

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

DECISIONS OF 107TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 05-11-2025
(MANUAL APPLICATIONS PART-II)

107th 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 5th November, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, CDI, Nominee of DGHS Balochistan	Member (attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
4.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member (attended meeting through videolink)
6.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
10.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)

11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary
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Sr. NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X
10.	Mr. Hanif Ullah	Deputy Director-XI

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

Item No. I(A): 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 New Chemical Centre, Basement, 3-Edward, Syed Mouj Darya Road, Lahore, Data Gunj Bukhsh Town, Lahore	Sadaqat Hussain BSc Biotechnology	Approved

2.	M/s Precimmo (Pvt) Ltd., F-748/N, Old Star Labour Colony, S.I.T.E, Karachi	Dr. Shoaib Rao Dr. rer. nat (Cancer Biology)	Deferred for approval of technical staff in accordance with Medical Devices Rules 2017
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Item No. I(B): APPLICATIONS FOR GRANT OF RENEWAL OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

Renewal Cases ELI

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Nwill Healthcare, Office/Godown: Office No. B-9, Royal Garden Hotel Building, 19-Birdwood Road, Lahore (ELI-00164)	Ms. Marium Ashraf Bhatti Pharm D	Naveed Sarwar	Approved
2.	M/s S.J Traders, Office/Godown: Office No. 14, 3 rd Floor, Majeed Plaza, Bank Road, Saddar Rawalpindi (ELI-00531)	Ms Hina Raees Pharmacist	Muhammad Saeed	Approved
3.	M/s Krestacrop, Office/Godown: 76-C, 3 rd Floor, Office No. 2, Khayaban-e- Jami, Street No. 9, DHA, Phase-7, Karachi (ELI-00258)	Ms. Farheen Jeelani, BSC Computer Science	Kanwer Nouman Haseeb Kanwar Abdul Haseeb	Approved
4.	M/s IBL Health Care, Section A, 2 nd Floor, One IBL Centre, Plot No. 1, Block 7&8, SMCHS, Tipu Sultan Road, Off Shahrah-e- Faisal, Karachi (ELI-00119) Godown:Plot No. 56, Sector 7/A, Korangi Industrial Area, Karachi	Dilawar Hussain Pharm D	Mufti Zia Ul Islam Rashid Abdullah Shahid Abdullah Syed Nadeem Ahmed Zubair Razzak Shuja Malik Mst. Ameena Saiyad	Approved

5.	M/s Tech Zone, Office/Godown: Ground Floor, Weal House, 8 Faiz Road, Old Muslim Town Lahore (ELI-00040)	Ms. Rabia Nafees Pharm D	Muhammad Ali Hassan Qadri	Approved
6.	M/s Novatek Pakistan, Office/Godown: P-20, 1 st Floor, Chenab Market, Susan Road, Madina Town, Faisalabad (ELI-00454)	Ms. Wajeeha Ashraf Pharm D	Munawwar Hussain Zahid	Approved
7.	M/s Biological Medical Systems, Office/Godown: Plot No. 224-B, Block-2, PECHS, Karachi (ELI-00346)	Engr Muhammad Shahid Ehsan Suri Bio Medical Engineer	Kamran Tahir	Approved
8.	M/s Surgical World, Office No. 105, 1 st Floor, Rehmani Chamber, Altaf Hussain Road, New Chali, Karachi Godown: Office No. 104, 1 st Floor, Rehmani Chamber, Altaf Hussain Road, New Chali, Karachi	Farhan Ahmed Ansari, Pharm D	Fahad Anis	Approved
9.	M/s Future D Pakistan, Office/Godown: 15A, Block G, Johar Town, Lahore (ELI-00568)	Sehrish Saeed BS Biotechnologist	Umer Hayat	Approved
10.	M/s Human Health Care, Office/Godown: 61 A, Revenue Employees Cooperative Housing Socety M A Johar Town, Lahore (ELI-00299)	Ms. Faiza Kanwal Shaukat Pharm D	Muhammad Arslan Latif	Approved
11.	M/s Mais Medical Products (SMC-Pvt) Ltd., Office/Godown: 149-M, MA Johar Town, Near Mughul Eye	Ms. Saima Gillani Pharm D	Salman Rashid	Change of godown to new location approved. For renewal the firm shall make a new application 60 days before expiry of

