

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

DECISIONS OF 138TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
06-08-2026 (MANUAL APPLICATIONS PART-II)

138th 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 06-08-2026. 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.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
4.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad	Member
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
7.	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)
8.	Mrs. Tazeen S Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co -Opted Expert (attended meeting through videolink)
9.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

Sr. NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. 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): GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES:

I. FRESH CASES:

S.No	Name of Establishment	Production In charge	Quality Control In charge	Decision
1	M/s Shine Surgicals (Pvt) Ltd, Plot No. 146/2-L, Street No. 7, Industrial Estate Gadoon Amazai, District Swabi.	Mr. Umar Farooq	Aliyar Ahmad	Approved. The Board considered the inspection report and approved establishment license to manufacture medical devices for the below sections: a) Syringes (Disposable and Auto disable) Section b) I.V Set Section. c) Packaging Section d) EO Sterilization.

II. M/s SagiTrix (Private) Limited, Office /godown: Office No. E-6, Executive Floor, Glass Tower, Teen Talwar, Clifton, Karachi - Addition of Cold Storage Facility.

M/s SagiTrix (Private) Limited, Office /godown: Office No. E-6, Executive Floor, Glass Tower, Teen Talwar, Clifton, Karachi Sindh Pakistan was issued licensed under the licence No. ELI-EN00000235 dated 28/07/2026 in 136th meeting of MDB.

Now Mr. Abdul Waheed, Deputy Director, DRAP, Karachi has sent a letter to MDMC division regarding cold storage facilities of the said firm, which is reproduced as below:

“I am directed to refer to the subject cited above and to submit that the undersigned inspected the premises of M/s. Sagi Trix (Private) Limited, E-06, Executive Floor, Glass Tower, Teen Talwar, Clifton, Karachi on 07-07-2026 in connection with the grant of Establishment License to import medical devices (Form-4).

During inspection, it was observed that firm has provided four (04) pharmaceutical grade refrigerators at the premises for the proper storage of temperature-sensitive products requiring controlled storage conditions of 2°C to 8°C. However, due to an inadvertent oversight, the cold storage facility was not reflected in the inspection checklist.

In view of the above, it is requested that the cold storage facility (2°C to 8°C) may kindly be incorporated in their Establishment License of the above-mentioned firm.

Any inconvenience caused in this regard is sincerely regretted”.

Submitted for consideration of MDB please.

Decision:

The board considered inspection report and approved cold storage facility (2°C to 8°C) in favor of M/s SagiTriX (Private) Limited, Office /godown: Office No. E-6, Executive Floor, Glass Tower, Teen Talwar, Clifton, Karachi ELI-EN00000235.

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

I. (FRESH RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (Private) Limited, Office/godown: Plot No. 34-A/7 & 8, Commercial Area, Hafeez Center, KECHS. ELI-000374	Sidra Urooj Malik Pharm D	Mr. Qinghua Yang Zahid Moeen Uddin Qureshi Mr. Shahid Moin Qureshi	Deferred. The board deferred the application for fee and documents for tech staff and godown.

II. DEFERRED CASES FOR RENEWAL OF -ELI):

Sr.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Three Stars Medical Supplies, Office: M-17-18, Mezzanine Floor, Seth Centre Syed Mouj Darya Road, Lahore Godown: Shop No. 14-18, Lower Ground Floor Seth Center Mouj Darya Road, Lahore. ELI-000353	Ms. Sadia Shahbaz Pharm D	Zaffar Ullah Alvi	Approved For room temp products

2.	M/s Nisa Impex, Office: plot no. 13-14, Usman Block jaddah town phase 1, GT road, Islamabad ELI-00064	Babar Bin Hamid Pharm D	M Inayat ullah Rakshanda anjum M wassi shan	Approved For room temp products
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Item No. I(C): PERSONAL HEARING AGENDA.

1.	M/s Bajwa Sons, Office: 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. Godown: 437-38, Nizam Block, Allama Iqbal Town Lahore ELI-00314	Zubaria Nazir Pharm D	Mr. Farhat Munawar Bajwa Mr. Usman Ahmed Bajwa	Decision: The board provided opportunity of personal hearing to the firm. Mr. Farhat Bajwa appeared before the board. He informed that the new office and godown site is 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. The board noticed that as per record of MDMC Division the approved storage site was 437-38, Nizam Block, Allama Iqbal Town Lahore, however the firm didn't obtain any approval for this change. The board advised the applicant to inform MDB and obtain approval for any regulatory change future. The board decided to re-inspect the site with following panel for renewal of ELI and furnish complete set of documents for qualified person and godown: a. Dr. Mahmood Member MDB b. Mr. Skh Rasheed DD DRAP Lahore.
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Licensing Additional Agenda

Item No. I(D): RENEWAL OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICE.

