rod.
Size	The size of the plot is about 02-kanl and 1 marla as informed by the management.
Recommendations	It is pertinent to mentioned here that a two storey building has already been constructed. The site of the plot is about 02 kanal and 01 marla as informed by the management. The above proposed site was located in the residential. Now the case is submitted for the MDB for further consideration.

Decision: **Deferred. The board noticed that the site is located in a residential area and per currently policy of Authority a site cannot be approved for establishment license to manufacture medical devices. As the subject matter is under review with DRAP Authority therefore board decided to defer the case till finalization of policy.**

Case No. 3

M/s Tapal Tex (Pvt) Ltd, Plot No. 48, M-3, industrial City P-2, FIEDMC, Faisalabad has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Plot No. 48, M-3, industrial City P-2, FIEDMC, Faisalabad. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. The site was inspected by Mr. Abdul Rashid Shaikh, Deputy Director, DRAP, Lahore on 27th April 2026. Recommendations/report of

the panel are reproduced as under: -

Location	The proposed site was located at 48, M-3, industrial City P-2, FIEDMC, Faisalabad
Surrounding	• On the front side of the proposed site there was main road • On the left side the proposed site their was Tapal Textile. • On the right and back sides the site their was open plots
Size	The size of the plot is about 04 acres as informed by the management.
Recommendations	The above observations led to the conclusion that the proposed site was suitable as of today and which may be consider for establishment of a manufacturing site for medial devices .

Decision:

The board considered the inspection report for site verification and decided to approve the site for establishment license to manufacture medical devices. This site approval shall remain valid for a period of 03 years; the firm needs to apply for establishment license to manufacture medical devices during the stipulated period failing which a new inspection for site approval shall be conducted.

Case No. 4

M/s Haymed, Daska road, Ghuki Daska, Sialkot has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Daska road, Ghuki Daska, Sialkot. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. The site was inspected by Mr. Abdul Rashid Shaikh, Deputy Director, DRAP, Lahore on 26-03-2026. Recommendations/report of the panel are reproduced as under: -

Location	The proposed site was located at Daska road, Ghuki Daska, Sialkot
Surrounding	• On the front side of the proposed site there was 20 ft wide street. • On the left side the proposed site their was open plot owned by the same firm • On the right side the their was also open plot. • On the back side the proposed site their was agricultural land.
Size	The size of the plot is about 03 kanal as informed by the management and documents provided by the management.
Recommendations	A building has already been constructed in the proposed site. The above observations led to the conclusion that the proposed site is suitable as of today and which may be consider for establishment of a manufacturing site for medical devices.

Decision: **The board considered the inspection report for site verification and decided to approve the site for establishment license to manufacture medical devices. This site approval shall remain valid for a period of 03 years; the firm needs to apply for establishment license to manufacture medical devices during the stipulated period failing which a new inspection for site approval shall be conducted.**

Case No. 5

M/s Esmico Trading company, 2nd, floor, Nigar Centre, Patiala ground 2-Link Mcleod road, Lahore has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at, 2nd, floor, Nigar Centre, Patiala ground 2-Link Mcleod road, Lahore. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. Recommendations/report of the panel are reproduced as under: -

Please refer to Drug Regulatory Authority of Pakistan, Islamabad letter No. 2-1/2024-MD dated 22-01-2026, on the subject cited above.

The undersigned try to contact but could not contacted, through one of their representative who informed that the management is out of country (China) when they will reached back after about two months the inspection will be conducted accordingly

Submitted for consideration of MDB.

Decision: **The board considered the request of the firm and approved the plea to delay site inspection for 02-month time. The board directed Mr. Abdul Rasheed Shaikh DD, DRAP Lahore to conduct site inspection after 02-month time and submit report for consideration of medical devices board.**

Case No. 6

M/s MM Surgical, 63-A, M-3, Industrial Estate, Sahianwal, Chak Jumra, Faisalabad has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at 63-A, M-3, Industrial Estate, Sahianwal, Chak Jumra, Faisalabad. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. Recommendations/report of the panel are reproduced as under: -

Please refer to Drug Regulatory Authority of Pakistan, Islamabad letter No. 4-10/2026-MD (M-125) dated 08-04-2026, on the subject cited above.

2. The undersigned contacted many times to Mr. Mujtaba cell No. 03216682252, but always he shown reluctance regarding this site inspection, some times he replies that the inspection has already been conducted but no any report was available. Then the undersigned even sent the decision of the Board (MDB) to Mr. Mujtaba regarding site inspection, through WhatsApp and informed him t regarding my availability in Faisalabad on Monday 27-04-2026. And asked him to ensure his or his representative availability for said inspection. But after continuously calls to him on Monday 27-04-2026, he did not attend the calls. After that the undersigned received a WhatsApp message that he is out of city so, the inspection could not be conducted.

Submitted for consideration of MDB.

Decision: **Rejected. The board considered the report sent by field office Lahore and took notice of the non-serious attitude of the applicant towards inspection of site and facility. The board therefore decided to reject the application of the firm for establishment license to manufacture medical devices and the site inspection under medical devices rules 2017. The firm may apply afresh for site verification and for establishment license to manufacture medical devices once they are ready for inspection.**

Case No. 7

M/s Vascular Medical Devices Pvt Ltd, 15A Babur Block Bahria town Lahore has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at 15A Babur Block Bahria town Lahore. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly, Additional Director, DRAP, Lahore was requested to assign inspection of the site to suitable officer in your area of jurisdiction for the said purpose and furnish its reports. Recommendations/report of the panel are reproduced as under: -

Please refer to Drug Regulatory Authority of Pakistan, Islamabad letter No. 2-1/2024- MD dated 22-01-2026, on the subject cited above.

The undersigned contacted to Mr. Shoaib Aziz Malik cell No. 0300-8639431, he informed that they are no more interested.

Submitted for consideration of MDB.

Decision: **Rejected. The board considered the report of field office Lahore and their communication with management of the firm that they are no longer interested. The board therefore decided to reject the application for establishment license to manufacture medical devices.**

Case No. 8

APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017 OF M/S MEDIGAR, CHAK NO. 78G, SATIANA ROAD, KHANUANA BYPASS, FAISALABAD.

Please refer to Drug Regulatory Authority of Pakistan, Islamabad letter No. 4-10/2026-MD (M-125) dated 08-04-2026, on the subject cited above.

Site inspection of M/s. Medigar, Faisalabad, was already conducted by then FID, DRAP, Lahore and report was sent to DRAP, Islamabad vide this office letter No. F.4-18/2020-FID(IV)/18387 dated 16-12-2020 (copy attached). (The site was approved by MDB in 26th meeting accordingly)

2. The undersigned contacted to Mr. Ahsan Sardar, regarding final inspection of the unit for grant of EML. But he informed that they are still not ready for the inspection.

Submitted for consideration of MDB.

Decision: **Rejected. The board considered the report sent by field office Lahore and took notice of the non-serious attitude of the applicant towards inspection of facility even though the site was approved in 26th meeting of MDB in 2020. The board therefore decided to reject the application of the firm for establishment license to manufacture medical devices under medical devices rules 2017. The firm may apply afresh for establishment license to manufacture medical devices once they are ready for inspection.**

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 HN Enterprises, Office/godown: Bismillah Centre 4. Dil.Muhammad, road, Lahore.	Muhammad Nazim Bs Biomedical Engineering Technology	Approved for room temp products
2.	M/s Ahmad International Traders,Office/Godown: Office No.425, 4th Floor, Pak Medical Centre, Khyber Bazar Peshawar.	Nazir Ahmad Bs Microbiology	Approved for room temp products

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

(FRESH RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Basic Pharmaceuticals (Pvt) Ltd, Office / godown: 14-A, Babar Block, New Garden Town Lahore ELI-00408	Ahmer Suhail Bhatti B-Pharmacy	Mr. Jaleel ur Rehman Mr. Rafiq Ur Rehman	Approved for room temp products
2.	M/s Abdullah Traders, Office/godown: 3 Green Town, Ghous-ul- Azam Road, Multan. ELI-00444	Syeda Sehrish Batool Ms in Bio Sciences	Mr. Asif Iqbal CEO	Approved for room temp products
3.	M/s Sakuf Trading, Office/godown: 2nd Floor, G-34 Phase-I Commercial Area DHA, Lahore ELI-00126	Ch Nawaz Khalid Pharm D	Muhammad Usman Malik CEO	Approved for room temp products
4.	M/s Mubarak Vision, Office/godown: 32-A Usman Center, Shah Alam Market, Lahore ELI-00045	Mehjran Saleem Pharm D	Nazir Ahmad Chohan CEO	Deferred. The board deferred the case for documents and fee for approval of qualified person.
5.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd, Office/godown: Plot No.36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi ELI-00496	Ms. Maimoona Hidayat Pharm D	Mr. Zafar Mahmood	Deferred. The board deferred the case for documents and fee for approval of qualified person.

6.	M/s Bajwa Sons, Office / godown: 13-Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. ELI-00314	Zubaria Nazir Pharm D	Mr. Farhat Munawar Bajwa Mr. Usman Ahmed Bajwa	Show cause notice. The board took a serious of the inspection findings regarding violations of medical devices rules 2017 and decided to issue show cause notice to firm with the direction to appear before the board for personal hearing.
7.	M/s Technoware , Office/godown: PS-65, 2nd floor, UBL Bank, Al-Jannat Building, Robert Road, Nila Gumbad, Lahore. ELI-00436	Muhammad Umer Jamal Bio Medical Engineer	Mr. Azhar Mehmood Khan CEO	Show cause notice. The board took a serious of the inspection findings regarding violations of medical devices rules 2017 and decided to issue show cause notice to firm with the direction to appear before the board for personal hearing.

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

(DEFERRED CASES FOR RENEWAL OF -ELI):

S.No	Name of Establishment	Name of Technical Person	Name of Proprietors	Decision
1.	M/s. Promed International Office: No. 310, 3 rd floor, ISE towers, Islamabad. Godown: Cb-6349, Amar Pak Plaza, Jhelum Road, Rawalpindi, Pakistan ELI-00044	Arooj Khalid alvi Pharmacist	Ahmed Jamal	Decision: The board considered the inspection report and endorsed the recommendations of the panel of experts. The board also showed satisfaction with the CAPA plan of the firm and decided to renew establishment license to import medical devices under medical devices rules 2017.
2.	M/s MIRAJ CORPORATION, Office/Godwon: Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi ELI-00326	Qindeel Mushtaq Ahmed M.Phil Biotechnology	Mushtaq Ahmad CEO	Approved for room temp products

3.	M/s ALFA Scientific Store, Office: 1-CD, Edward Road, Lahore Godown: LG-1, LG-2, LG-3, Lower Ground, South Center, 10-Edward Road, Lahore . (ELI-00148)	Muhammad Imtiaz BS in Biochemistry (Hons)	Muhammad Sajjad	Approved for room temp products
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Item No. I(E): ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES - INVALID

Following Establishment License for Import has become invalid for not submitting renewal applications, the relevant clause Rule 7(5) of Medical Devices Rules 2017 is reproduced as under:

“If an application for renewal is made after expiry of the period of validity of licence, the applicant shall deposit an additional fee equivalent to applicable renewal fee for each month till one year of the expiry of the establishment licence and after one year the establishment licence shall cease to exist and the application shall be treated as a fresh application for grant of establishment licence.”

