

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

DECISIONS OF 129TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
06th & 7th May, 2026 (MANUAL APPLICATION PART-II)

129th 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 6th & 7th 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.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
9.	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)
10.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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.

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

(EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR))

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

i. FRESH CASES-ELM:

S.No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1	M/s M&M Impex, Office/godown: Plot No. LA 8/17, Block 22, Federal B Industrial Area, Karachi.	Muhammad Talha Malik Bs Biomedical Engineer	Muhammad Minhaj BS (Biosciences)	The Board considered the inspection report and approved following sections for manufacturing of medical devices: 1. Drape Kits 2. Surgical Gowns
2	M/s Aga Khan Hospital and Medical College Foundation, Stadium road, Karachi,			Rejected. The board considered the report of inspector that the applicant is no more interested in obtaining establishment license to manufacture medical devices and decided to reject the application. In case the applicant is interested in obtaining establishment license to manufacture medical devices in future, they need to make a new/fresh application for the purpose.
3	M/s Crespak Medical Industries, 8 th Km Manga Raiwind road, Lahore.			Deferred. The board decided to defer renewal inspection for a period of 2 months and advised the firm to complete all requirements/ upgradation with the specified timeline.

ii. TRANSFER OF LICENSE FROM DRUG MANUFACTURING LICENCE (DML) TO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES (ELM):

S.No	Name and Address of Establishment	Name of Production In charge	Name of QC In charge	Decision
1.	M/s Seagull Pharma, Factory Address: Tower Point Baig Colony, Gojra Road, Jhang.	Muhammad ali B. pharmacy	Amjad Iqbal Sajid Bsc Chemistry	The Medical Devices Board considered the application of the firm regarding transfer of Drug Manufacturing License (DML) to Establishment License to Manufacture Medical Devices (ELM) under Medical Rules 2017 and subsequent inspection conducted for the purpose and made

				following decision: 1. The firm was initially granted Drug Manufacturing License (DML No. 00482) by Central Licensing Board at the premises M/s Seagull Surgical cotton and bandages, Factory, tower point Gojra road, Jhang on 23-11-2000. 2. After promulgation of Medical Devices Rules 2017, the firm applied for transfer of DML into ELM on 11-03-2025. The license of the firm was valid for the period 23-11-2020 to 22-11-2025 at the time of this application as per Drugs (L, R& A) Rules 1976. 3. Accordingly, a panel was constituted and inspection of the facility was conducted by a panel of experts. The board considered the report and approved transfer of license from Drug Manufacturing License to Establishment License to Manufacture Medical Devices w.e.f. 23-11-2025 to 22-11-2030 under Medical Rules 2017 for the following sections: I. Open Wove Bandage and Cotton Crepe Bandag (Non-sterile) II. Absorbent Cotton Wool Section (Non-sterile).
2.	M/s Umer Usman Surgical cotton industries, Factory Address: Faisalabad Road Kot Sai Singh, Jhang.	Rana Tauseef Mehmood,	Muhammad Waqas Khan	The Medical Devices Board considered the application of the firm regarding transfer of Drug Manufacturing License (DML) to Establishment License to Manufacture Medical Devices (ELM) under Medical Rules 2017, as per record of the DRAP and subsequent inspection conducted for the purpose and made following decision:

				1. The firm was initially granted Drug Manufacturing License (DML No-000361) by Central Licensing Board at the premises M/s Umer Usman cotton industries, Faisalabad road, Jhang Saddar on 18-09-1994. 2. After promulgation of Medical Devices Rules 2017, the firm applied for transfer of DML into ELM on 16-09-2020. The license of the firm was valid for the period 18-09-2015 to 17-09-2020 at the time of this application Under Rule 6 of Drugs (L, R&A) Rules, 1976. 3. However, the board noticed that firm has not provided evidence for submission of renewal application for the period 17-09-2025 to 16-09-2030. Therefore, the board decided to defer the case for evidence of renewal application if submitted earlier. In case the firm has not submitted renewal application, the applicant shall make renewal application with applicable late fee as defined under Medical Devices Rules 2017.
3.	M/s Chishti Pharmaceutical Industries, Office/godown: Faisalabad road, 111/7-R, Tehsil Chichawatni, District, Sahiwal.	Mr. Khalil Ahmad	Muhammad Anas Tariq	The Medical Devices Board considered the application of the firm regarding transfer of Drug Manufacturing License (DML) to Establishment License to Manufacture Medical Devices (ELM) under Medical Rules 2017 and subsequent inspection conducted for the purpose and made following decision: 1. The firm was initially granted Drug Manufacturing License (DML No. 000483) by Central Licensing Board at the premises Faisalabad Road, 111/7-R, Tehsil Chichawatni, District, Sahiwal 19-12-2000. 2. After promulgation of Medical Devices Rules 2017, the firm