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	M/s DKT Pakistan (Pvt.) Limited, Office/godown: Plot No. 34-C, Khalid commercial, Street No. 1, DHA Phase VII,	05/02/2025	Not submitted. In response to our letter Ref No. 2-1/2024-MD dated 22 nd December 2025, the firm failed to provide any	The board observed that the license of the firm was declared invalid in 129 meeting of MDB as the renewal record was not traceable for renewal application submitted for the period 05-02-2025 to 04-02-2029. The applicant was asked in writing to furnish this information vide

	Karachi. ELI No. 00515		evidence of submission of application for Renewal of Establishment License to import Medical Devices.	letter F.No. 2-1/2024-MD Dated 22-12-2025 however the firm did not respond in time. As the required information is now available and the firm has provided requisite information, therefore it was decided to revoke earlier decision of the board and establishment license to import medical devices issued in favor of M/s DKT Pakistan (Pvt.) Limited, Karachi ELI No. 00515 is declared valid under medical devices rules 2017. The board also authorized Additional Director DRAP Karachi or his nominee to conduct renewal inspection and submit report for consideration of MDB.
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Item No. III:

MISCELLANEOUS CASES

EVALUATOR: RANA AHSAN UL HAQ ATTAR (DEPUTY DIRECTOR)

Case No. 1. CHANGE OF LEGAL MANUFACTURER ADDRESS AND LABEL OF ALREADY REGISTERED MEDICAL DEVICES FOR IMPORT.

S. No.	Name of Firm	Details of Medical Device	Existing Legal Manufacturer name & address	Proposed change in Legal Manufacturer address.	Decision
1	M/s Essity Pakistan Limited, A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 28-12-2023. 23-07-2026.	Leukomed I.V. Film Transparent Film Dressing [4.5cm x 4.5cm 6cm x 8cm 7cm x 9cm 8.5cm x11.5cm] Reg. No: MDIE-0000373 Class: A Shelf life: 05 Years	M/s BSN Medical GmbH Quickbornstrasse 24 20253, Hamburg, Germany	M/s BSN Medical GmbH Schutzenstraße 1-3, 22761 Hamburg, Germany.	Approved subject to submission of differential fee.
2	M/s Essity Pakistan Limited, A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 28-12-2023. 23-07-2026.	Cutimed Cavity 72621-00 72621-01 72621-02 72621-03 Reg. No: MDIR-0000249 Class: C Shelf life: 03 Years	M/s BSN Medical GmbH Quickbornstrasse 24 20253, Hamburg, Germany	M/s BSN Medical GmbH, Schutzenstraße 1-3, 22761 Hamburg, Germany.	Approved subject to submission of differential fee.

Case No. 2. CHANGE OF LEGAL MANUFACTURER NAME & ADDRESS AND LABEL OF ALREADY REGISTERED MEDICAL DEVICES FOR IMPORT.

S. No.	Name of Firm	Details of Medical Device	Existing Manufacturer name & address	Proposed Legal Manufacturer name & address.	Decision
1	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 28-12-2023. 23-07-2026.	Cutimed Sorbact gel (Bacteria and fungi binding dressing. Swab with hydrogel) Gel Dressing [7.5cm x 7.5cm 7.5cm x 15cm 15cm x 20cm] Reg. No: MDIR-0005721 Class: C Shelf life: 03 Years	M/s BSN Medical GmbH Quickbornstrasse 24 20253, Hamburg, Germany	M/s ABIGO Medical AB, Vapenvagen 1, SE-696 33 Askersund, Sweden.	Deferred for the followings: 1. Submission of differential fee, 2. submission of valid registration letter. 3. Justification/ Reason for the change of Legal manufacturer along with documentary evidence from Notified body or relevant regulatory authority.

Case No. 3. REQUEST FOR LOCAL PRINTING ON THE ALREADY REGISTERED MEDICAL DEVICES FOR IMPORT.