	Firm Name	Address	Licence No	Date Of Issuance	Validity/Renewal Date	Date of Renewal application	Decision
1	M/s Jafri Medical, Office/godown: Suit No. 104C/11, Maryam Heights, Block 7/8, KCHS, PECHS, Shaheed e Millat Road, Karachi	Office/godown: Suit No. 104C/11, Maryam Heights, Block 7/8, KCHS, PECHS, Shaheed e Millat Road, Karachi	ELI-00358	27/02/2019	26/02/2024	28/04/2026	Invalid. The board observed that the applicant has not made renewal application after lapse of more than one year of expiry of license therefore license stands invalid/ cease to exist under rule 7(5) of medical devices rules 2017. The applicant need to apply afresh for grant of license in case they are interested in obtaining establishment license to import

							medical devices. Similarly, registrations/ enlistments granted to the applicant also stands invalid/ cease to exist which requires submission of fresh applications as well.
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Item No. I(F): APPLICATIONS FOR GRANT OF RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

PERSONAL HEARING CASES

The following firms have applied for Renewal of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The recommendations of the panels and decisions of MDB taken in its different meetings are as mentioned against each:-

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Ahmad Care International, Office/godown: 2 nd Floor, 7 Shahrah e Taj bagh, phase 1, main market, opp unique solution girls high school, Tajbagh housing scheme, Lahore. ELI-00361 M-119	Syed amin abbas	Amir Ijaz butt CEO	Decision: The board provided opportunity of personal hearing to the applicant. Mr. Amir Butt, CEO of the firm, appeared before the board. He informed the board that his warehouse was not maintained because he has no product registration under this license currently. However, he has shifted his godown to a new location and he's ready for inspection. He also informed that the qualified person has also changed. The board considered his request for inspection of godown at his new location (Office 24, 1st floor, Orchard Mall, Phase 2 Bahria Orchard Main Raiwand Road Lahore) with following panel and advised the panel to furnish a detailed report with required documents of godown and new qualified person on priority. • Dr. Fareed Khan Member MDB. • Mr. Abdul Rasheed Shaikh, DD, DRAP Lahore.

Item No. I(G):

Subject: M/s MOODY GLOBAL SERVICES - APPLICATION FOR GRANT OF ENLISTMENT/ REGISTRATION OF MEDICAL DEVICE FOR IMPORT.

Inspection of M/s MOODY Global Services, Islamabad was conducted by following panel for verification of cold storage facility as per decision of the board in 127th meeting:

- Mr. Muhammad Amin, DD, DRAP Isb.

- Dr. Ghayour Ahmad DD, DRAP Isb.

The panel visited the premises and submitted following report.

Reference your letter No. F-21/2026-Md (M-127) dated 11th May 2026 on the subject cited above, it is informed that M/s MOODY Global Services (ELI-00926), Office No. 14, 2nd Floor, Mujahid Plaza, Blue Area and godown No. 17, 2nd Floor, Mujahid Plaza, Blue Area, Islamabad, was inspected on 19th May 2026, and the following observations were noted at the time of inspection.

I. The godown mentioned in the Establishment License (ELI-00926) was not available at M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue Area, Islamabad. Mr. Sarfaraz, CEO of the firm informed that the godown mentioned in the current Establishment Licence at Office No. 17, 2nd Floor, Mujahid Plaza, Blue Area, Islamabad, had recently been vacated by the owner, and currently no godown facility is available. When the lease agreement was checked it was revealed that the lease agreement (copy attached) was valid only up to 31-07-2023. Therefore, the required cold storage facility was not available and could not be verified.

II. The qualified person Aisha Duad, was not present at the time of inspection. Mr. Sarfaraz informed that she come to the office on and off because she is married now.

III. Mr. Sarfaraz was requested to provide the SOPs related to Good Storage and Distribution Practices particularly for cold storage and other operational processes however, he was unable to produce the required SOPs during the inspection.

In view of above findings, the Medical Device Board is requested to take appropriate action under the Medical Device Rules 2017.

The case is submitted for the consideration of the Board, please

Decision: The board considered the inspection report and took serious notice of the inspection findings and violations of medical devices rules 2017. The board noticed that the applicant doesn't possess storage facility presently and doesn't hold a full time qualified person which is a mandatory requirement under medical devices rules 2017. Similarly, absence of SOPs for good storage and distribution practice was also taken seriously as the firm holds many registrations/ enlistments of products including cold storage medical devices.

The board therefore decided to issue show cause notice to the firm with the direction to appear before the board in next meeting.

Item No. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

Deferred Cases

Evaluator: HAJIRA ABID (Intern-2)

Sr No	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc.	Decision of MD
1.	Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1st Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi ELI-01036 Date of R&I 30-04-2025 Fee Details: 6,000 Paid Fee: 83922473	Shenzhen New Industries Biomedical Engineering Co., Ltd., (SNIBE Co., LTd.,) No. 23, Jinxiu East Road, Pingshan District, 518122, Shenzhen, P.R.China. LOA Issue: 03-12-2029 FSC: China Validity:03-11-2026 FSC: Germany Issue date: 30-01-2025 ISO Validity: 31-12-2025 EC Certificate: Validity:14-12-2025	Brand name: Satlars Generic Name: Laboratory Automation System Class-A Shelf life: 10 years Models/ Specification:	Deferred with final opportunity for Justification of Multiple models as per MDR 2017 with documentary evidence i.e. catalog, brochure etc. along with submission of the fee for the relevant code or select one model/code to be considered in the current application. And apply other codes/models separately through online portal.
2.	M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1 st Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi ELI-01036 Date of R& I 30.04.2025 Fee: Rs.`62000/ through slip no. 510750113	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.,) NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China LOA: Valid till: 03-12-2029 (Copy) FSC: Validity Date: 03-08-2025 (Copy) Reference Country FSC Issue Date: 30-01-2025 (Copy)	Brand Name: MAGLUMI Generic: Toxo IgM (CLIA) and Toxo IgM (CLIA) controls Applied as: Kit Class C Shelf Life: 18 months Code/sizes:	Deferred for submission of the following: - Valid legalized Free Sale Certificate (FSC) of product Toxo IgM (CLIA) of country of origin mentioning all the manufacturers & the applied codes of the product. - Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. - Provide a Valid ISO certificate

		ISO - Validity Date: 31-12-2025 (Copy) EC Certificate Valid till: 14-12-2025 (Copy)	Toxo IgM (CLIA): 100 tests/kit, 50 Tests/kit, 30 Test/kit Toxo IgM (CLIA) Controls Negative Controls: 1x1.0ml Positive Control: 1x1.0ml	
3.	Snibe Diagnostic Pakistan (SMC-Private) Limited, Office No. A107, 1st Floor, Fortune Towers, PECHS, Shahra-e-Faisal, Karachi ELI-01036 Date of R&I 30-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 7681066025	<u>Legal Manufacturer:</u> M/s Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.,) NO. 23, Jinxiu East Road, Pingshan District, 518122. P.R China LOA: Valid till: 03-12-2029 FSC: Validity Date: 03-08-2025 Reference Country FSC (Germany) Issue Date: 30-01-2025 ISO - Validity Date: 31-12-2025 (Copy) EU QMS Certificate MDR Valid till: 14-12-2025 (Copy)	MAGLUMI Vitamin B12 (CLIA) and Vitamin B12(CLIA) controls Class-B Shelf Life: 18 months Code/sizes: Vitamin B12 (CLIA): 100 tests/kit, 50 Tests/kit, 30 Test/kit Vitamin B12(CLIA) Controls Control 1: 1x1.5ml Control 2: 1x1.5ml	Deferred for submission of the following: - Valid legalized Free Sale Certificate (FSC) of product Vitamin B12 (CLIA) of country of origin mentioning all the manufacturers & the applied codes of the product. - Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. - Provide a Valid ISO certificate

4.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Tianck Medical Co. Ltd., 1- 2 Floor, Building C, No. 16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119 Guangdong P.R. China	Cestbien Pressure Transducer Kit (Disposable Pressure Transducer) Class C	APPROVED only single code DPT-01-ABBOT Other Models/Codes Sizes Should Be Applied Separately Through Online portal
5.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Tianck Medical Co. Ltd., 1- 2 Floor, Building C, No. 16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119 Guangdong P.R. China	Cestbien Ureteral Stent Kit (Ureteral Stent Kit) Class C	APPROVED only single code 1a-S-4Fx24cm Other Models/Codes Sizes Should Be Applied Separately Through Online Portal.
6.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Anesthesia Breathing Circuit System Class B	APPROVED only single code BCCA-100 Other Models/Codes Sizes Should Be Applied Separately Through Online Portal. Also provide catalog number.
7	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Closed Suction System Class B	APPROVED only single code CSS-A05PY Other Models/Codes Sizes Should Be Applied Separately Through Online Portal.
8.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS OXYGEN MASKS Class B	APPROVED only single model OXYGEN MASK , sizes S, M, L , XL Other Models/Codes Sizes Should Be Applied Separately Through Online Portal.

9.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS Disposable Breathing Filter Class B	APPROVED only codes BVF , HMEF Other Models/Codes Sizes Should Be Applied Separately Through Online Portal.
10	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117)	Shaoxing Undis Medical Technology Co., Ltd., No. 12, Yuexing Technology Park, No. 11 Fanrong Road, Binhai New Area, 312366 Shaoxing, Zhejiang Province P.R. China	KESYS NEBULIZER MASK FOR SINGLE USE Class B	APPROVED only single code WHG-0101 Other Models/Codes Sizes Should Be Applied Separately Through Online Portal.
11	Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061) Date of R&I 18-04-2025 Rs.62000/- Slip#	<u>Legal Manufacturer:</u> STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany <u>Manufacturing Site</u> Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16, 400 13 Castel Maggiore (BO) Italy Critical suppliers for production: _ RS ELETTRONICA SRL - Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN) FSC (Italy) No. DGDMF/3/P/1.5I.e. I/2024/2347: Dated 19-11-2024 (Apostille) LOA Validity: 31-12-2027 (Original Notarized) CE Certificate (FQA) Validity: 26-05-2024 with Extension letter (Notarized) ISO 13485 for legal manufacturer Validity: 28-01-2025 (Notarized) & copy of ISO 13485 valid up to 17-11-2027. ISO 13485 for manufacturing site Validity: 19-12-2025 (Notarized)	Stema HF-U Pro Touch Electrosurgical Unit Class C Apply as System Shelf Life: N/A Codes/Sizes (if any) as mentioned in the remarks	Deferred with final opportunity for 1 Justification of Multiple codes as per MDR 2017 with documentary evidence i.e. catalog, brochure etc. along with submission of the fee for group system, or select one model/code to be considered in the current application and apply other codes/ models separately through online portal 2 For Revised, original, notarized LOA with correct address. 3 Firm hasn't clarified the name of legal manufacturer STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany on FSC, FQA and ISO.

12	Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061) Date of R&I 18-04-2025 Rs. 62,000/- Slip# 17374570547	<u>Legal Manufacturer:</u> STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany <u>Manufacturing Site</u> Alsa Apparecchi Medicali S.R.L Via C. Bonazzi, 16, 400 13 Castel Maggiore (BO) Italy Critical suppliers for production: _ RS ELETTRONICA SRL - Assembling and soldering of PCB Via dei Tigli, 17, 60027 Osimo (AN) FSC (Italy) No. DGD MF/3/P/I.5I.e.I/2024/2347: Dated 19-11-2024 (Apostille) LOA Validity: 31-12-2027 (Original Notarized) CE Certificate (FQA) Validity: 26-05-2024 with Extension letter (Notarized) ISO 13485 for legal manufacturer Validity: 28-01-2025 (Notarized) & copy of ISO 13485 valid up to 17-11-2027. ISO 13485 for manufacturing site Validity: 19-12-2025 (Notarized)	Stema HF-U PRO Electrosurgical Unit Class C Apply as System Shelf Life: N/A Codes/Sizes (if any) as mentioned in the remarks	Rejected on following grounds:- - As applied model/sizes in form 7A not found in FSC. - Also not clarified the name of legal manufacturer STEMA Medizintechnik GmbH Take off Gewerbepark 74 78579 Neuhausen ob Eck/Germany on FSC, FQA and ISO
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13	Applicant Name: Cardiac Care, 848-C, Shadman-1 Lahore- 54610 ELI-00070 Date of R&I 02-06-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 346047687	Name of Manufacturer: On-X Life Technologies, Inc. 1300 East Anderson Lane building B Austin, TX USA LOA Validity: 31-12-2025 (Copy) FSC: USA Issue Date: 28-01-2027 (Copy) ISO Validity: 29-03-2026 (Copy) EU QA/ EC Certificate Validity: 26-05-2024 Design examination certificate Valid till 26.05.2024 extension letter given	Brand name: ON-X conform –X Aortic Prosthetic Heart Valve On-X Confrom-X Mitral Prosthetic Heart Valve Generic Name: Heart Valve Aortic/Mitra Class-D Shelf life: 6 years Models/ Specification: ONXACE-19 ONXACE-21 ONXACE-23 ONXACE-25 ONXACE-27/29 ONXMC-25/33	Rejected on following grounds - Not submitted valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. - Not submitted Valid Design examination certificate
14	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e- Haq Road, Blue Area, Islamabad. (ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 385805908790 Fee: 62,000/- Slip: 2870872457	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China. LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 06-05-2027 ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 CE Certificate or FSC of reference country Not submitted	Brand name: Luofucon Extra Silver Gelling Fiber Dressing Generic Name: Wound Dressing Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application): - SD100100R (100x100mm) - SD150150R (150x150mm) - SD300200R (300x200mm) - SD1000230R (1000x230mm) - SD54040R (540x450mm) Shelf life: 3 Years	Approved. But provide brief description of product