				applied for transfer of DML into ELM on 11-11-2024. The license of the firm was valid for the period 19-12-2020 to 18-12-2025 at the time of this application Under Rule 6 of Drugs (L, R&A) Rules, 1976. 3. Accordingly, a panel was constituted, and inspection of the facility was conducted by a panel of experts. The board considered the report and approved transfer of license from Drug Manufacturing License to Establishment License to Manufacture Medical Devices w.e.f. 19-12-2025 to 18-12-2030 under Medical Rules 2017 for the following sections: I. Cotton Wool Section (Non-Sterile) II. Gauze Section (Non-Sterile) III. Bandage Section (Non-Sterile)
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Item No. I(B): RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES:

Fresh Renewal Cases:

S.#	Name of Establishment	Production In charge	Quality Control In charge	Decision
1.	M/s Faisal Pharmaceutical Industries, Office/godown: 602-B, small industrial estate, sargodha, road, Faisalabad. ELM-0019	Noor Fatima Pharm D	Zarnilah Aroos Pharm D	Approved. The board considered inspection report and approved following sections for renewal of establishment license to manufacture medical devices. I. Gauze Section (Sterile/Non-Sterile) II. Eye Pad Section (Sterile) III. Tulle Section (Sterile) IV. Surgical Bandage Section V. Sponge Section (Sterile) VI. Crepe Bandage Section

II.	M/s General Pharma, Office/godown: Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. ELM-0038	Miss Shama	Mr. Muhammad Saeed Pharm-B, M.Phil	Deferred. The board deferred the case for submission of fee for grant of additional section (POP) and production in-charge with relevant documents.
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Item No. I(C): GRANT OF ADDITIONAL SECTION TO MANUFACTURE MEDICAL DEVICES – M/S RANACON PHARMA LTD., PLOT NOL 6, PHASE-II, FAISALABAD INDUSTRIAL ESTATE, DEVELOPMENT & MANAGEMENT COMPANY, FAISALABAD.

S.#	Name of Establishment	Production In charge	Quality Control In charge	Decision
1.	M/s Renacon Pharma Ltd, Office/godown: : Plot No. 6, Phase-II, Faisalabad Industrial Estate, Development & Management Company (FIEDMC), Faisalabad ELM-0024	Salman Idrees Pharm D	Fareed Ahmed M. Phil Chemistry	The board approved following additional section for manufacture of medical devices. • Disinfectant Solution Section.

Item No. I(D): 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 Alliance Medical, Office/godown: 12-B, 1 st Floor, Agro Flats, Shadman, Lahore. ELI-00147	Fatima Jahshaid Pharm D	Wasim Ijaz CEO	Approved. For room temp products
2.	M/s Al Waali Care Concepts, Office/godown: 86- Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi Shahu, District Lahore ELI-00386	Muhammad Waleed Pharm D	Abdul Waheed M Abu bakar Siddique	Approved. For room temp products
3.	M/s Onyx International, Office: M1, 107C Ayesha Arcade, Khalid Bin Waleed Road, PECHS Block 2, Karachi Godown: Basement-96/A/2 PECHS Block 2, Karachi ELI-00467	Engr Syed Shoaib Ali Zaidi Bs Bio Medical Engineer	Jawas Saleem Fawad Saleem Partners	Approved. For room temp products
4.	M/s Biomed International, Office/godown: House No. 348, Block-R, Model Town Lahore, Gulberg Town	Syed Waseel Hiader Zaidi Pharm D	Mr. Javed Iqbal Mr. Muhammed Farooq Arshad	Approved. For room temp products