S. No.	Name & Address of the Firm / Importer	Detail of Medical Device	Proposed Printing details	Decision
1	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Cutimed Cavity Class: C Shelf Life: 3 Years Reg. No. MDIR-0000249	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-0000249 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
2	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Cutimed Gel Class: C Shelf Life: 3 Years Reg. No. MDIR-0000248	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-0000248 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
3	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road,	Cutimed Siltec Class: C Shelf Life: 3 Years	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.

	Karachi ELI No. 00011 R&I Date: 23-07-2026	Reg. No. MDIR-0000250	0000250 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	
4	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Dynacast Prelude (Synthetic Splint System) Class: A Shelf Life: 3 Years Reg. No. MDIE-0000032	Name of Medical Device L. No. ELI-00011 Registration No. MDIE- 0000032 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
5	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Leukomed T Plus Class: A Shelf Life: 5 Years Reg. No. MDIE-0000013	Name of Medical Device L. No. ELI-00011 Registration No. MDIE- 0000013 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
6	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Leukomed Class: A Shelf Life: 5 Years Reg. No. MDIE-0000011	Name of Medical Device L. No. ELI-00011 Registration No. MDIE- 0000011 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
7	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Fixomull Stretch Class: A Shelf Life: 5 Years Reg. No. MDIE-0000012	Name of Medical Device L. No. ELI-00011 Registration No. MDIE- 0000012 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
8	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Cutimed Sorbact Hydroactive Class: C	Name of Medical Device L. No. ELI-00011	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.

	Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Shelf Life: 3 Years Reg. No. MDIR-0000715	Registration No. MDIR-0000715 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	
9	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Bactigras Class: C Shelf Life: 3 Years Reg. No. MDIR-0002912	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-0002912 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
10	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Opsite Transparent Polyurethane Film Dressing Class: B Shelf Life: 5 Years Reg. No. MDIR-0002913	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-0002913 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
11	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Delta-Net Stockinette Class: A Shelf Life: N/A Reg. No. MDIE-0000160	Name of Medical Device L. No. ELI-00011 Registration No. MDIE-0000160 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
12	M/s Essity Pakistan Limited A-69, S.I.T.E, Manghopir Road, Karachi ELI No. 00011 R&I Date: 23-07-2026	Leukomed Control Class: C Shelf Life: 3 Years Reg. No. MDIR-0000810	Name of Medical Device L. No. ELI-00011 Registration No. MDIR-0000810 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.
13	M/s Essity Pakistan Limited	Flashcast Fiberglass Cast Bandage Tape	Name of Medical Device L. No. ELI-00011	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for

	A-69, Manghopir Karachi S.I.T.E, Road, ELI No. 00011 R&I Date: 23-07-2026	Class: A Shelf Life: 5 Years Reg. No. MDIE-0000010	Registration No. MDIE-0000010 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	verification of the facility for printing.
14	M/s Essity Pakistan Limited A-69, Manghopir Karachi S.I.T.E, Road, ELI No. 00011 R&I Date: 23-07-2026.	Soffban Plus Class: A Shelf Life: 5 Years Reg. No. MDIE-0000029 Size: 5cm x 2.7m 7.5cm x 2.7m 10cm x 2.7m 15cm x 2.7m	Establishment License No. ELI-00011 Registration No. MDIE-0000029 Imp. & Mkt. By: Essity Pakistan Ltd. (Formally BSN Medical (Pvt) Ltd). M.R.P.	The Board constituted the panel comprising of the additional director DRAP Karachi or his nominee for verification of the facility for printing.

Item No. IV:

PERSONAL HEARING CASES

EVALUATOR: SAADAT ALI KHAN (DEPUTY DIRECTOR)

Personal Hearing Cases Deferred In 68th MDB Meeting

Case No:01: REGISTRATION OF MEDICAL DEVICES FOR IMPORT - PERSONAL HEARING NOTICE

Reference to the subject cited above and say that below mentioned application(s) by M/s Sind Medical Stores, 13- B, Block 6, PECHS, Shahrah -e- Faisal, Karachi for transfer of registration of medical devices from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore to their name were discussed by the Medical Device Board in its 126th meeting held on 1st April, 2026 and decided as mentioned below against each: -

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision of 126 th Meeting of MDB
1.	M/s. Sind Medical Stores, Karachi. Lic. No.: ELI-00010 DRAP (R&I) Dated: 24-05-2024 Fee Challan No.: 553744454035 PKR: 50,000/-	M/s. Medtrade Products Ltd Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL, England, UK LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023	Celox RAPID Gauze Hemostatic Gauze Class: D [Size & Codes] FG08839021 MDIR-0000307 Applied as: Single Shelf life: 5 Years	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 2. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 3. Clarification of the difference in the name of the Registration holder (Previous) in the termination letter.