	Hospital Lahore (ELI-693)			validity of license in accordance with Medical Devices Rules 2017. For Technical staff the firm shall make a new application with applicable fee as post license variation application
12.	M/s Cure Traders (SMC) Pvt. Ltd., Office/Godown: House No. 236, Street No. 1, Sector F-8, Phase-6, Hayatabad Peshawar (ELI-00491)	Muhammad Faraz Shah Pharm D	Muhammad Rafiq	Deferred for approval of technical staff first in accordance with Medical Devices Rules 2017.
13.	M/s Imtiaz Brothers, Suite No. 4, 3 rd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore (ELI-00133) Godown: Shop No. 22, Lower Ground Floor, Abrar Business, 25 Main Wahdat Road, Lahore	Ms. Ayesha Sharief Pharm D	Saqib Ameen	Approved
14.	M/s Al-Amin Associates, Office/Godown: 125 Habitat Flats, Shadman Colony 2, Lahore (ELI-00104)	Mahzaib Nisar BS Electrical Engineering	Dr. Mian Khalid Rashid Mian Tahir Rashid	Deferred for approval of technical staff first in accordance with Medical Devices Rules 2017.

Item 1(c):

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

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

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

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

The case is placed before MBD Board for consideration.

Decision: The board deliberated on the matter in the light of the application filed by qualified person of the firm to Wafaqi Mohtasib (Ombudsman) Secretariat, Lahore and subsequent request received from the management of the firm to cancel their ELI.

The board noticed that the MIS division has already removed her name, however to complete the requirement of law, the firm shall be provided opportunity of personal hearing in next meeting of the board to decide the matter.

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

Dr. Hanif Ullah (Deputy Director-XI)

I. APPLICATIONS SUBMITTED ON CASE MANAGEMENT SYSTEM:

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Jawad Surgical, Office No. 13, Naz Medicine Market Namak Mandi, Peshawar ELI-00913 R&I Date: 20.05.2025 Fee: 31,000/- Slip #5469353573	Name of Manufacturer: Ningbo Great Mountain Medical Instruments CO., Ltd., Address: No. 309 Xigu Road Xiangshan County 315700 Ningbo City, Zhejiang Province People's Republic of China LOA Type: Copy	Brand Name: Neo Medical Generic Name: urine bag Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 100ml, 500ml, 750ml, 1000ml, 2000ml, 2000ml/2600ml+200ml/400m/500ml	Deferred for: <i>Declaration on Stamp paper issued in the name of the firm / signatory is required.</i> <i>Notarized LOA is required.</i> <i>The firm shall apply as separate families.</i> <i>Legalized FSC in the country of origin issued by the Government of People's Republic of China is required.</i> <i>Legalized FSC in reference country</i>

		Notarization: No Issue date: 07.03.2025 FSC Type: Copy Issued By: China Chamber of Commerce for Import and Export of Medicines and Health Product Legalization: No Validity: For two years from 24.03.2025 ISO – Certificate: Type: Copy Notarization: No Validity: 19.12.2025 CE certificate: Not submitted.	Shelf Life: 5 years	or CE marking document is required. Notarized ISO – Certificate:
2.	M/s. Fabnos Traders (Pvt) Ltd., Building # 26-C, 3rd Floor Touheed Commercial Area, Street No. 26, Phase - V, D.H.A, Karachi Warehouse: Plot No. 8-C, Shop No. 02, Badar Commercial Area, DHA, Karachi ELI-00750 R&I Date: 27.05.2025	Name of Manufacturer: Shandong Huge Dental Material Corporation, Address: No. 68 Shanhai Road, Danggang District, Rizhao City, Shandong Province, 276800 P.R. China LOA Type: Copy Notarization: Yes (China Council for the Promotion of International Trade China Chamber of International Commerce)	Brand Name: PERFIT Generic Name: Elastomeric Impression Material Model: Type 3 (Light Body) Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Type 3 (Light Body) Shelf Life: 3 years	Deferred for: Stamp paper shall be issued in the name of the firm / signatory. Submission of fee challan. The shelf life in the verification report is 2 years with verification period from March, 2022 to May, 2024. Clarification is required. English translation of the issuing authority in FSC is required.