15	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. (ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 7702892492 Fee: 62,000/- Slip: 83809649	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China. • LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 06-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 • EU QMS country Type: Original Attested By: CCPIT Validity: 04-09-2027	Brand name: Suntouch Soluble Hemostatic Gauze Generic Name: Wound Dressing Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application): • SG030030P (30x30mm) • SG050030P (50x30mm) • SG050050P (50x50mm) • SG100050P (100x50mm) • SG100100P (100x100mm) • SG200100P (200x100mm) • SG220100PA (220x100cm) • SG011011p4 (11x11mm) • SG015015P4 (15x15mm) • SG015015P2 (15x15mm) • SG019019PA (19x19mm) • SG50007R (φ5x7mm) • SG50012R (φ5x12mm) Shelf life: 3 Years	Approved, But provide brief description of product with composition of Soluble Haemostatic Gauze.
16	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. (ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 876041728 Fee: 62,000/- Slip: 31705284371	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China. • LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled	Brand name: Luofucon Silicon Postoperative Dressing Generic Name: Wound Dressing Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application):	Approved. But provide brief description of product.

		Validity: 06-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 • EU QMS country Type: Original Attested By: CCPIT Validity: 04-09-2027	• OP150090A (150x90mm) • OP100100A (100x100mm) • OP150100A (150x100mm) • OP200100A (200x100mm) • OP300100A (300x100mm) • OP350100A (350x100mm) • OP250200A (250x200mm) • OP500200A (500x200mm) Shelf life: 3 Years	
17	M/s Global Clinical Cura Pvt. Limited, 18, Mian Iqbal Road, Westridge 1, Rawalpindi (ELI-00196) R&I Date: 03-06-2025 Fee: 6,000/- Slip # 849167929.	Name of Manufacturer: Shandong Chengwu Medical Products Factory, Address: Southern end of Quancheng Road, Chengwu County, Heze City, Shandong Province, P.R. China LOA: Type: Copy Notarization: No Issue Date: 05-06-2024 Validity: 04-06-2029 FSC: Not submitted ISO – Certificate: Type: Copy Notarization: No Validity: 19-02-2026	Brand Name: Disposable Urine Containers Generic Name: Disposable Urine Containers Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model:-- Shelf life: 5 years (Room temperature)	REJECTED on following grounds that FSC not provided and ISO not valid.
18	Applicant Name: Summit Inter Trade, Suit No. 12-A First Floor, Nadir House I.I. Chundrigarh Road, Karachi ELI-00463 Date of R&I 03-03-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 86385144937	M/s. Anqing Yipak Packaging Material Co., Ltd., Intersection of Fangxing Road, and Huangpu Road, Development Zone, Anqing, 246008 Anhui, P.R. China LOA Validity: 26-02-2028 (Copy) FSC: China Validity: 23-02-2027 (Copy) ISO Validity:	Brand name: MaxiCare Generic Name: Sterilization Packaging and Control Products Class-A Shelf life: 05 years Models/ Specification:	Rejected on following grounds FSC not issued by concerned regulatory authority mentioning the applied product.

19	Applicant Name: Summit Inter Trade, Suit No. 12-A First Floor, Nadir House I.I. Chundrigarh Road, Karachi ELI-00463 Date of R&I 10-03-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 41500037	M/s. BF Medikal Sanayi Ithalat Ihracat Ticaret Ltd., Sti SteriVision Company, Feridunn Celik Mah. 1048. Cad. No. 139/BAltindag/Ankara/ Turkey LOA Validity: 23-02-2028 (Copy) FSC: Turkiye Validity:06-11-2027 (Copy) ISO Validity: 27-07-2025 (Copy) EC Certificate: Validity: 27-07-2025 (Copy)	Brand name: SteriVision Generic Name: SteriVision Class-A Shelf life: Models/ Specification:	Rejected on following grounds: - The applied product is not specifically mentioned in the submitted FSC. Furthermore, no product codes, sizes, or classification details have been provided - No clarification of self-life - No brand name clarification. - Not provided any description regarding product use.
20	M/s Business Medical International Office No: Suite101& 102, Trade Centre, Plot#23-F Muhammad Ali Housing Society, Karachi. (ELI-00262) D.O.I: 22-10-2018 Dy. No.: DRAP (R&I) Dated: 04-04-2025 Fee Challan No.: 2860419821 PKR: 31,030 /- Dated: 23RD MARCH, 2025	<u>Legal Manufacturer:</u> CONMED CORPORATION 1311 Concept Blvd, Largo, FL 33773, USA, ISO 13485 Certificate validity: 15-03-2025	Electrosurgical Unit with Standard accessories Class: B Service life: 10 Years	Rejected on following grounds:- - The manufacturer's address mentioned on the FSC is different from the address provided in the applied documents. - Valid legalized LOA is not submitted

21	M/S Mediland Pakistan Pvt Ltd Office no B09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 26-06-2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf-DieselStrabe 5, 59199 Bonen Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitzsoehne.com FSC: LOA: 01-10-2026	Brand Name: Patient Trolley (Generic Name): Transport Trolley Class: A Shelf Life: N/A Codes/sizes: STL 285, STS 282, STX 280	Deferred withy final opportunity; Firm hasn't provided the fee challan
22	M/S Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 12-08-2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf-Diesel-Strabe 5, 59199 Bonen Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitz-soehne.com FSC: LOA: 01-10-2026 EC Certificate: ISO 13485:	Brand Name: Treatment Chairs (Generic Name): Examination Chairs Class: B Shelf Life: N/A Codes/sizes: medi-matic, arco-matic,	Approved only One model MEDI-MATIC in current application. And apply other codes/models separately through online portal.
23	Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 29-06-2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf-Diesel-Strabe 5, 59199 Bonen Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitz-soehne.com FSC: LOA: 01-10-2026 EC Certificate: ISO 13485:	Brand Name: Gynecological Examination Chairs (Generic Name): Gynecological Examination Chairs Class: B Shelf Life: N/A Codes/sizes: Arco 100 Arco 100 M Arco 200 M Arco-matic 200 M Arco Matic 300 M	Deferred with final opportunity - Justification of Multiple models as per MDR 2017 with documentary evidence i.e.catalog, brochure etc. along with submission of the fee for the - relevant code or select one model/code to be considered in the current application. - And apply other codes/models separately through online portal. - Also no differential fee challan no. mention to justify it. - Clarification of the class of the product in light of DOC & MDR 2017.

24	M/S Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 12-08-2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf-Diesel-Strabe 5, 59199 Bonen Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitz-soehne.com FSC: LOA: 01-10-2026 EC Certificate: ISO 13485:	Brand Name: Vidan 2 (Generic Name): Video colposcope Class: B Shelf Life: N/A Codes/sizes: As per FSC	Approved. Clarification of the class of the product in light of DOC & MDR 2017.
25	M/S Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 18-08-2022	Medivators Inc. 14605 28th Avenue North Minneapolis, MN 55447 USA Toll Free: +1.800.444.4729 Web Site: www.medivators.com FSC:30-08-2025 LOA: 16-10-2025 EC 30-07-2028 ISO: 05-07-2027	Brand Name: Washer Disinfector System Division (Generic Name): Washer Disinfector System Class: B Shelf Life: N/A Codes/sizes: SSD-102LT DSD 201 DSD EDGE Rapid AER CER OPTIMA ADVANTAGE PLUS ADVANTAGE PLUS Pass-thru	Deferred with final opportunity for Justification of Multiple codes as per MDR 2017 with Documentary evidence i.e. catalog, brochure etc. along with submission of the fee for the relevant code or select one model/code to be considered in the current application. And apply other codes/models separately through online portal.
26	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 02-06-2025 Fee: 62,000/- Slip # 277180414775	Name of Manufacturer: Erba Lachema s.r.o. Karasek 2219/1d 62100 Brno-Reckovice, Czech Republic. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • FSC Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Validity: 31-03-2026 (Original submitted vide	Brand name: UndekaPHAN Auto Generic Name: Multiple Urine Analyte IVD Kit Applied as: Kit Class: C Code/sizes (as per FSC, DOC & Application): Asset No. 00228005 (Cat. No. URP0031) Shelf Life: 12 Months	Approved

		letter No. SMI/mm/RA/308/2025 dated 07-07-2025) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-12-2027 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • CE/EU QMS Certificate: Not Submitted		
27	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 02-06-2025 Fee: 62,000/- Slip # 123953877	Name of Manufacturer: Erba Lachema s.r.o. Karasek 2219/1d 62100 Brno-Reckovice, Czech Republic. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • FSC Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Validity: 18-01-2026 (Original submitted vide letter No. SMI/mm/RA/308/2025 dated 07-07-2025) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-12-2027 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • CE/EU QMS Certificate: Not Submitted	Brand name: Erba Protime LS 100 Generic Name: PT Time IVD Kit Applied as: Kit Class: C Code/sizes (as per FSC, DOC & Application): Asset No. 00044046 (Cat. No. EHL00047) Shelf Life: 18 Months (2-8oC)	Approved

28	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 02-06-2025 Fee: 62,000/- Slip # 767936649187	Name of Manufacturer: Erba Lachema s.r.o. Karasek 2219/1d 62100 Brno-Reckovice, Czech Republic. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • FSC Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Validity: 18-01-2026 (Original submitted vide letter No. SMI/mm/RA/308/2025 dated 07-07-2025) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-12-2027 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • CE/EU QMS Certificate: Not Submitted	Brand name: Erba Actime 50 Generic Name: Activated Partial Thomboplastin Time (APTT) IVD Kit Applied as: Kit Class: C Code/sizes (as per FSC, DOC & Application): Asset No. 00043959 (Cat. No. EHL00004) Shelf Life: 30 Months (2-8oC)	Approved
29	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town. ELI-00160 Date of R& I 02-06-2025 Fee: 31,000/- Slip # 904546857415	Name of Manufacturer: Erba Lachema s.r.o. Karasek 2219/1d 62100 Brno-Reckovice, Czech Republic. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • FSC Type: Copy Issued By: Regulatory Body Legalization: Not Legalized	Brand name: Laura XL Generic Name: Urine Analyzer Applied as: Single Class: B Code/sizes (as per FSC, DOC & Application): Asset No. 00227985 (Cat. No. INS00065) Service Life: Not mentioned	Approved subject to submission of valid/legalized FSC.