	Dated: 22-05-2024 BGE-MRH-AUGH	Validity: 26-06-2029 Termination letter of previous Importer (M/s Healthline Pharmaceutical Corporation): Type: Scan copy of non-notarized copy. Date of issuance: 20-05-2024 FSC Type: Scan copy of notarized copy Issued by: MHRA, UK Issuance Date: 18-05-2024 Validity: 15-03-2028 ISO 13485 Certificate: Type: Scan copy of non-notarized copy. Validity: 26-04-2027 EU Technical Documentation Assessment Certificate: Type: Scan copy of notarized copy. Validity: 15-03-2027		Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore, to M/s Sind Medical Stores, Karachi.
2.	M/s. Sind Medical Stores, Karachi. Lic. No.: ELI-00010 DRAP (R&I) Dated: 24-05-2024 Fee Challan No.: 553744454035 PKR: 50,000/- Dated: 22-05-2024 BGE-MRH-AUGH	M/s. Medtrade Products Ltd Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL, England, UK LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 26-06-2029 Termination letter of previous Importer (M/s Healthline Pharmaceutical Corporation): Type: Scan copy of non-notarized copy. Date of issuance: 20-05-2024 FSC	Celox Granules 15g Hemostatic Granules Class: D MD group: Single Shelf life: 5 Years [Size & Codes] FG08830181 MDIR-0000308	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 2. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 3. Clarification of the difference in the name of the Registration holder (Previous) in the termination letter. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore, to M/s Sind Medical Stores, Karachi.

		Type: Scan copy of notarized copy Issued by: MHRA, UK Issuance Date:18-05- 2024 Validity: 15-03-2028 ISO 13485 Certificate: Type: Scan copy of non-notarized copy. Validity: 26-04-2027 EU Technical Documentation Assessment Certificate: Type: Scan copy of notarized copy. Validity: 15-03-2027		
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Decision of 138th Meeting of MDB:

The MDB has decided to cancel the registration of M/s Healthline Pharmaceuticals Corporation (Pvt.) Limited, Lahore, of products (CeloX RAPID Gauze Hemostatic Gauze, MDIR-0000307 and CeloX Granules 15g Hemostatic Granules, MDIR-0000308) as the firm failed to appear before the Board despite being provided multiple opportunities for a personal hearing.

The firm, M/s. Sind Medical Stores, Karachi, is required to submit the deficiency documents for further processing of registration applications.

Case No:02: REGISTRATION OF MEDICAL DEVICES FOR IMPORT - PERSONAL HEARING NOTICE

Reference to the subject cited above and say that below mentioned application(s) by M/s Mediland Pakistan Pvt, Office No. B-09, 2nd Floor Masood Arcade, IJP Road near Saidpur Road Rawalpindi for registration were discussed by the Medical Device Board in its 126th meeting held on 1st April, 2026 and decided as mentioned below against each: -

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision of 126 th Meeting of MDB
1.	M/s Mediland Pakistan Pvt. Ltd., Rawalpindi. ELI:00202 R&I Receiving: 12-08-2022 Fee: Rs. 25000/- Fee challan no. 6632301451 for	Manufacturer as per FSC: Medi-Care Solutions s.r.l Via Della Zecca, 1-40121 Bologna (BO) – Italy. Site Address: Via P. Nenni, 3 40026 Imola (BO), Italy. LOA:	Otocompact Otocompact professional Otocompact professional EVO Otocompact professional TS Otocompact STEEL Otoplus ENT Unit	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Clarification of the difference in the name of the manufacturer in FSC & Form-7A. 3. Justification of the grouping along with catalog & family fee. Different System/model shall be applied separately via online MDMC portal. 4. Valid notarized ISO 13485