	Fee: 6,000/- Slip #70884324	Issue date: 18.03.2025 FSC Type: Copy Issued By: People's Republic of China Legalization: Notarized and Apostille after notarization Validity: 20.10.2026 ISO – Certificate: Type: Original Notarization: Yes Validity: 20.02.2026		
3.	M/s. Fabnos Traders (Pvt) Ltd., Building # 26-C, 3rd Floor Touheed Commercial Area, Street No. 26, Phase - V, D.H.A, Karachi Warehouse: Plot No. 8-C, Shop No. 02, Badar Commercial Area, DHA, Karachi ELI-00750 R&I Date: 27.05.2025 Fee: 6,000/- Slip #70884324	Name of Manufacturer: Shandong Huge Dental Material Corporation, Address: No. 68 Shanhai Road, Danggang District, Rizhao City, Shandong Province, 276800 P.R. China Copies of LOA, FSC and ISO – Certificate of preceding case attached.	Brand Name: PERFIT Generic Name: Elastomeric Impression Material Model: Type 0 (Putty Hand-Mix) Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Type 0 (hand-mix) Shelf Life: 3 years	Deferred for: Stamp paper shall be issued in the name of the firm / signatory. Submission of fee challan. The shelf life in the verification report is 2 years with verification period from March, 2022 to May, 2024. Clarification is required. English translation of the issuing authority in FSC is required.
4.	M/s. Fabnos Traders (Pvt) Ltd., Building # 26-C, 3rd Floor Touheed Commercial Area, Street No. 26, Phase - V, D.H.A, Karachi	Name of Manufacturer: Shandong Huge Dental Material Corporation, Address: No. 68 Shanhai Road, Danggang District,	Brand Name: HUGE Generic Name: Kaili synthetic polymer teeth spec: 28*1*4) Model:	Deferred for: Stamp paper shall be issued in the name of the firm / signatory. The firm shall apply as separate families.

	Warehouse: Plot No. 8-C, Shop No. 02, Badar Commercial Area, DHA, Karachi ELI-00750 R&I Date: 27.05.2025 Fee: 31000/- Slip #9505007724	Rizhao City, Shandong Province, 276800 P.R. China LOA Type: Copy Notarization: Yes (China council for the Promotion of International Trade China Chamber of International Commerce) Issue date: 03.09.2024 Validity: 02.09.2029 FSC Type: Copy Issued By: People's Republic of China Legalization: notarized and Apostille after notarization Validity: 10.09.2025 ISO – Certificate: Type: Copy Notarization: Yes Validity: 20.02.2026	Applied as: Single Class: B Models/Code/sizes (as per FSC & application Upper Anterior: S2, S4M S6, S8, T2, T4, T6, T8, T10, Lower Anterior: L2, L4, L6, L8, L10; Upper Posterior: 30, 32, 34, 36, 28S, 30S, 32S, 28M, 30M, 32M, 34M, 36M; LOWER POSTERIOR: 30, 32, 34, 36, 28S, 30S, 32S, 28M, 30M, 32M, 34M, 36M Shelf Life: 10 years	Submission of fee challan. Legalized FSC in reference country or CE marking document is required. English translation of the issuing authority in valid FSC is required.
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Item II (b) DEFERRED APPLICATIONS OF M/S AKRAM BROTHERS, LAHORE FOR REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.

EVALUATOR: MRS. SADAF AHMAD, DEPUTY DIRECTOR-III

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision of M-94
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1.	M/s Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1523-P Evaluator: AD-III	<u>Legal Manufacturer:</u> FOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO Plain Gut Sutures (Sterile Absorbable surgical suture) Class-D Shelf Life: 5 years Code & Sizes: List provided	The board discussed that applied medical device was previously registered as drug since 2011 and was being imported by the firm since years before applying under Medical Devices rules, 2017, therefore, the board decided to take expert opinion regarding safety and performance of applied product from three surgeons from different hospitals for consideration of the Board.
2.	M/s Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1522-P Evaluator: AD-III	<u>Legal Manufacturer:</u> FOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China. FSC China Valid till: 07.05.2020	WEGO CHAROMIC CATGUT Sterile Absorbable Surgical Suture) Class-D Shelf Life: 5 years Codes: Not provided	The board discussed that applied medical device was previously registered as drug since 2011 and was being imported by the firm since years before applying under Medical Devices rules, 2017, therefore, the board decided to take expert opinion regarding safety and performance of applied product from three surgeons from different hospitals for consideration of the Board.