	Lahore ELI-00591			
5.	M/s Pharm Canada Pakistan, Office/godown: 334-C, Faisal Town, Lahore. ELI-00389	Mr. Muhammad Faraz Bs Microbiology/ M.Phil	Mr. Asadullah Khan Mr. Assad Maqbool	Approved. For room temp products. The firm shall submit an undertaking that the facility shall not be used for residential purposes and could be inspected any time without hindrance.
6.	M/s Mezan International, Office/godown: 59 BR II, Opp. DCO House, Haji Meherban Road, Jhelum ELI-00096	Shahzada Kashif Nadeem Pharm D	Rehan Ur rehman	Approved. For room temp products
7.	M/s Care Scientific, Office/godown: 13-14, C/A Ist Floor Chuburji Center Multan Road Lahore. ELI-00487	Mr. Tariq abbas Bachelor of Science in Applied Microbiology	Mr. Amir Khan	Approved. For room temp products
8.	M/s Blue Birds Enterprises, Office: Office No.1, Ashraf Plaza, Iqbal Road, Rawalpindi. Godown: Office No.4, Ashraf Plaza, Iqbal Road, Rawalpindi. ELI-00206	Aiman Hassan Pharm D	Mr Waseem Aslam	Approved. For room temp products
9.	M/s Asto Life Sciences (Pvt) Ltd, Office/godown: Plaza Nol 1, Block Orchard 1, Paragon City, Barki road, Lahore. ELI-00103	Khawaja Asim Omer Pharm D	Rao Tofique Ahmad Khajwa Asim Omer	Approved. For room temp products

10.	M/s Suafa Traders, Office: 11 Model Town, R.Y.Khan Godown: 5-Canal View, Bukhari Street, Rahim Yar Khan ELI-00255	Ghulam Abbas B. Pharmacy	Syed Farjad Ali Bukhari Syed Shamshad Ali. Ms. Uroosa Shamshad	Approved. For room temp products
11.	M/s Amtronech, Office/godown: 560, A Block Faisal Town, Lahore ELI-00173	Ms. Laraib Abid Bs Microbiology	Mr. Abid Ali Mr Maqsood Alam	Approved. For room temp products
12.	M/s Tianshi International Pakistan Co.,(Pvt) Ltd, Office/godown: Plot 1C, Alfateh Market, G-9/3, Islamabad. ELI-00502	Saddam Ud Dim Pharm D	Mr.Li Jinyuan Mr. Yan Yupeng Mr. Li Tao	Approved. For room temp products
13.	M/s Capital Dental Supply, Office / godown: Office No. 17, First Floor, Poonch House Complex, Adam Jee Road, Saddar Rawalpindi ELI-00508	Rao Zubiar Ahmed Pharm D	Mr. Ameer Abdullah	Approved. For room temp products
14.	M/s Quality Medical Services, Office/godown: H-49, Gordon College road, Rawalpindi. ELI-00123	Muhammad Farhan Pharm D	Aleem Shahzad CEO	Deferred for submission of fee and documents for tech staff.
15.	M/s 3M Surgical, Office/godown: Plot No 5/172, Sarwar road, Rawalpindi.	Lamiya Sattar Pharm D	Syed Munawar Rasheed shah CEO	Deferred for submission of fee and documents for tech staff.

	ELI-00122			
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Item No. I(E): APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

(DEFERRED CASES FOR RENEWAL OF -ELI):