	Euroclinic ENT Unit.	Type: Scan copy of notarized copy. Validity: 31-21-2025 FSC Type: Scan copy of notarized copy. Issued by: Italy Issuance Date: 20-03-2025 Validity: without expiry date ISO 13485 not provided Instead copy of ISO 9001:2015 attached.	Applied as Family Class-B Product code: Otocompact Professional Otocompact Professional Evo Otocompact Steel OtoPlus Otocompact Plus Shelf life: N/A	Furthermore, both parties (M/s Mediland Pakistan Pvt. Ltd., Rawalpindi, and M/s Biologic Medical Systems, Karachi) shall be called upon for a personal hearing in the matter to determine the authorization of the applied product.
2	M/s Mediland Pakistan Pvt. Ltd., Rawalpindi. ELI:00202 R&I Receiving: 24-06-2022 Fee challan not attached. Tracking ID: X7W-GGS-9WT9	Manufacturer (as per Form-7A: Getinge AB Lindholmospiren 7A P.O. Box 8861 SE-417 56 Göteborg Sweden. Legal Manufacturer as per FSC: MaquetGmbH Kehler StraBe 31 76437 Rastatt Germany Manufacturing Site as per FSC: Getinge IC Production, Poland Sp. z O.O., Szkolna 3D, 62-064 Plewiska, Poland. LOA: Type: Scan copy of notarized copy. Validity: 31-10-2025 FSC Type: Scan copy of notarized copy. Issued by: Germany Issuance Date: 01-08-2024 Validity: without expiry date ISO 13485: Type: Scan copy of notarized copy. Validity: 15-10-2027	Getinge Poladus 150 Low Temperature Sterilizer Applied as Family Class-C Product code: 6034510000, 6034510001, 6034510002, 6034510003, 6034510004, 6034510005, 6034510006 Shelf life: N/A	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Verifiable copy of fee slip 3. Clarification of the difference in the name of the manufacturer in FSC & Form-7A. 4. Justification of the grouping along with catalog & family fee. Different System/model shall be applied separately via online MDMC portal. 5. Valid notarized ISO 13485 6. Clarification of the class of the product in light of DOC & MDR 2017. Furthermore, both parties (M/s Mediland Pakistan Pvt. Ltd., Rawalpindi, and M/s Biologic Medical Systems, Karachi) shall be called upon for a personal hearing in the matter to determine the authorization of the applied product.

Decision of M-138:

“The Board decided to grant final opportunity of personal hearing to M/s Biologic Medical Systems, Karachi to prove its authorization of the product from the foreign principle.

Furthermore, deferred for submission of the following by M/s Mediland Pakistan Pvt. Ltd., Rawalpindi:

- 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product.*
- 2. Verifiable copy of fee slip*
- 3. Clarification of the difference in the name of the manufacturer in FSC & Form-7A.*
- 4. Justification of the grouping along with catalog & family fee. Different System/model shall be applied separately via online MDMC portal.*
- 5. Valid notarized ISO 13485*
- 6. Clarification of the class of the product in light of DOC & MDR 2017.”*

Case No:03: REGISTRATION OF MEDICAL DEVICES FOR IMPORT - PERSONAL HEARING NOTICE

Reference to the subject cited above and say that below mentioned application(s) by M/s Radiant Medical Private Limited Address: 06-Sher Shah Block New Garden Town Lahore for registration of medical device to import were discussed by the Medical Device Board in its 117th meeting held on 14th January, 2026. The operative part of the decision is reproduced below against each: -

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision of 117 ^h Meeting of MDB
1.	M/s Radiant Medical Private Limited Address: 06-Sher Shah Block New Garden Town Lahore, Pakistan Lic. No: ELI-00135 Date of R&I 13-06-2024 Fee Details: Paid Fee: 50,000/- Fee Challan No: 59192959891.	M/S Livetec Ingenieurbüro GmbH Marie-Curie-Strasse 8 79539 Lorrach Germany. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2026. • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 16-10-2023 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy	Pace T20 Pacemaker External Cardiac Pacemaker Applied as family: Class-C Shelf life: 7 years Codes/Model/Sizes: 103722.	Deferred for provision of shelf life studies. Furthermore the MDB decided to call for personal hearing to both the firms i.e M/S Novatek Pakistan and M/s Radiant Medical Lahore for clarification about the valid Letter of Authorization about the said product.