In compliance to the aforesaid decision of MDB, letters to following hospitals were issued to take expert opinion regarding safety and performance of applied products. Replies received from the hospitals are tabulated below:-

S.#	Name of Hospital	Name of Product	Expert Opinion received from Hospitals
1.	Prof. Dr Aatif Inam Shami, Professor of General Surgery, Pakistan Institute of Medical Sciences, Islamabad.	WEGO Chromic Catgut Suture (Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	I have used WEGO plain gut and chromic sutures and found them to be satisfactory.
2.	Dr. Naveed Ullah Khan, Head Department of Surgery, Federal Government Polyclinic Hospital, Islamabad.	WEGO Chromic Catgut Suture (Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	Not personally used in last 20 years of surgical practice. Not needed/recommended for General/Laparoscopic surgical repairs of skin, fascia, intestines, stomach, colon, gallbladder, breast, thyroid and abdominal surgeries.
3.	Dr. Syed Fahd Shah, Surgeon Federal	WEGO Chromic Catgut Suture	Obsolete suture and it is no more used in

	General Hospital, Prime Minister National Health Complex, Chak Shahzad, Islamabad.	(Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	surgical clinical practice.
4.	Prof. Dr. Anis Ahmed, Professor of Surgery, Surgical Unit-I, Benazir Bhutto Hospital, Murree Road, Rawalpindi.	WEGO Chromic Catgut Suture (Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	Satisfactory. Satisfactory.
5.	DR. M Zafar Iqbal, Associate Professor Surgery, Rawalpindi Medical University (District Headquarter Hospital), Kashmiri Bazar, <u>Rawalpindi</u> .	WEGO Chromic Catgut Suture (Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	Satisfactory. Satisfactory.
6.	Prof. Jhangir Sarwar Khan, Head of Surgical Unit-I, Holy Family Hospital, Holy Family Road, Block F, Satellite Town, <u>Rawalpindi</u> .	WEGO Chromic Catgut Suture (Sterile Absorbable Surgical Suture) WEGO Plain Gut Sutures (Sterile Absorbable surgical suture)	Satisfactory. In view of above, the applied products are found satisfactory for surgical use. Satisfactory. In view of above, the applied products are found satisfactory for surgical use.

DECISION: The board discussed that the inspection of foreign manufacturer was already conducted and thereafter the subject product was registered as drug. Furthermore, the opinion on safety and performance of most of the experts regarding the applied medical device was also satisfactory. Keeping in view of the above facts and policy regarding registration of medical devices registered as drug before promulgation of medical device Rules 2017 and opinion on safety and performance furnished by the experts the Board after through deliberation unanimously decided to approve both the applied products.

REGISTRATION OF MEDICAL DEVICES FOR IMPORT (PERSONAL HEARING).

EVALUATOR: DR. GHAYOUR AHMED, DEPUTY DIRECTOR-IV

Case No.01:

Below mentioned application(s) for enlistment/registration of medical devices submitted by M/s Sadqain Healthcare Pvt. Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi, was considered by the Medical Device Board (MDB) in its 100th meeting held on 18th September, 2025, 2024 and decided as mentioned below:-