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s The Cure Old office address; first floor office#6 capri center 12ulberg market 12ulberg 111 Old Godown address: First Floor, House 77, Block XX, DHA Phase III ELI-0000567 New office address: , House 77, First floor, street No. 12, Block XX, DHA Phase III, Lahore. New godown address: Suit No 15-F 3/1, commercial Amjad Bukhari market, Punjab cooperative housing society, main boulevard, ghazi road, Lahore.	Fariha intikhab Pharm D	Umair Mughees CEO	Decision Approved
2.	M/s SAFEWAY SYSTEMS PAKISTAN Office/Godown: First Floor, Ayub Plaza, Misrial Road, Near Bhata Chowk, Rawalpindi. ELI-00308	Muhammad Luqam BS Biotechnology	Zeeshan Haider CEO	Approved
3.	M/s FM Health Care, 203, Al Rahman Centre, Block 7/8, KCHS, Shaheed-e-Millat Road, Karachi (ELI-00082)	Faiza Nazir Pharm D	Sheikh Masood Ahmad Chhabra Sheikh Zafar Masood Chhabra Muhammad Tariq Masood	Approved
4.	M/s Standard Supply Agencies, Shop No 20, 21 & 22, Khyber Bazar, Peshawer. ELI-00018	Haider khan Pharm D	Saleem Shahzad Waseem shahzad	Approved

5.	M/s Medcraft International, M-1, 107-D, West View Appartment, Khalid Bin Waleed Road, Block 2, PECHS, Karachi	Old Technical Person: Bakht Amir New Technical Person: Muhammad Zakaria Sami Pharm D	Shaikh Haris Hameed	Approved
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Item No. I(F): APPLICATIONS FOR GRANT OF RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

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 decision of MDB taken in its different meetings are as mentioned against each:

S. No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Cold Chain (Yes/No)	Decision
1.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi Godown: B-41, Street No. 27, Sector F, DHA Phase 1, Islamabad ELI-00327	Muhammad Aqib Shahzad Pharmacist	Shagufta Naz	No.	The board considered the inspection report submitted by Dr. Aleem Awan Member MDB and Area FID Islamabad regarding renewal of license and appreciated the efforts made by the firm. The board therefore decided to approve renewal of establishment license to import medical devices issued to the applicant.

Item No. I(G): 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	License No	Date Of Issuance	Validity/Renewal Date	Date of Renewal application/Remarks
1	TraMax Health Systems, A-337 Block -D, North Nazimabad, Karachi.	ELI-00026	03/Aug/18	02/Aug/23	Not submitted
2	Ison Medical Corporation, Plot No.18- B, Block-D (Commercial) Valencia, Lahore.	ELI-00032	03/Aug/18	02/Aug/23	Not submitted
3	Apsta International, 38-A , M.A. Johar Town, Lahore.	ELI-00042	03/Aug/18	02/Aug/23	Not submitted
4	Saving Life Technologies (SLT) 427-K, Block Model Town, Lahore.	ELI-00053	03/Aug/18	02/Aug/23	Not submitted
5	M/s Healthline Pharma, 170-D, Johar Town, Lahore	ELI-00060	03/Aug/18	02/Aug/23	Not submitted
6	CKD Pharmaceuticals Pakistan (Pvt) Ltd., Plot 50/28, Korangi Industrial Area, Karachi.	ELI-00080	03/Aug/18	02/Aug/23	Not submitted
7	Biogenics Pakistan Pvt Ltd, 201, Fortune Centre, P.E.C.H.S Block No 6, Sharae Faisal, Karachi	ELI-00085	03/Aug/18	02/Aug/23	Not submitted

8	Prism Health Pakitan, 705-706, Anum Blessings, Block 7/8, KCHSU, Karachi.	ELI-00088	03/Aug/18	02/Aug/23	Not submitted
9	Mars Enterprises, Office No.S-43, GlassTower, 2nd Floor, Block-8, Frere Tower, Clifton,Saddar Town, Karachi-South Karachi	ELI-00097	03/Aug/18	02/Aug/23	Not submitted
10	Pharma Plus International, H# 9A, Opp. Qayyum Stadium, Rafiqui Lane, Old Bara Road, Peshawar	ELI-00101	03/Aug/18	02/Aug/23	Not submitted
11	M/s Healthline Pharmaceuticals Pvt. Limited, 65-D-I, Office No.402, Al-Hafeez Heights, 4th Floor, Gulberg-3, Lahore.	ELI-00107	03/Aug/18	02/Aug/23	Not submitted
12	Dora Enterprises, 54-B, Model Town Lahore. Godown: 1st floor, Office No.2, 35-M Civic Centre, Model Town Extension, Lahore	ELI-00108	03/Aug/18	02/Aug/23	Not submitted
13	Al-Yahya Enterprises, 203, Sana Plaza Garrison, Golf Club, Bahar Shah Road, Al- Faisal Tower, Lahore	ELI-00111	03/Aug/18	02/Aug/23	Not submitted
14	Bionext Pharmaceutica, 251-A, Karim Block, Allama Iqbal Town, Lahore	ELI-00116	03/Aug/18	02/Aug/23	Not submitted
15	Optimus Entrepot, 194- F/1 - Block, Johar Town, Lahore	ELI-00125	03/Aug/18	02/Aug/23	Not submitted