		Validity: 14-04-2028		
2.	Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore. ELI: 00135 Date of R& I 21-02-2024 (4638-P) Fee Rs. 50,000/	(LEGAL MANUFACTURE R) M/s Livetec Ingenieurburo Marie-Curie-Stasse 8 79539 Lorrach, Germany. FSC Germany Issuance 16-10-2023 (Original & attested) LOA valid till 31-12-2026 (Original and notarized) Production Quality Management System Certificate (ISO 13485) Valid till 14-04-2025 (valid and notarized) Full Quality Assurance Certificate or Equivalent: Issued by TUV, Germany (0197) validity 26-05-2024 (Notarized) Design Examination N/A Declaration of Conformity (Doc): Provided	Pace T10 External Cardiac Pacemaker Class C Codes/ sizes/models: 103721(T10)	Deferred in 69th meeting for provision of shelf life studies. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/S Novatek Pakistan and M/s Radiant Medical Lahore for clarification about the valid Letter of Authorization about the said product.

Decision of M-138:

*The Board decide to grant **final opportunity of personal hearing to M/s Novatek Pakistan P-20, 1st Floor, Office No.1, Channab Market, Susan Road, Madina Town, Faisalabad to prove its authorization of the product from the foreign principle.** Furthermore, the case of M/s Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore is deferred for provision of shelf life studies & justification the class of the applied product as the applied product is in Class-D.”*

Case No:04: REGISTRATION OF MEDICAL DEVICES FOR IMPORT - PERSONAL HEARING NOTICE

Reference to the subject cited above and to say that below mentioned applications of M/s Hospital Services & Sales, 13-C Annexe, Block 6, PECHS, Karachi for transfer of registration of medical devices from M/s Mars Enterprises, Karachi to their name were discussed by the Medical Device Board in its 126th meeting held on 1s April, 2026 and decided as mentioned below against each: -

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision of 126 th Meeting of MDB
1.	Hospital Services & Sales 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 5,000/- Challan No.: 825361398	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01-2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Three-way Stopcocks for single use (with or without extension tube) (MDIE-0000246) MD group: Single Class: A Shelf life: 5 Years [Size & Codes] (with or without extension tube)	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 2. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi

2.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	A Anhui Easyway Medical Supplies CO., LTD Address: No.737, Tianshe Road, Tianshe Road, Tianshe Road, Anhui Province, China Product: Disposable Sterile Blood Transfusion Set for single use (With filter) Type: Scan copy of notarized copy. Validity: 22-01-2024 to 22-01-2029 Issuance: 22-01-2024 MDIR-0002349 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (With filter, with or without needle) Copy of NOC for Registration of products (M/s Mars Enterprises, Karachi Enterprises), dated 2023. Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 21-06-2025 to 21-06-2026 Q13485: Copy of NOC for notarized copy. Validity: 06-07-2026 to 06-07-2026 Q13485: Copy of NOC for notarized copy. Validity: 26-05-2024 to 26-05-2024 letter head dated 15-08-2023.	I Care Disposable Sterile Blood Transfusion Set for single use (With filter, with or without needle) MDIR-0002349 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (With filter, with or without needle)	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
3.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details:	A Anhui Easyway Medical Supplies CO., LTD Address: No.737, Tianshe Road, Tianshe Road, Tianshe Road, Anhui Province, China Product: Disposable Sterile Blood Transfusion Set for single use (With filter) Type: Scan copy of notarized copy. Validity: 22-01-2024 to 22-01-2029 Issuance: 22-01-2024 MDIR-0002349 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (With filter, with or without needle) Copy of NOC for Registration of products (M/s Mars Enterprises, Karachi Enterprises), dated 2023. Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 21-06-2025 to 21-06-2026 Q13485: Copy of NOC for notarized copy. Validity: 06-07-2026 to 06-07-2026 Q13485: Copy of NOC for notarized copy. Validity: 26-05-2024 to 26-05-2024 letter head dated 15-08-2023.	I Care Sterile Disposable Infusion Set for single use (With filter, with or without needle) MDIR-0002350 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] Model No. (YW-1, YW-2, YW-3, YW-4, YW-5, YW-6, YW-7, YW-8), Needle Gauge: 0.4mm, 0.45mm, 0.5mm,	Deferred for submission of the following: 7. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 8. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 9. Properly filled Form-7A along all the required annexures