		Validity: 31-03-2026 (Original submitted vide letter No. SMI/mm/RA/308/2025 dated 07-07-2025) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-12-2027 (Original submitted vide letter No. SMI/mm/RA/006/2025 dated 13-01-2025) • CE/EU QMS Certificate: Not Submitted		
30	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 486100869 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Brand name: Cardiolipin IgG Control Generic Name: Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC001 Class-B LOA validity: 31-Dec-2025 Shelf life: 24 Months Storage Conditions: 2 - 8°C FSC country of origin validity: 20-Dec-2026	Approved

31	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 27-08-2020 Fee: PKR 25,000/- Slip # 1932183 Dated: 21-04-2020	Legal Manufacturer Boule Medical AB, Domnarvsgatan 4, SE-163 53, Spanga, Sweden Documents Submitted: ISO 13485 certificate validity: 20-05-2025 LOA validity: 31-Dec-2024 FSC country of origin validity: 25-May-2022	Brand name: Swelab Alfa Plus Sampler BD AR Generic Name: Swelab Alfa Plus Sampler BD AR Models/ Specification (as per Free sale certificate): 1420046 Class-B Shelf life: 08 Years Storage Conditions: 18 - 32°C	Approved
32	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 27-08-2020 Fee: PKR 25,000/- Slip # 1932184 Dated: 21-04-2020	Legal Manufacturer Boule Medical AB, Domnarvsgatan 4, SE-163 53, Spanga, Sweden Documents Submitted: ISO 13485 certificate validity: 20-05-2025 LOA validity: 31-Dec-2024 FSC country of origin validity: 25-May-2022 FSC RRA validity: N/A	Brand name: Swelab Lumi System Generic Name: Swelab Lumi Instrument: (Swelab Lumi D-Diluent, Swelab Lumi L1 & L2 Lyse, Boule Cal 5 Diff A1, Boule Con 5-Diff A1, Boule Easy cleaner) Models/ Specification (as per Free sale certificate): 1620040 Class-B Shelf life: N/A	APPROVED

33	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 27-08-2020 Fee: PKR 25,000/- Slip #1932184 Dated: 21-04-2020	Legal Manufacturer Boule Medical AB, Domnarvsgatan 4, SE-163 53, Spanga, Sweden Documents Submitted: ISO 13485 certificate validity: 20-05-2025 LOA validity: 31-Dec-2024 FSC country of origin validity: 25-May-2022 FSC RRA validity: N/A	Brand name: Boule Cal 5 Diff A1, Boule Con 5-Diff A1, Tri, Norm, Low & High Generic Name: Swelab Cal-5 Diff A1 1x3ml Swelab Con-5 Diff A1 Tri 3x2x3ml Swelab Con-5 Diff A1 low 1x3ml Swelab Con-5 Diff A1 Norm 1x3ml Swelab Con-5 Diff A1 Norm 6x3ml Swelab Con-5 Diff A1 High 1x3ml Models/ Specification (as per Free sale certificate): Swelab Cal-5 Diff A1 1x3ml: 1504517 Swelab Con-5 Diff A1 Tri 3x2x3ml: 1504518 Swelab Con-5 Diff A1 low 1x3ml: 1504521 Swelab Con-5 Diff A1 Norm 1x3ml: 1504520 Swelab Con-5 Diff A1 Norm 6x3ml: 1504519 Swelab Con-5 Diff A1 High 1x3ml: 1504522 Class-B Shelf life: Closed Container: 60 days from day of manufacturing. Storage Conditions: 2 - 8°C	APPROVED
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34	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 27-08-2020 Fee: PKR 25,000/- Slip # 1932185 Dated: 21-04-2020	Legal Manufacturer Boule Medical AB, Domnarvsgatan 4, SE-163 53, Spanga, Sweden Documents Submitted: ISO 13485 certificate validity: 20-05-2025 LOA validity: 31-Dec-2024 FSC country of origin validity: 25-May-2022 FSC RRA validity: N/A	Brand name: Swelab Lumi Diluent & Lyse Generic Name: Swelab Lumi D-Diluent Swelab Lumi L1 Lyse Swelab Lumi L2 Lyse Models/ Specification (as per Free sale certificate): Swelab Lumi D-Diluent - 1504514 Swelab Lumi L1 Lyse: 1504515 Swelab Lumi L2 Lyse: 1504516 Class-B Shelf life: 24 Months Storage Conditions: 2 - 30°C	APPROVED
35	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, Lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 13499254326	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Brand name: Electrical Operation Table Generic Name: Electrical Operation Table Class: A Models/Sizes: SXD8801, SXD-8802 Applied as: Single Shelf life: 10 Years	Rejected on following grounds Discrepancy in fee challan, as the product name Shadow less Lamp Sx-11-700L mentioned on the challan does not match the applied product name Grouping not justified as two models are applied in a single group The applied models SXD8801 and SXD-8802 have already been approved in M-79 under the firm M/s Medimage Services Address: 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan with the brand name Jiangsu Suxin (OPERATING TABLE)

36	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, Lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 62347435	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Brand name: Electrical Operation Table Generic Name: Electrical Operation Table Class: A Models/Sizes: SXD8804(B) Applied as: Single Shelf life: 10 Years	Rejected on following grounds The applied model SXD8804(B) is already been approved in M-79 under the firm M/s Medimage Services Address: 5B, Ground Floor, Peshawar Medical Center, Peshawar, Pakistan with the brand name Jiangsu Suxin (OPERATING TABLE)
37	M/s Maven Healthcare, House No. 11, Canel Park, Gulberg II, Lahore. ELI-00771 Date of R& I 07-05-2025 Fee: PKR 6,000/- Slip # 13499254326	Name of Manufacturer: M/s. Jiangsu Suxin Medical Equipment Co., Ltd., No. 268, Tongchuang Road, Zhangqiao Town, Taixing City, Jiangsu, China. • LOA Type: Copy Notarization: Not notarized Validity: 28-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Legalization: Apostilled Validity: 11-10-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: Not readable	Brand name: Surgical Shadowless Lamp Generic Name: Surgical Shadowless Lamp Class: A Codes/Sizes: SX-11-700L Applied as: Single Shelf life: 12 Months	Rejected on following grounds The applied model SX-11-700L it not mentioned in FSC

38	M/s Medtronic Pakistan Private Limited	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000 Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II, Bayan Lepas, Pulau Pinang, Malaysia 11900. MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus Manufacturing Sdn Bhd Bayan Lepas Free Industrial Zone, Phase II. Bayan Lepas Pulau Pinang MALAYSIA 11900	Patient Connector 24967 Shelf life: 5 years Class: A COPY of USFDA FSC valid till June 2022	Rejected on following grounds Discrepancy in fee challan, as the product name Patient Reader for Smart Sync mentioned on the challan does not match the applied product name
39	M/s. Moon Enterprises Address: 5/6 Rabani Road, Old Anarkali Lahore (ELI:000356) R&I Details: 07-06-2023 Fee: PKR 5000/- Slip: 5598479629 Dated:	Legal Manufacturer: M/S AYSET TIBBİ ÜRÜNLER VE PLASTİK ELEKTRONİK GIDA TEMİZLİK MADDELERİ SAN. A.Ş. Sarihamzalı Mah. 47007 Sk No:36/A Seyhan Turkey. <u>LOA</u> Validity: 16-10-2027 <u>FSC validity:</u> <u>EC Certificate</u> Validity:	Brand: AYEST Generic: VACCUM BLOOD COLLECTION TUBE Models: <i>as per FSC</i> Class A Shelf Life: 48 months Storage condition: Store in cool and dry place.	Rejected on following grounds Discrepancy in fee challan, as the product name Pet Sodium Heparin, Pet Lihtium Heparin TUBE mentioned on the challan does not match the applied product Vaccum Blood Collection Tube.

40	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 8391162735 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	Cardiolipin IgM Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC002 Class-B Shelf life: 24 Months	APPROVED
41	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 685420964 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025	Brand name: Anti-Cardiolipin Control Generic Name: Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC003 Class-B Shelf life: 24 Months	APPROVED

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

43	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 5743354991 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	β2-Glycoprotein I IgM Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC005 Class-B Shelf life: 24 Months	APPROVED
44	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 89386551801 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025	Anti-β2-Glycoprotein Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC006 Class-B Shelf life: 24 Months	APPROVED

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

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

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

49	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 2161617539 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	PR3 IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC011 Class-B Shelf life: 24 Months	APPROVED
50	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 220039638 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025	AMH Control Immunoassay Controls (Low: 2×3.0ml) (High: 2×3.0ml) Models/ Specification (as per Free sale certificate): ZCC027 Class-B Shelf life: 18 Months	APPROVED

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

52	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 9763829370 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	PG I & PG II Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (as per Free sale certificate): ZCC037 Class-B Shelf life: 18 Months	APPROVED
53	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 76342670 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025	GBM IgG Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC038 Class-B Shelf life: 24 Months	APPROVED

		CE Mark validity: N/A		
54	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 26633480720 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise); SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	HA Control Immunoassay Controls (Low: 1×1.0ml) (High: 1×1.0ml) Models/ Specification <i>(as per Free sale certificate):</i> ZCC039 Class-B Shelf life: 24 Months	APPROVED

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

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

58	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 84120563 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	ICA Control Immunoassay Controls (Negative: 2×1.0ml) (Positive: 2×1.0ml) Models/ Specification (as per Free sale certificate): ZCC052 Class-B Shelf life: 18 Months	APPROVED
59	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 990785393 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025	ACTH Control Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (as per Free sale certificate): ZCC078 Class-B Shelf life: 24 Months	APPROVED

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

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

		CE Mark validity: N/A		
63	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 31,000/- Slip # 28493169392 Dated: 26-03-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Commissioned Production Enterprise); SHENZHEN YHLO BIOTECH CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 FSC country of origin validity: 20-Dec-2026 ISO 13485 certificate validity: 14-Nov-2025 CE Mark validity: N/A	SHBG Control Immunoassay Controls (Low: 1×1.0ml) (High: 1×1.0ml) Models/ Specification (as per Free sale certificate): ZCC129 Class-B Shelf life: 24 Months	APPROVED

64	Decent Traders, KH No. 2312, Tape Road, Sheesh Mehal, Near UVAS, Lahore Pakistan. ELI-00516 1194-P 5,000/-	<u>Legal Manufacturer:</u> Zhejiang Hongyu Medical Commodity Co., Ltd, No. 668 Chanhua Road, Fotang Town Industrial Functional Area, Yiwu City, 322002, Zhejiang Province, China. FSC: China. Validity: 15-04-2025.	Smileplus Film Island wound dressing Class-A Shelf Life: 3 Year Sizes as per FSC	APPROVED
65	Decent Traders, KH No. 2312, Tape Road, Sheesh Mehal, Near UVAS, Lahore Pakistan. ELI-00516 1192-P 5,000/-	<u>Legal Manufacturer:</u> Zhejiang Hongyu Medical Commodity Co., Ltd, No. 668 Chanhua Road, Fotang Town Industrial Functional Area, Yiwu City, 322002, Zhejiang Province, China. FSC: China. Validity: 15-04-2025.	Smileplus Transparent Film Dressing Wound dressing Class-A Shelf Life: 3 Year Sizes as per FSC	APPROVED