S.#	Importer Name	Manufacturer Name	Medical Device Name	Decision of 100 th Meeting of MDB
1.	Applicant Name: M/s Sadqain Healthcare Pvt. Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi ELI-00020 Date of R&I 14-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 3662459837	Name of Manufacturer: Insightra Medical, Inc, 2543 Madison Street #105, Clarksville, TN, 37043 United States of America Contract Manufacturing: Done at Dolphin life science LLC Block No 133 Village Dhamdod NR . Hotel Supreme .ta .Mangrol Surat , Gujrat , India . LOA Validity: 16-03-2028 (Copy) FSC: USA Validity: 06-06-2026 (Original) ISO Validity: 23-04-2027(copy) EU QA/ EC Certificate Not given	Brand name: Ultra IABP Catheter kit Generic Name: Ultra aortic Balloon Catheter kit Class-D Shelf life: 5 years Models/ Specification Ultra IABP 7Fr Catheter Kit, System, Balloon, Intra Aortic and Control IMU7F-20 System, Balloon, Intra Aortic and Control IMU7F-25 System, Balloon, Intra Aortic and Control IMU7F-30 System, Balloon, Intra Aortic and Control IMU7F-35 System, Balloon, Intra Aortic and Control IMU7F-40 System, Balloon, Intra Aortic and Control	Deferred for submission of the valid and notarized LOA, ISO 13485, Design examination certificate. The firm is further advised to submit revise the Form 7A as per FSC. Submit clarification of the manufacturing site and the manufacturing steps undertaking in india. Submit Differential Fee of family. Furthermore, the board decided to provide personal hearing to both the firm for proving the LOA of this product.

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Proceedings and Decision of The Board:

The representative of M/s Sadqain Healthcare Pvt. Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi, namely Mr Irfan Bhatti National Sales Manager and Mr. Imran Majeed Regulatory Affairs Manager appeared before the Board. They produced the notarised letter of Authorization for the few codes which is applied here and few applied codes were not present in the LOA. The company representative stated that they will withdraw the others codes which are not covered in the LAO. The firm further produced another letter for clarification of the sterilization site of one of the 7Fr of the catheter kit that is sterilised in USFDA.

M/s Cardiac Care, Lahore did not appear before the MDB. Therefore, the Board decide to grant final opportunity of personal hearing to M/s Cardiac Care, Lahore to prove its authorization of the product from the foreign principle.

MINUTES OF ADDITIONAL AGENDA OF 107TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 05-11-2025

(MANUAL APPLICATIONS PART-II)

Item: Personal Hearing of M/s MAZ International, Lahore, M/s Delta Plus (Pvt.) Ltd., Islamabad & M/s Defence Resource Group, Lahore

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision of 97 th MDB
5.	M/s MAZ International Office No. 42,43,44, Ibrahim Block, Al- Hafeez Garden Phase-I, Manawan, G.T. Road, Lahore. (ELI-00862) Date of R& I 16-04-2022 Fee: 5,000/- Slip # 14077184996	Name of Manufacturer: A1 Globe SDN. BHD. A1- 2, Block A, Jalan Haruan 5/9, Pusat Komercial Oakland II, 70300, Seremban, Negeri Sembilan, Malaysia. LOA Type: Copy of Notarized Notarization: Notarized Validity: 24-10-2027 • FSC Type: Copy of Legalized Issued By: MOH Legalization: Legalized Issue Date: 19-06-2027 • ISO – Certificate: Type: Copy of Notarized Notarization: Notarized	Brand Name: Handex Glove Generic Name: Powdered Latex Examination Gloves Powder Free Latex Examination Gloves Applied as: Single Class: A Models/Code/sizes Small Medium Large Extra Large Shelf Life: 5 Years	The Board decided to call the instant applicant alongwith two other applicants for personal hearing with the direction to present following documents before the Board; i.Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii.Copy of Receiving (R&I) of application(s) under discussion. The Board further directed the Division of MD&MC to convey following deficiencies to the instant applicant; • Justification of applying two types of examination gloves (Powdered & Powder Free) in single application, is required. • Evidence of available sizes is required. • Stability studies data confirms shelf life of 3 Years, while, the applicant has claimed 5 years in

		Validity: 26-09-2027		Form.
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Item II: **Deferred Cases**

1.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad (ELI-01008)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	Brand Name: Mindray Generic Name: Hamatology Control (BC-6D) Model No: H: 4.5×1, 4.5×6 N: 4.5×1, 4.5×6 L: 4.5×1, 4.5×6 Class: B Applied as: Kit	Approved
2.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad (ELI-01008)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	Brand Name: Mindray Generic Name: SC CAL PLUS Hematology Calibrator Model/Specifications: 3×1ml, 3×2ml, 3×6ml Class: B Applied as: Kit	Approved

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