	Paid Fee: 25,000/- Challan No.: 705185019	Validity: 22-copy 01-2029 Determination letter of copy of NOC for (With filter, Importation of M/s Mars Products by M/s Mars Enterprises, Karachi Letterhead dated 15-08- 2023 Scan copy Type: Scan copy of Dated copy. Issued by: NMPA - China Validity: 19-06-2025 Copy 18400C Type: Scan copy of Registration copy. Validity: 06-07-2026 ECMPQA Certificate: Type: Scan copy of Karachi copy. Validity: 26-05-2024 dated 15-08- 2023.	Class: B Shelf life: 5 Years [Size & Codes] 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm	duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
4	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No. ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Anhui Easyway Medical Sapipiles CO., LTD Address: No. 737, Shenghe Road, Tiaohu Add: Anhui Province, China No. 737, Shenghe Road, Tiaohu Jilin Road, Anhui Province, China Type: Scan copy of Andriod copy. Validity: 22-01-2029. Determination letter of Type: Scan copy of Myro Enterprises, Karachi Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025	I Care Sterile Insulin Disposable Syringe for single use (0.5ml, 1ml) Sterile Blood Transfusion MDIR-0002351 Set for single use Class: B Shelf life: 5 Years [Size & Codes] 0.5ml, 1ml	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi

		2023 13485: Copy of NOC Copy of notarized copy. RV Validity: 06-07-2026 the QPQA Certificate: Type: Scan copy of Entapizes copy. K Validity: 26-05-2024 letter head dated 15-08- 2023.		
5	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI- 00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Anhui Easyway Medical Medipiles CO., LTD Address: No. 737, Shenghe Road, Tianshan City, Anhui Province, P.R. CHINA. Jinsha Road, Type: Scan copy of Ambir Pev copy. Validity: 22-01-2029. Examination letter (MDIR- Type: Scan copy of Mars Enterprises, Karachi Type: Scan copy of MDIR-002349) MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (With filter, With or without needle) Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 21-06-2025 2023 13485: Copy of NOC Copy of notarized copy. RV Validity: 06-07-2026 the QPQA Certificate: Type: Scan copy of Entapizes copy. K Validity: 26-05-2024 letter head dated 15-08- 2023.	I Care Disposable Sterile Syringe for Single use Transfusion (1ml, 10ml, 20ml) MDIR-0002352 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 1ml, 10ml, 20ml	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi

	Paid Fee: 25,000/- Challan No.: 705185019	Validity: 22-copy 01-2024 Notarized copy. Termination: 22-01-2024 Letter of Copy of NOC for (With filter, Importation of M/s Mars Products by M/s Mars Enterprises, Karachi Katahead dated 15-08-2023 Scan Copy of Type: Scan copy of Notarized copy. Issued by: NMPA - China Validity: 19-06-2025 Copy 18400C Type: Scan copy of Registration copy. Validity: 06-07-2026 ECNQA Certificate: Type: Scan copy of Karachi copy. Validity: 26-05-2024 dated 15-08-2023.	Class: B Shelf life: 5 Years [Size & Codes]	duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
8	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No. ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Anhui Easyway Medical Sapipiles CO., LTD Address: No. 737, Shanshe Road, Tiaohu, Addys, Anhui Province, No. 737, HANA, Jilong Road, Tianjin Type: Scan copy of Notarized copy. Validity: 22-01-2024 Termination letter (MDIR-0002349) Type: Scan copy of Notarized copy. Validity: 22-01-2024 Termination: 22-01-2024 Letter of Copy of NOC for (With filter, Registration of M/s Mars Enterprises, Karachi Katahead dated 15-08-2023) Type: Scan Copy of Type: Scan copy of Notarized copy. Issued by: NMPA - China Validity: 19-06-2025	I Care Disposable Sterile Intravenous Sterile Blood Needle for single use Transfusion MDIR-0002355 Set for single MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (with wings) – (0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm) Class: B Shelf life: 5 Years [Size & Codes] (With filter, with or without needle)	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi

10	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Ahhui Easyway Medical Supplies CO., LTD Address: No. 737, Tianshe Road, Tiaojishan, Anhui Province, China. Disposable Sterile Blood Transfusion Set for single use (With filter) Type: Scan copy with or without notarized copy. Validity: 22-01-2024 to 22-01-2029. MDIR-0002349 Type: Scan copy of Enterprises, MD group: Single Class: B MDIR-0002349 Issuance: 22-01-2024 MDIR-0002349 Shelf life: 5 Years MDIR-0002349 Size & Codes] (With filter, needle) Registration of (M/s Mars Enterprises, Karachi) dated 2023. Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 21-06-2025 to 21-06-2026 MDIR-0002349 Copy of NOC for notarized copy. Validity: 06-07-2026 to 06-07-2026 MDIR-0002349 Copy of NOC for notarized copy. Validity: 26-05-2024 to 26-05-2024 letter head dated 15-08-2023.	I Care Disposable Sterile Infusion set with Burette Chamber for single use MDIR-0002357 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 80ml, 100ml, or 150ml	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
11	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details:	Ahhui Easyway Medical Supplies CO., LTD Address: No. 737, Tianshe Road, Tiaojishan, Anhui Province, China. Disposable Sterile Scalp Vein Set for single use (With filter) Type: Scan copy with or without notarized copy. Validity: 22-01-2024 to 22-01-2029. MDIR-0002349 Type: Scan copy of Enterprises, MD group: Single Class: B MDIR-0002349 Shelf life: 5 Years MDIR-0002349 Size & Codes] (With filter, needle) Registration of (M/s Mars Enterprises, Karachi) dated 2023. Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 21-06-2025 to 21-06-2026 MDIR-0002349 Copy of NOC for notarized copy. Validity: 06-07-2026 to 06-07-2026 MDIR-0002349 Copy of NOC for notarized copy. Validity: 26-05-2024 to 26-05-2024 letter head dated 15-08-2023.	I Care Disposable Sterile Scalp Vein Set for single use MDIR-0002358 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 14g, 15g, 16g, 18g, 19g, 20g, 21g, 22g, 23g, 24g, 25g, 26g, 27g, 28g, 29g, 30g.	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures

	Paid Fee: 25,000/- Challan No.: 705185019	Validity: 22-copy 01-2029 Determination: 22-01-2024 letter of Copy of NOC for (With filter, Importation of M/s Mars Products by M/s Mars Enterprises, Karachi Katahead dated 15-08- 2023 Scan copy Type: Scan copy of Dated copy. Issued by: NMPA - China Validity: 19-06-2025 Copy 18400C Type: Scan copy of Registration copy. Validity: 06-07-2026 MEC NPA Certificate: Type: Scan copy of Karachi copy. Validity: 26-05-2024 dated 15-08- 2023.	Class: B Shelf life: 5 Years [Size & Codes]	duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
12	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No. ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Anhui Easyway Medical Sapipiles CO., LTD Address: No. 737, Shenghe Road, Tiaohu, Anhui Province, China. No. 737, HANA. use Jinhe Road, (With filter Type: Scan copy with or without needle) Determination letter (MDIR- Type: Scan copy Myro Enterprises, MD group: Type: Scan copy Validity: 22-copy. Class: B 01-2029 Determination: 22-01-2024 letter of Copy of NOC for (Size & Codes) provided for registration of (With filter, Importation of M/s Mars Enterprises, Karachi Katahead dated 15-08- 2023) Type: Scan copy Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025	I Care Disposable Sterile Syringe for Sterile Blood use Transfusion MDIR-0002359 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 30ml, 50ml, 60ml, 100ml	Deferred for submission of the following: 4. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 5. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 6. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi

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® 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: Production Quality Management System Certificate (ISO 13485) Full Quality Assurance Certificate	Marketing Authorization Letter: Validity Date: 31 st December, 2024 Production Quality Management System Certificate (ISO 13485) Validity Date: 31 st March, 2025 Full Quality Assurance Certificate or Equivalent: Validity Date: 26 th May, 2024

or Equivalent:	Design Examination Validity Date: Not Provided
Design Examination	
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>

Decision of 138th Meeting of MDB:

“The MDB after through deliberation decided to cancel registration of product Compoflex® 4F 63ml CPDA-1 PDS-V of M/s Fresenius Kabi Pakistan (Pvt.) Ltd., Lahore. MDB decided to approve the application for registration of above referred product in the name of M/s Uniplan Trade International Pvt. Ltd 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.”

CASE NO.02: 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
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

Decision of 138th Meeting of MDB:

The MDB has decided to cancel the registration of M/s Medic Ally (Pvt.) Ltd., Lahore and approve in the name of M/s Biowel Sciences of following products;

MDIE-0000766	Humeca Mesher (Mesher) [6.HM01]
MDIE-0000817	MEEK Micrografting machine (Micrografting machine) [3.MD, 3.HD]
MDIE-0000816	Humeca Skin Transplantation carrier (Skin Transplantation Carriers)

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