66	Bio Indus, B-526, B Satellite Town, Rawalpindi. ELI-00979	(Legal Manufacture) Name: M/s Zhejiang CuraWay Medical Technology Co. Ltd. located at Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018 Hangzhou City, Zhejiang Province, China Free Sale Certificate Validity: (21-07-2026) ISO 13485 certificate validity: (missing) EC certificate Validity: (not provided) Letter of authorization: Validity: 31-12-2026 510(K) Number: K242322	CuraWay Bone Marrow Biopsy Needle Models/ Sizes: BNMA/1-1.2(18G)/25 、 BNMA/1-1.2(18G)/40、 BNMA/1-1.2(18G)/55、 BNMA/1-1.6(16G)/25 、 BNMA/1-1.6(16G)/40、 BNMA/1-1.6(16G)/55、 BNMA/1-1.8(15G)/25 、 BNMA/1-1.8(15G)/40、 BNMA/1-1.8(15G)/55 、 BNMA/1-2.1(14G)/25、 BNMA/1-2.1(14G)/40、 BNMA/1-2.1(14G)/55 、 BNMA/CB-1-3.5(9G)/70 BNMA/CB-1-3.5(9G)/100 BNMA/CB-1-3.5(9G)/150 BNMA/CB-1-3.0(11G)/70 BNMA/CB-13.0(11G)/100 BNMA/CB-13.0(11G)/150 BNMA/CB-1-2.4(13G)/70 BNMA/CB-12.4(13G)/100 BNMA/CB-12.4(13G)/150 BNMA/1F-1.2(18G)/25 BNMA/1F-1.2(18G)/40 BNMA/1F-1.2(18G)/55 BNMA/1F-1.6(16G)/25 BNMA/1F-1.6(16G)/40 BNMA/1F-1.6(16G)/55 BNMA/1F-1.8(15G)/25 BNMA/1F-1.8(15G)/40 BNMA/1F-	APPROVED First 20 Models are approved Other Models/Codes Should Be Applied Separately Through Online Portal
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			1.8(15G)/55 BNMAB-1F- 2.1(14G)/25 BNMAB-1F- 2.1(14G)/40 BNMAB-1F- 2.1(14G)/55 BNMA/CB-1F- 3.5(9G)/70 BNMA/CB- 1F3.5(9G)/100 BNMA/CB- 1F3.5(9G)/150 BNMA/CB- 1F3.0(11G)/70 BNMA/CB1F3.0(11G)/1 00 BNMA/CB1F3.0(11G)/1 50 BNMA/CB- 1F2.4(13G)/70 BNMA/CB1F2.4(13G)/1 00 BNMA/CB1F2.4(13G)/1 50 BNMDB-1F- 1.2(18G)/25-3.5(9G)/70 、 BNMDB-1F- 1.2(18G)/25-3.5(9G)/100 、 BNMDB-1F- 1.2(18G)/25-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/25-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/25- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/25- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/25-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/25- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/25- 2.4(13G)/150、 BNMDB-1F- 1.2(18G)/40-3.5(9G)/70 、 BNMDB-1F- 1.2(18G)/40-3.5(9G)/100	
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			、 BNMDB-1F- 1.2(18G)/40-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/40-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/40- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/40- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/40-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/40- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/40- 2.4(13G)/150、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/70 、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/100 、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/55-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/55- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/55- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/55-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/55- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/55- 2.4(13G)/150 BNMDB-1F- 1.6(16G)/25-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/25-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/25-3.5(9G)/150	
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			、 BNMDB-1F- 1.6(16G)/25-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/25- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/25- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/25-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/25- 2.4(13G)/100、 BNMDB-1F- 1.6(16G)/25- 2.4(13G)/150、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/150 、 BNMDB-1F- 1.6(16G)/40-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/40- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/40- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/40-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/40- 2.4(13G)/100、 BNMDB-1F- 1.6(16G)/40- 2.4(13G)/150、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/150 、 BNMDB-1F-	
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			1.6(16G)/55-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/55- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/55- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/55-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/55- 2.4(13G)/100、 BNMDB-1F- 1.6(16G)/55- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/25-3.0(11G)/70 、 BNMDB-1F- 1.8(15G)/25- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/25- 3.0(11G)/150、 BNMDB-1F- 1.8(15G)/25-2.4(13G)/70 、 BNMDB-1F- 1.8(15G)/25- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/25- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/40-3.0(11G)/70 、	
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			BNMDB-1F- 1.8(15G)/40- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/40- 3.0(11G)/150、 BNMDB-1F- 1.8(15G)/40-2.4(13G)/70 、 BNMDB-1F- 1.8(15G)/40- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/40- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/55-3.0(11G)/70 、 BNMDB-1F- 1.8(15G)/55- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/55- 3.0(11G)/150、 BNMDB-1F- 1.8(15G)/55-2.4(13G)/70 、 BNMDB-1F- 1.8(15G)/55- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/55- 2.4(13G)/150、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/70 、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/100 、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/150 、 BNMDB-1F- 2.1(14G)/25-3.0(11G)/70 、 BNMDB-1F- 2.1(14G)/25-	
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			3.0(11G)/100、 BNMDB-1F- 2.1(14G)/25- 3.0(11G)/150、 BNMDB-1F- 2.1(14G)/25-2.4(13G)/70 、 BNMDB-1F- 2.1(14G)/25- 2.4(13G)/100、 BNMDB-1F- 2.1(14G)/25- 2.4(13G)/150、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/70 、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/100 、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/150 、 BNMDB-1F- 2.1(14G)/40-3.0(11G)/70 、 BNMDB-1F- 2.1(14G)/40- 3.0(11G)/100、 BNMDB-1F- 2.1(14G)/40- 3.0(11G)/150、 BNMDB-1F- 2.1(14G)/40-2.4(13G)/70 、 BNMDB-1F- 2.1(14G)/40- 2.4(13G)/100、 BNMDB-1F- 2.1(14G)/40- 2.4(13G)/150、 BNMDB-1F- 2.1(14G)/55-3.5(9G)/70 、 BNMDB-1F- 2.1(14G)/55-3.5(9G)/100 BNMDB-1F- 2.1(14G)/55-3.5(9G)/150 、 BNMDB-1F- 2.1(14G)/55-3.0(11G)/70 、 BNMDB-1F- 2.1(14G)/55- 3.0(11G)/100、 BNMDB-1F- 2.1(14G)/55-	
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			3.0(11G)/150、 BNMDB-1F- 2.1(14G)/55-2.4(13G)/70 、 BNMDB-1F- 2.1(14G)/55- 2.4(13G)/100 BNMDB-1F- 2.1(14G)/55- 2.4(13G)/150 Class-B Shelf life: 3 Years	
67	Applicant Name: M/s ACP Systems 13&23 Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi ELI-00001 Date of R& I 18.04.2025 Fee: PKR 62000/- Slip: 573709244	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028 Shelf Life: not provide	Brand name: HeartMate Touch Communication System (Touch Communication System) Model: HMT1150 Components: 1-Power Adapter for HeartMate Touch Communication System HMT2133. 2-USB Cable for HeartMate Touch Communication System HNT2166. 3-Flash Drive for HeartMate Touch Communication System HMT2900. Fee 62000/- Class D	Rejected on following grounds Legalized FSC not provided
68	Applicant Name: M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18-04-2025 Fee: Rs.62000 Slip: 31788176	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028	Brand name: HeartMate 3 Surgical Hand Tools – 10002222INT Class D Shelf Life: nil years	Approved

		QMSC validity: 30.03.2028 EU technical documentation 25.07.2028		
69	Applicant Name: M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18.04.2025 Fee: Rs.62000 Slip: 4909987157	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028	Brand name: HeartMate Apical Coring Knife Model: 1050 Class D Shelf Life: 03 years Fee 62000/- DOC: 26.04.2024	Approved
70	Applicant Name: M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 18.04.2025 Fee: Rs.62000 Slip: 673039094464	Legal Manufacturer: Abbott Medical, 6035 Stoneridge Drive Pleasanton, CA 94588, USA Apostille FSC: (US FDA) Validity:12/06.2026 Notarized LOA: valid date: 31.12.2026 ISO 13485 Validity: 20-02-2028 QMSC validity: 30.03.2028 EU technical documentation 25.07.2028	Brand name: HeartMate 3 Tunneling Lance and Handle – 10010372GB Class D Shelf Life: nil years Fee 62000/-	Approved

71	Radiant Medical (Pvt) Ltd, 06 Sher Shah Block, New Garden Town, Lahore. ELI-00135 Date of R&I 21-04-2025 Rs.62000/- Slip# 219703842410	Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. LOA Validity: 31-12-2025 (Notarized) FSC (Germany) Dated 01-07-2024 without validity (Apostille) EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized) ISO 13485 Validity: 03-04- 2027 (Notarized)	ERBE VIO 300D Electrosurgical Unit Class C Apply as Family Shelf Life: N/A Codes/Sizes (if any): 10140-100 ERBE VIO 300 D 10140-200 ERBE VIO 200 D 10140-300 ERBE VIO 300 S 10140-400 ERBE VIO 200 S 10140-550 ERBE VIO 50 C 10140-500 ERBE VIO 100 C 10160-000 VIO 3	Approved
72	Radiant Medical (Pvt) Ltd, 06 Sher Shah Block, New Garden Town, Lahore. ELI-00135 Date of R&I 21-04-2025 Rs.62000/- Slip# 81413971	Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. LOA Validity: 31-12-2025 (Notarized) FSC (Germany) Dated 01-07-2024 without validity (Apostille) EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized) ISO 13485 Validity: 03-04- 2027 (Notarized)	ERBE CRYO 2 Cryosurgical Unit Class C Apply as Family Shelf Life: N/A Codes/Sizes (if any): 10402-000	Approved

73	Radiant Medical (Pvt) Ltd, 06 Sher Shah Block, New Garden Town, Lahore. ELI-00135 Date of R&I 21-04-2025 Rs.62000/- Slip# 3624385046	Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. LOA Validity: 31-12-2025 (Notarized) FSC (Germany) Dated 01-07-2024 without validity (Apostille) EU Certificate for the assessment of the QMS Validity: 12-07-2026 (Notarized) ISO 13485 Validity: 03-04- 2027 (Notarized)	ERBE VIO 3 Electrosurgical Unit Class C Apply as Family Shelf Life: N/A Codes/Sizes (if any): 10140-100 ERBE VIO 300 D 10140-200 ERBE VIO 200 D 10140-300 ERBE VIO 300 S 10140-400 ERBE VIO 200 S 10140-550 ERBE VIO 50 C 10140-500 ERBE VIO 100 C 10160-000 VIO 3	Approved
73	IRTEQA BIOTEK (ELI-00218)	<u>Legal Manufacturer:</u> M/S PRECISION BIOSENSOR INC. South Korea Manufacturing Site: 306, Techno 2-ro, Yuseong- gu, Daejeon, South Korea Date of R&I 30th Nov 2022 FSC: Country of Origin: South Korea Valid & FSC: FSC of Reference Country: Germany Valid LOA Validity: 15-02-2025 Attached EC Certificate Valid ISO 13485 Validity: 04-04- 2025	Exdia Trop I Exdia NT proBNP Exdia D Dimer Exdia Hs CRP Exdia 3 in 1 Test (Trop I + Myoglobin + CKMB) Exdia SOB Test (Trop I + NT proBNP + D Dimer) Exdia TRF Plus Analyzer Class-B Shelf life: 1 year	Approved

74	IRTEQA BIOTEK (ELI-00218)	Legal Manufacturer: M/S PRECISION BIOSENSOR INC. South Korea Manufacturing Site: 306, Techno 2-ro, Yuseong- gu, Daejeon, South Korea Date of R&I 30th Nov 2022 FSC: Country of Origin: South Korea Valid & FSC: FSC of Reference Country: Germany Valid LOA Validity: 15-02-2025 Attached EC Certificate Valid ISO 13485 Validity: 04-04- 2025	Exdia Trop I Exdia NT proBNP Exdia D Dimer Exdia Hs CRP Exdia 3 in 1 Test (Trop I + Myoglobin + CKMB) Exdia SOB Test (Trop I + NT proBNP + D Dimer) Exdia TRF Plus Analyzer Class-B Shelf life: 1 year	Approved
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EVALUATOR: MINAHIL JAVED (intern I)

Deferred Cases:

Sr.No	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc	Decision
1.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20483; 10-Jul-2025 Fee: 31,000/- Slip # 13802338116	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Hemostasis Valve set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model: HV, HV-1, HV-2 Shelf Life: 3 years	Approved as generic name: Hemostasis Valve rather than set Code: HV

2.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20484; 10-Jul-2025 Fee: 6,000/- Slip # 5849181988	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Radial Artery Closure Band Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 3 years	Approved Code: TB-01.
3.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20486; 10-Jul-2025 Fee: 25,000/- Slip # 9432362065 challan no 52668702815 Rs.27200 Total fee paid:52200	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Balloon Inflation Device Applied as: kit Class: A Models/Code/sizes (as per FSC & application Model): BID1, BID2 Shelf Life: 3 years	Approved in class b
4.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20487; 10-Jul-2025 Fee: 50,000/- Slip # 26189518009	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026	Brand Name: Daseon Generic Name: Guide Wires Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model): 0.032/0.035/0.038*150c m, J tip, S tip 0.032/0.035/0.038*180c m, J tip, S tip 0.032/0.035/0.038*260c m, J tip, S tip Shelf Life: 3 years	Approved

		ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026		
5.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20482; 10-Jul-2025 Fee: 31,000/- Slip # 89015929200	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Three-way stopcocks Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: ST-01 Shelf Life: 3 years	Approved
6.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20486; 10-Jul-2025 Fee: 31,000/- Slip # 919902280186	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Manifolds Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: M02, m03 Shelf Life: 3 years	Approved

7.	Med Lab Services, Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala Scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi. ELI-00056 R&I Date: 15.07.2025 3354-A-Punjab Fee: 6000/- Slip #271065586	Legal Manufacturer: GeneProof a.s, Videnska 101/119, Dolni Herspice 619 00 Brno Czech Republic LOA Type: Original Notarization: Yes Validity: 31.12.2028 FSC Type: copy Issued by: Czech Republic Legalization: no (just notarized) Issue date: 05.06.2025 ISO – Certificate: Type: Copy Notarization: No Validity: 26.11.2026	Brand Name: GeneProof Generic Name: croBee NA16 Nucleic Acid Extraction System Plus Applied as: Single Class: A Models/Code/sizes (as per FSC & application CBNA/16P Shelf Life: NA	Approved
8.	Name & Address Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore ELI: 00135 Date of R&I 21-02-2024 (4636-P) Fee Rs. 50,000/	(LEGAL MANUFACTURER) M/s Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany <u>Manufacturing Facility:</u> medPhoton GmbH KarolingerstaBe 16, 5020 Salzburg, Austria FSC Original: Austria Issued on 20-05-2019 (Original & attested) Marketing Authorization Letter: LOA valid till 31-12-2025 Production Quality Management System Certificate (ISO 13485) Valid till 04-10-2026 Full Quality Assurance Certificate or Equivalent: Issued by TUV, Germany (0123) valid till 26-05-2024 (Expired but valid upon submission) Design Examination N/A Declaration of Conformity (Doc): Provided	Brand Name ImagingRing m-Loop-X Mobile Imaging Robot (ImagingRing m) Codes/ sizes/models P04 Class: C Expected Service Life: 10 years	Approved

9.	ASSU Healthcare, House No. 186-C Pak Arab Housing Society Feroz Pur Road, Lahore ELI-00867 R&I Date: 12-06-2025 Fee: Rs. 6,000 vide deposit slip no. 1015681176	Name of Manufacturer: Hebei Houde Hanfang Medical Devices Group Co., Ltd., Address: Beisun Village, Zhengding County, Shijiazhuang City, Hebei Province China LOA Type: Copy Notarization: Notarized validity date: 21-04-2030 FSC: Type: Copy Issued By: Hebei Houde Hanfang Medical Devices Group Co., Ltd. Legalization: Apostille Validity: Not mentioned ISO – Certificate: Type: Copy Notarization: No Validity: 27-01-2028	Brand Name: Easy Save Fever Generic Name: Hydro Gel Patch Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life: 2year (2 – 8oC)	Rejected on following grounds: FSC is by manufacturer itself not by the relevant regulatory authority of country of origin. No clarification for applied product size/codes
10.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44- A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 8226727936 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec- 2025 (Copy) FSC (China) validity: 20- Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate	Procalcitonin Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Applied as: Kit Class-C Shelf life: 24 Months Models/ Specification: Low: 2x2.0mL, High: 2x2.0 mL	Approved

		validity: 14-Nov-2025 (Copy)		
11	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 6533457219 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)	SCCA Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml) Applied as : Kit Class-C Shelf life: 18 Months	Approved

12	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 74958374905 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)	BNP Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml) Applied as : Kit Class-C Shelf life: 24 Months	Approved
13	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 1790232865 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-	CYFRA 21-1 Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml) Applied as : Kit Class-C Shelf life: 24 Months	Approved

		2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)		
14	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 25999604631 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)	HE4 Control Immunoassay Controls (Low: 2×2.0ml) (High: 2×2.0ml) Models/ Specification (Low: 2×2.0ml) (High: 2×2.0ml) Class-C Shelf life: 18 Months	Approved

15	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R& I 14-04-2025 Fee: PKR 62,000/- Slip # 04694918 Dated: 08-04-2025	Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China Manufacturing Site: Shenzhen Yhlo Biotech CO., LTD. Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China. LOA validity: 31-Dec-2025 (Copy) FSC (China) validity: 20-Dec-2026 (Apostille)) FSC (Germany) issued on 19-03-2025 (Embassay Attested) ISO 13485 certificate validity: 14-Nov-2025 (Copy)	NSE Control Immunoassay Controls (Low: 2×1.0ml) (High: 2×1.0ml) Models/ Specification (Low: 2×1.0ml) (High: 2×1.0ml) Class-C Shelf life: 24 Months	Approved
16	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 572173279554 fee paid 26,130/- challan no : 47492874 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China. • LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N240 (As per FSC) Applied as: Kit Shelf life: 10 Years	Rejected on following grounds: Firm has not provided original documents of LOA & ISO certificate.

		• ISO Certificate Type: Copy of Attested Attested By: CCPIT Validity: 31-08-2026		
17	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 8291315693 fee paid 26,130/- challan no:10401528 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China, China. • LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026 • ISO Certificate Type: Copy of attested Attested By: CCPIT Validity: 31-08-2026	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N60 (As per FSC) Shelf life: 10 Years	Rejected on following grounds: Firm has not provided original documents of LOA & ISO certificate.
18	M/s. MR Medical Pakistan Pvt Ltd., Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad. (ELI- 01008) R&I detail 20-05-2025 Fee: 6,000/- Slip: 55281339 fee paid 26,130/- challan no: 54607466453 Dated: 16-05-2025	Name of Manufacturer: M/s. Shenzhen Mindray Bio-Medical Electronics Co. Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, China. • LOA Type: Copy of attested Attested By: CCPIT Validity: 14-04-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 22-12-2026 • ISO Certificate	Brand name: Mindray Automated Blood Culture System Generic Name: Automated Blood Culture System Class: A Codes/Sizes: FA-N120 (As per FSC) Applied as: Kit Shelf life: 10 Years	Rejected on following grounds: Firm has not provided original documents of LOA & ISO certificate.

		Type: Copy of attested Attested By: CCPIT Validity: 31-08-2026		
19	Applicant Name: Johnson & Johnson Pakistan (Pvt) Ltd., Office No. 506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton Karachi (ELI-00154) Date of R&I 23-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 049133449	Name of Manufacturer: Deputy Ireland UC, Loughbeg, Ringaskiddy, Co, Cork, Ireland Physical Manufacturer: Johnson & Johnson Medical (Suzhou) No. 299, Changyang Street, Suzhou Industrial Park, Suzhou, 215126, China LOA Issue date: 19-01-2023(Copy) FSC: Ireland Issue date: 30-06-2023(Copy) ISO Validity: 15-07-2027 (Copy) EU QA Certificate Validity: 10-06-2025 (Copy) EU technical doc Validity 8.11.2027	Brand name: Smart Oval Dome Patella Generic Name: Sigma Oval Dome Patella Class-D Shelf life: 5 Years Applied as: System Models/ Specification 960100 960101 960102 960103	Approved as sigma oval dome patella 3- Peg Cemented 3mm.
20	Applicant Name: Johnson & Johnson Pakistan (Pvt) Ltd., Office No. 506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton Karachi (ELI-00154) Date of R&I 23-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 849950997620	Name of Manufacturer: Deputy Ireland UC, Loughbeg, Ringaskiddy, Co, Cork, Ireland LOA Issue date: 19-01-2023(Copy) FSC: Ireland Issue date: 30-06-2023(Copy) ISO Validity: 15-07-2027 (Copy) EU QA Certificate Validity: 10-06-2025 (Copy) EU tec doc Certificate Validity: 08.11.2027 (Copy)	Brand name: PFC Sigma Tibial Insert Rotating Platform Stabilized Generic Name: PFC Sigma Tibial Insert Rotating Platform Stabilized Codes as per FSC Class-D Shelf life: 5 Years Applied as: System Models/ Specification	Rejected on following grounds: Firm has not submitted design Examination certificate. ISO expired Eu quality management system certificate expired

21	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e- Iqbal, Karachi (ELI-00691) Date of application 18.04.2025 Fee Rs 62000	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China Notarized LOA valid till 25.02.2030 Copy of Netherlands FSC Valid till: 31.12.2031 ISO valid till 19.06.2027 Copy of FQA valid till 27.05.2024 and complete extension letter having code not provided Notarized LOA valid till 25.02.2030 Copy of Design examination 27.05.2024 FSC china Valid till: 08- 04-2026	Restenix (Drug (Paclitaxel) Coated Balloon Catheter) Shelf life 02 years Fee 62000/- Challan no 303210117199 Class D PCB20010, PCB20014, PCB20018, PCB20022, PCB20026, PCB20030, PCB20034, PCB20038, PCB22510, PCB22514, PCB22518, 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,	Rejected on following grounds: As per OEM applied brand name should be on LOA, DOC or FSC. Other shortcomings were also not fulfilled.
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			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	
22	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e- Iqbal, Karachi (ELI-00691) Date of application 18.04.2025	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China apostille china FSC Valid till: 08-04-2026 USFDA FSC Valid till: 03- 04-2026 ISO valid till 19.06.2027 Notarized LOA valid till 25.02.2030	Valvoflex (Valvuloplasty Balloon Catheter) Shelf life 03 years VBC1540、 VBC1840、 VBC2140、 VBC2340、 VBC2640、 VBC2940: Class D	Rejected on following grounds: As per OEM applied brand name should be on LOA, DOC or FSC. Other shortcomings were also not fulfilled.

23	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 SD40030	Rejected on following grounds: As per OEM applied brand name should be on LOA, DOC or FSC. Other shortcomings were also not fulfilled.
24	Royal Medical, Office No. 26th, 3rd United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi ELI-00691 Date of R&I 22-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 501445524411 R&I Date 18-09-2025	<u>Legal Manufacturer:</u> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Validity: 16-02-2030 FSC: China Validity: 26-10-2025 ISO Validity: 30-10-2026 EU QA Certificate Validity: 05-02-2029	Antmed Maniflod Class-B Shelf life: 3 Years Models/ Specification; MD-M-1 MD-M-2 MD-M-3 MD-M-4 MD-L-1 MD-L-2	Approved in 112th meeting and registration letter is already been issued.

25	Royal Medical, Office No. 26th, 3rd United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi ELI-00691 Date of R&I 22-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 086749938764 R&I Date 18-09-2025	<u>Legal Manufacturer:</u> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Validity: 16-02-2030 FSC: China Validity: 26-10-2025 ISO Validity: 30-10-2026 EU QA Certificate Validity: 05-02-2029	Antmed Inflation Device Class-B Shelf life: 5 Years Models/ Specification; ID-1000 ID-1001 ID-3000 ID-3001	Rejected on following grounds: Firm has not submitted: Ce certificate for clarification of Cardiac Angiography Devices class Fee for the family
26	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan- e-Iqbal Karachi. (ELI-00294) 3994-C 62,000/-	<u>Legal Manufacturer:</u> Bio Med Devices Inc. 61 Soundview Road, Guilford, CT 06437, USA FSC US FDA validity 07- 02-2026	BMD Air Oxygen Blender Class-C Service life: 10years Model: 2003FFE1	Rejected on following grounds: Firm has not provided any documentary evidence for changing or clarification brand name as biomed for applied product.
27	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST- 3, Block-3, Gulshan- e-Iqbal Karachi (ELI-00294)	Shandong Ande Healthcare Apparatus Co., Ltd. No. 999, Zunxian Road, New & Hi-Tech Zone, Zibo Shandong, P.R.China	Disposable IV Catheter	Rejected on following grounds: Types of cannula were not mentioned on FSC and issuing authority is in Chinese language. Multiple codes are applied on form 7 A without its clarification whereas fee is only paid for 16,18,20,22,24

28	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 14-05-2025 Fee: 31,000/- Slip # 99364681800.	Name of Manufacturer: Bonree Medical Co.Ltd. Address: 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang 528451 Zhongshan, Guangdong, People's Republic of China LOA: Type: Copy Notarization: Apostille Issue Date: December, 2024 Validity: 30-12-2028 -- FSC: Type: Copy Issued By: Not mentioned Legalization: Apostille Validity: 24-10-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 26-05-2024	Brand Name: Bonree Ureteral Stent Sets Generic Name: Ureteral Stent Sets Applied as: Single Class: B Models/Code/sizes (as per FSC & application Types: 4.0Fr, 4.7Fr, 5.0Fr, 6.0Fr, 7.0Fr, 8.0Fr Shelf life: 05 years (Room temperature)	Rejected on following grounds: Applied Brand name VISTA FOR THE product Ureteral Stent Sets is not mentioned either on LOA or FSC.
29	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 14-05-2025 Fee: 6,000/- Slip # 94778916156.	Name of Manufacturer: Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd Address: Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou, China LOA: Type: Copy Notarization: Apostille Issue Date: 22-04-2025 Validity: 30-12-2028 -- FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-09-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 20-10-2025	Brand Name: Closed Wound Drainage Catheter for Single Use Generic Name: Closed Wound Drainage Catheter for Single Use Applied as: Single Class: A Models/Code/sizes (as per FSC & application Types: SY-Fr10, SY-Fr12, SY- Fr14, SY-Fr16, SY-Fr18, SY-Fr20, SY-Fr22, BY- 7*3, BY 7*5, BY- 10*4, BY 10*5, YY-Fr4, YY-Fr14, YY Fr16, YY- Fr18, YY Fr20, YY-Fr22, YY Fr24, YY-Fr28, YYFr32, YY-Fr36 Shelf life: --	Rejected on following grounds: Applied Brand name VISTA FOR THE product Closed Wound Drainage Catheter for Single is not mentioned either on LOA or FSC.

30	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 04-06-2025 Fee: 31,000/- Slip # 60124851216447.	Name of Manufacturer: Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd Address: Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou, China LOA: Type: Copy Notarization: Apostille Issue Date: 22-04-2025 Validity: 30-12-2028 FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-09-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 20-10-2025 Copy of CE certificate submitted	Brand Name: Chest Drainage Catheter for single use Generic Name: Chest Drainage Catheter for Single Sue / Disposable thoracic drain catheter without trocar Chest Drainage Catheter for single use with Trocar Applied as: Class: B Models/Code/sizes (as per FSC & application Model: WI, WII, WII, ZI, ZII, ZIII Shelf life: 03 years	Rejected on following grounds: Applied Brand name VISTA FOR THE product thoaracic/ Chest Drainage Catheter for single use for Single is not mentioned either on LOA or FSC.
31	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 04-06-2025 Fee: 31,000/- Slip # 42005857827.	Name of Manufacturer: Jinhua Huacheng Medical Appliance Co, Ltd Address: Building 54,177 Shicheng Street, Wucheng District, Jinhua City, 321016 Zhejiang, P.R. China. LOA: Type: Copy Notarization: No Validity: 20-5-2030 FSC: Not submitted ISO – Certificate: Type: Copy Notarization: No Validity: 01-09-2026	Brand Name: Disposable Electrosurgical Pencil Generic Name: Disposable Surgical Active Electrodes (Electro surgical pencils) Applied as: Single Class: B Models/Code/sizes (as per FSC & application Models: HC-EP1/A/70, HC-EP1-B, HC-EP1-C, HC-EP1-A/100, HC-EP1- A/120, HC-EP1-A/140 Shelf life: 3 years (-20°C – 60°C)	Rejected on following grounds: FSC is not of revlent regulatory authority. Applied Brand name VISTA FOR THE product Disposable Electrosurgical Pencil issuee is not mentioned either on LOA or FSC.
32	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 04-06-2025 Fee: 31,000/- Slip # 387137159631.	Name of Manufacturer: Jiangsu Jianzhiyuan Medical Instruments Technology Co., Ltd Address: Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou, China LOA: Type: Copy Notarization: Apostille Issue Date: 22-04-2025 Validity: 30-12-2028 -- FSC: Type: Copy	Brand Name: Irrigation and Suction Catheter in Endoscopic Surgery for Single Use Generic Name: Irrigation and Suction Catheter in Endoscopic Surgery Applied as: Single Class: B Models/Code/sizes (as per FSC & application Models: CX-3 x 280-A CX-5 x 280-A CX-8 x 280-A	Rejected on following grounds: Applied Brand name VISTA FOR THE product Irrigation and Suction Catheter in Endoscopic Surgery for Single Use is not mentioned either on LOA or FSC.

		Issued By: Not mentioned Legalization: No Validity: 20-09-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 20-10-2025 Copy of CE certificate has been submitted.	CX-10 x 280-A CX-3 x 330-A CX-5 x 330-A CX-8 x 330-A CX-10 x 330-A CX-3 x 420-A CX-5 x 420-A CX-8 x 420-A CX-10 x 420-A CX-3 x 280-B CX-5 x 280-B CX-8 x 280-B CX-10 x 280-B CX-3 x 330 B CX-5 x 330-B CX-8 x 330-B CX-10 x 330-B CX-3 x 420-B CX-5 x 420-B CX-8 x 420 B CX-10 x 420-B Shelf life:	
33	M/s Cabbot Surgical, 09 Rose Lane 1 Gulberg Avenue New Lallzar Rawalpindi (ELI-00415) R&I Date: 14-05-2025 Fee: 31,000/- Slip # 88157474.	Name of Manufacturer: Bonree Medical Co.Ltd. Address: 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang 528451 Zhongshan, Guangdong, People's Republic of China LOA: Type: Copy Notarization: Apostille Issue Date: December, 2024 Validity: 30-12-2028 FSC: Type: Copy Issued By: Not mentioned Legalization: Apostille Validity: 24-10-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 26-05-2024 Copy of CE certificate valid till 31-07-2025 has been submitted	Brand Name: Bonree Nelaton Catheters Generic Name: Nelaton Catheters Applied as: Class: B Models/Code/sizes (as per FSC & application) Type/Size: For Female: Fr6, Fr8,Fr10,Fr12,Fr14, Fr16, Fr18, Fr20,Fr22, Fr24 For male: Fr6, Fr8,Fr10,Fr12,Fr14, Fr16, Fr18, Fr20,Fr22, Fr24 Shelf life: 05 years (Room temperature)	Rejected on following grounds: Applied Brand name VISTA FOR Nelaton catheters is not mentioned either on LOA or FSC.

34	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 6,000/- Slip # 14591733201	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027	Brand name: Cam Source® LED Generic Name: Camera & Light Source System Applied as: Single Class: A Model/Codes/Sizes: 1. CSFHD01-Camsource® LED Control Unit 2. CSFHD01CC-Camera Head Combo for Cam Source® LED Joimax® single cable technology, with function buttons 3. CSFHD01CO-Camera Head Ocular for Cam Source® LED with function buttons. 4. CSFHD01COAS-Fiber Optic Cable Adapter. Service life: Not mentioned	Approved
35	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 6,000/- Slip # 452409000328	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027	Brand name: Vitegra® Generic Name: Visual Integration System Applied as: Single Class: A Model/Codes/Sizes: 1. ICS0401S-Joimax Vitegra Visual Integration System Fully integrated Full HD documentation system. 2. ICS0401-Joimax Vitegra Control Unit 3. ICS0401D-Joimax Vitegra DICOM Module 4. JECTTHS-Joimax Vitegra Tablet mount set joimax tablethalter set 5. JESTTH-Adapter plate.	Approved

			6. JVFS0001- Joimax Vitegra Foot Switch. Service life: Not mentioned	
36	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: Not submitted	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029	Brand name: Intracs® EM Sytem Generic Name: Integrated Navigation Tracking & Control System Applied as: Single Class: B Model/Codes/Sizes: 1. JINT01S-Intracs EM System. Integrated Navigation Track & Control. 2. JINTCU1115-Intracs EM Control Unit 3. JINTFG1125-Intracs EM Field Generator. 4. JINTPM2245-AP- Intracs EM Patient Mapper-AP 5. JINTPM2245-LAT- Intracs EM Patient Mapper-LAT 6. JINTSC2205-Intracs EM Sensor Clip 7. JINTPT2235-Intracs EM Patient Tracker. Service life: 3 Years	Approved
37	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 31,000/- Slip # 4337260846	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned	Brand name: Versicon® Spine Pump Generic Name: Irrigation Pump Applied as: Single Class: B Model/Codes/Sizes: JISP3000 Service life: 3 Years	Approved

		• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029		
38	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 6,000/- Slip # 2960963069 paid of 20100 challan no 911399370341	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027	Brand name: Intralaminar Endoscopic Surgical System (ILESSYS) Transforaminal Endoscopic Surgical System (TESSYS) Cervical Endoscopic Surgical System (CESSYS) Generic Name: Intralaminar Endoscopic Surgical System (ILESSYS) Transforaminal Endoscopic Surgical System (TESSYS) Cervical Endoscopic Surgical System (CESSYS) Applied as: Single Class: A Model/Codes/Sizes: Not mentioned in application. Service life: Not mentioned	Rejected on following grounds: Multiple codes/models are mentioned on FSC No justification/clarification provided for grouping while multiple models/codes are applied in single.
39	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 62,000/- Slip # 476366701	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body	Brand name: Endovapor® 2 Generic Name: Multi Radio Frequency System Applied as: Single Class: C Model/Codes/Sizes:	Approved

		Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029	1. JEVD0201-Endovapor 2 Device (Power rating 220-240V) 2. JEVD0202-Endovapor 2 Device (Power rating 100-127V) 3. REFUSS01-Footswitch Endovapor 2 Service life: 3 Years	
40	Sadqain Healthcare Pvt. Ltd. Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi, Pakistan ELI -00020 R&I Date:15.09.2023 Fee: 25000/- Slip # 6845118953 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 2N3-3AG-596J	Legal Manufacturer: Intersurgical Limited. Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom Manufacturing site: UAB Intersurgical Arnioniu 60, Pabrade, Lithuania LOA Type: scanned copy Notarization: No Validity: 01.03.2026 FSC Type: scanned copy Issued by: MHRA, UK Legalization: Yes, legalized the apostille of notarization. Issue date: 30.06.2029 ISO – Certificate: Type: Scanned copy Notarization: Yes Validity: 26.11.2026 CE certificate / EU QMS certificate (MDR) Type: scanned copy Notarization: No (notarized the statement of manufacturer, not the certificate) Validity: 26.11.2023 Extended till 31.12.2028	Brand Name: i-flo™ High flow nasal cannula Generic Name: Suction and irrigation oral care toothbrush Applied as: Set Class: B Models/Code/sizes (as per FSC & application: 7302000: Large Adult 7301000: Medium Adult 7300000: Small Adult 2060310: 22mm flex tube single heated wire limb with auto fill chamber and extra limb $\geq 1.6m$ Shelf Life: 3 years	Approved Code: 7300000: Small Adult

41	Sadqain Healthcare Pvt. Ltd. Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi, Pakistan ELI -00020 R&I Date: 05.05.2023 Fee: 25000/- Slip # 57417224140 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 2N3-3AG-596J	Legal Manufacturer: Intersurgical Limited. Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom Manufacturing site: UAB Intersurgical Arnioniu 60, Pabrade, Lithuania LOA Type: scanned copy Notarization: No Validity: 01.03.2026 FSC Type: scanned copy Issued by: MHRA, UK Legalization: Yes, legalized the apostille of notarization. Issue date: 30.06.2029 ISO – Certificate: Type: Scanned copy Notarization: Yes Validity: 26.11.2026 CE certificate / EU QMS certificate (MDR) Type: scanned copy Notarization: No (notarized the statement of manufacturer, not the certificate) Validity: 26.11.2023 Extended till 31.12.2028	Brand Name: OroCare Sensitive oral suction wand Generic Name: Suction and irrigation oral care toothbrush Applied as: Single Class: B Models/Code/sizes (as per FSC & application: 3017000 Shelf Life: 3 years	Approved
42	M/s. Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI-01234) R&I Date: 26-05-2025 Fee: 6,000/- Slip # 751688293	Name of Manufacturer: Hangzhou Tuopusi Medical Products Co., Ltd., Room 606, Mutouqiao 8-36, Donglian Village, Liangzhu Street, Yuhang District, Hangzhou City, Zhejiang Province, China LOA Type: Original Notarization: Apostille Issue Date: 05-02-2025 Validity: 04-2026 • FSC Type: Original Issued By: Zheijiang Medical product Administration Legalization: Apostille Issue Date: 21-02-2025 Validity: 20-02-2027 • ISO – Certificate: Type: Copy	Brand Name: CURE+ Hydrocolloid Dressing Generic Name: Hydrocolloid Dressing Applied as: Family Class: A Models/Code/sizes (as per FSC & application Model:	Rejected on following grounds: Product falls in class B as per MDR 2017 while applied in class A.

		Notarization: Yes Validity: 26-03-2027	1.25cmx5y ; 2.5cmx5y ; 5cmx5y ; 7.5cmx5y ; 10cmx5y; 1.25cmx10y; 2.5cmx5y ; 5cmx10y ; 7.5cmx10y; 10cmx10y ; 12" x10y; 1.25cmx5m; 2.5cmx5m ; 5cmx5m ; 7.5cmx5m ; 10cmx5m ; 5cmx5cm; 10cmx10cm; 1.25cmx10m; 2.5cmx10m; 5cmx10m; 7.5cmx10m ; 10cmx10m; 1.25cmx1m; 2.5cmx1m; 15cmx10m ; 20cmx20cm; 15cmx15cm 100cmx4.5m; 100cmx5m; 100cmx10m etc	
			Shelf Life: 5 years	
43	M/s. Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI-01234) R&I Date: 26-05- 2025 Fee: 6,000/- Slip # 46346456765	Name of Manufacturer: Hangzhou Tuopusi Medical Products Co., Ltd., Room 606, Mutouqiao 8-36, Donglian Village, Liangzhu Street, Yuhang District, Hangzhou City, Zhejiang Province, China LOA Type: Original Notarization: Apostille Issue Date: 05-02-2025 Validity: 04-2026 • FSC Type: Original Issued By: Zheijiang Medical product Administration Legalization: Apostille Issue Date: 21-02-2025 Validity: 20-02-2027 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 26-03-2027	Brand Name: CURE+ Hydrogel Dressing Generic Name: Hydrogel Dressing Applied as: Family Class: A Models/Code/sizes (as per FSC & application 1.25cmx5y ; 2.5cmx5y ; 5cmx5y ; 7.5cmx5y ; 10cmx5y; 1.25cmx10y; 2.5cmx5y ; 5cmx10y ; 7.5cmx10y; 10cmx10y ; 12" x10y; 1.25cmx5m; 2.5cmx5m ; 5cmx5m ; 7.5cmx5m ; 10cmx5m ; 5cmx5cm; 10cmx10cm; 1.25cmx10m; 2.5cmx10m; 5cmx10m; 7.5cmx10m ; 10cmx10m; 1.25cmx1m; 2.5cmx1m; 15cmx10m ; 20cmx20cm; 15cmx15cm 100cmx4.5m; 100cmx5m; 100cmx10m etc Model: Shelf Life: 5 years	Rejected on following grounds: Product falls in class B as per MDR 2017 while applied in class A.

44	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 Fees: Rs 62000 Challan # 287678899 Date of R& I 05-05-2025	<u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China. <u>LOA:</u> Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized) <u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) <u>FSC: Spain</u> Issue date:12-03-2024 (Original Notarized) EC Certificate valid until:05-08-2029 (Original Notarized) <u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)	Biosky-Disposable Bilirubin Adsorption Column Class C Shelf Life: 3 years Codes/Sizes: DX100, DX150, DX250, DX350, DX400	Rejected on following grounds: Issuance date is not mentioned on LOA.
45	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 Fees: Rs 62000 Challan # 341787471002 Date of R& I 05-05-2025	<u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China. <u>LOA:</u> Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized) <u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) <u>FSC: Spain</u> Issue date:12-03-2024 (Original Notarized) EC Certificate valid until:05-08-2029 (Original	BIOSKY - DISPOSABLE HEMOPERFUSION CARTRIDGE Class C Shelf Life: 3 years Codes/Sizes: MG80, MG100, MG120, MG130, MG150, MG180, MG200, MG230, MG250, MG280, MG300, MG330, MG350, MG380, MG400	Rejected on following grounds: Issuance date is not mentioned on LOA.

		Notarized) <u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)		
46	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20101; 07-Jul-2025 Fee: 31,000/- Slip # 256572022	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued by: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-6000 Super Inductive System Generic Name: High-Intensity Electromagnetic Therapy Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model: BTL-6000 Super Inductive System 1. BTL-6000 Super Inductive System Pro 2. Inductive BTL-6000 Super Inductive System Elite 3. Planar field applicator BTL- 299-1 4. Focused field applicator BTL- 299-2 Shelf Life: 5 years	Approved BTL-6000 Super Inductive System

Item No. III: **PERSONAL HEARING CASES**

Case No. 01

Name Address of Importer	Name M/s Uniplan Trade International Pvt Ltd Address of Importer 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.
Detail of ELM/ELI	Establishment License No. ELI-00132

Name Address of Manufacturer	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Company Address: 61346, Bad Homburg Germany. Contact: +49 6172 686 0 Website: https://www.fresenius-kabi.com/ Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.
Name of exporting country	Germany
Brand Name	Compoflex® 3F 63ml CPDA-1 PDS-V
Country of origin FSC	FSC: Germany Issuance Date: 17 th October, 2023
Date of application received along with Fee	R & I 28-04-2024 (4706-P) Fee Amount & Fee Submission Date: Rs. 50,000
Class of medical device	D
Brief Description of the Medical Device with intended use	Blood donation system with anti-coagulant solution intended for collection, processing and storage of blood and blood components
Stability data/ service life	Shelf Life: 24 Months
Documents submitted	
Marketing Authorization Letter:	Marketing Authorization Letter: Validity Date: 31 st December, 2024
Production Quality Management System Certificate (Iso 13485)	Production Quality Management System Certificate (ISO 13485) Validity Date: 31 st March, 2025
Full Quality Assurance Certificate or Equivalent:	Full Quality Assurance Certificate or Equivalent: Validity Date: 26 th May, 2024
Design Examination	Design Examination Validity Date: Not Provided
Declaration of Conformity (Doc):	Declaration of Conformity (Doc): Provided
Codes/ sizes	Compoflex® 3F 63ml CPDA-1 PDS-V T331150
Remarks	Products are already registered in the name of M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore.
Decision	<i>Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for</i>

	personal hearing for the confirmation of valid letter of authorization.
	<i>In compliance to the decision of MDB, personal hearing notices to both the firms have been issued</i> <i>Submitted for consideration of MDB.</i>

Case No. 02

Name Address of Importer	Name M/s Uniplan Trade International Pvt Ltd Address of Importer 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.
Detail of ELM/ELI	Establishment License No. ELI-00132
Name Address of Manufacturer	LEGAL MANUFACTURER M/s. Fresenius Kabi AG Company Address: 61346, Bad Homburg Germany. Contact: +49 6172 686 0 Website: https://www.fresenius-kabi.com/ Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.
Name of exporting country	Germany
Brand Name	Compoflex® 4F 63ml CPDA-1 PDS-V
Country of origin FSC	FSC: Germany Issuance Date: 17 th October, 2023
Whether the product is applied on CE certificate basis or free sale in reference countries	Reference Country FSC (Germany)
Date of application received along with Fee	R & I 28-04-2024 (4721-P) Fee Amount & Fee Submission Date: Rs. 50,000
Class of medical device	D
Brief Description of the Medical Device with intended use	Blood donation system with anti-coagulant solution intended for collection, processing and storage of blood and blood components
Stability data/ service life	Shelf Life: 24 Months
Documents submitted	
Marketing Authorization Letter:	Marketing Authorization Letter: Validity Date: 31 st December, 2024

Production Quality Management System Certificate (ISO 13485)	Production Quality Management System Certificate (ISO 13485) Validity Date: 31 st March, 2025
Full Quality Assurance Certificate or Equivalent:	Full Quality Assurance Certificate or Equivalent: Validity Date: 26 th May, 2024
Design Examination	Design Examination Validity Date: Not Provided
Declaration of Conformity (Doc):	Declaration of Conformity (Doc): Class D
Codes/ sizes	Compoflex® 4F 63ml CPDA-1 PDS-V T431150
Remarks	Products are already registered in the name of M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore.
Decision	<i>Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for personal hearing for the confirmation of valid letter of authorization.</i>
	<i>In compliance to the decision of MDB, personal hearing notices to both the firms have been issued</i> <i>Submitted for consideration of MDB.</i>

Accordingly, the personal hearing letter was issued to both of the firm on 14 May, 2026 for M-131.

Proceedings and Decision of 131st Meeting of MDB:

- The representative M/s Uniplan Trade International Pvt. Ltd 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore, namely Javed Ahmed senior sales representative appeared before the Board. But he was not authorized for the board meeting.
- No representative from M/s. Fresenius Kabi AG, appeared before the Board despite due notice.

Decision: The Board decided to grant a final opportunity of personal hearing to M/s Uniplan Trade International Pvt. Ltd. and M/s Fresenius Kabi Pakistan (Pvt.) Ltd., Lahore, in the matter regarding the registration of medical devices manufactured by M/s Fresenius Kabi AG, as the applied product is already registered in the name of M/s Fresenius Kabi Pakistan (Pvt.) Ltd., Lahore.

Both firms are directed to clarify their position regarding the authorization/registration status of the above-mentioned products and submit relevant documentary evidence in support of their claim/authorization

CASE NO.03: CANCELLATION OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

With reference to the subject noted above, it is to state that following medical devices manufactured by Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands have been registered with M/s Medic Ally (Pvt) Ltd, Lahore :-

S.#	Regn. No.	Name of Medical Device	Date of Registration
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1.	MDIE-0000766	Humeca Mesher (Mesher) [6.HM01]	18-12-2023
2.	MDIE-0000817	MEEK Micrografting machine (Micrografting machine) [3.MD, 3.HD]	18-04-2024
3.	MDIE-0000816	Humeca Skin Transplantation carrier (Skin Transplantation Carriers)	18-04-2024

2. The above mentioned manufacturer has cancelled the Agency Agreement with M/s Medic Ally (Pvt) Ltd, Lahore.

3. Keeping in view the above, the case was placed before the Medical Device Board (MDB) in its 115th meeting held on 1st January, 2026 for consideration. The MDB decided as under:-

“Mr. Eman Iqbal, representing M/s Biowel Sciences, appeared before the Board and informed that M/s Humeca B.V. has already terminated the Letter of Authorization (LoA) issued in favor of M/s Medic Ally (Pvt.) Ltd. and has appointed M/s Biowel Sciences as its authorized distributor in Pakistan. No representative from M/s Medic Ally (Pvt.) Ltd., Lahore, appeared before the Board despite due notice. After due consideration of the facts placed before it, the Board decided to initiate the process for de-registration of the above-mentioned products currently registered in the name of M/s Medic Ally (Pvt.) Ltd., and to issue Show Cause Notice to M/s Medic Ally (Pvt.) Ltd., Lahore under the relevant provisions of the applicable Medical Devices Rules/Regulations, calling upon them to explain why the registration/enlistment of the said medical device(s) should not be cancelled.

4. In compliance to the decision of MDB, show cause notice was issued to M/s Medic Ally (Pvt) Ltd, Lahore under Medical Devices Rules, 2017.

5. **Notice for Personal hearing to M/s Medic Ally (Pvt) Ltd, Lahore has been issued to the firm.**

Submitted for consideration of MDB pleaser.

Proceedings and Decision of 131st Meeting of MDB:

- No representative from M/s Medic Ally (Pvt.) Ltd., Lahore, appeared before the Board despite due notice.

Decision: The Board decided to grant a final opportunity of personal hearing to M/s Medic Ally (Pvt.) Ltd., Lahore, in the matter regarding the registration of medical devices manufactured by Humeca B.V., Oostermaat 5, 7623 CS Borne, The Netherlands, under the case of cancellation of registration of medical devices.