16	Anthro Pharmaceuticals (Pvt) Limited, C-19D, Badar Commercial Lane 5, Phase 5 Ext. DHA Karachi.	ELI-00127	03/Aug/18	02/Aug/23	Not submitted
17	Mukhtar Enterprises, 55 Block B, Faisal Town Lahore	ELI-00131	17/Oct/18	16/Oct/23	Not submitted
18	3A Nutra, 12-F - 1 BlockMohamod Chowk, Johar Town, Lahore	ELI-00134	17/Oct/18	16/Oct/23	Not submitted
19	Horizon Group of Company, 603, Kamran Block, Allama Iqbal Town Lahore	ELI-00140	17/Oct/18	16/Oct/23	Not submitted
20	Cardiovascular Medical System, 210-Block, J-2 Ground Floor, Johar Town, Lahore.	ELI-00143	17/Oct/18	16/Oct/23	Not submitted
21	M.S. Associates, H#127-C, Batala Colony Near Babar Chowk, Faisalabad	ELI-00144	18/Oct/18	17/Oct/23	Not submitted
22	Novum Life Solutions, 328/16, W-Block, DHA, Lahore.	ELI-00145	17/Oct/18	16/Oct/23	Not submitted
23	Safmed, 124- A Shadman-1. Lahore.	ELI-00168	17/Oct/18	16/Oct/23	Not submitted
24	Denovo Pharma, Flat No. D-7, 90- C Shreef Colony, Canal Park, Gulberg-II Lahore	ELI-00188	17/Oct/18	16/Oct/23	Not submitted
25	S.M. Diagnostics, 42-C, Asghar Mall Scheme, Rawalpindi.	ELI-00195	18/Oct/18	17/Oct/23	Not submitted

26	Shaheen Aerotraders, Air Port Road, Opposite Benazir Bhutto International, Chaklala Rawalpindi.	ELI-00216	25/Feb/19	24/Feb/24	Not submitted
27	Sveda Health Care, Office No, 4, 3rd Floor MB City Plaza 1/8 Markaz Islamabad.	ELI-00222	18/Oct/18	17/Oct/23	Not submitted
28	Perfect Vision, Ali Plaza Near Rahat Bakers, Chur Chowk, Main Peshawar Road, Rawalpindi.	ELI-00227	18/Oct/18	17/Oct/23	Not submitted
29	Medworks, 327 Haider Ali Road, Block -3 DMCHS, Karachi	ELI-00231	19/Oct/18	18/Oct/23	Not submitted
30	A.T Associates, Flat No. F1, 1st Floor, 51-C, Block-6 , PECHS, Karachi.	ELI-00235	19/Oct/18	18/Oct/23	Not submitted
31	GD Traders, Plot No 110-C, Mezzanine floor in Between 9th & 10th Commercial Street Phase -IV DHA, Karachi.	ELI-00245	22/Oct/18	21/Oct/23	Not submitted
32	Flying Distribution Network, M-57, Mezzanine Floor Glass Tower Main Clifton Road Karachi.	ELI-00256	22/Oct/18	21/Oct/23	Not submitted
33	Fresenius Kabi Pakistan (Pvt) Ltd Tanvir Ahmed Medical Centre (TAMC), First Floor, MM Alam Road, 27-C/3, Gulberg III, Lahore	ELI-00266	17/Oct/18	16/Oct/23	Not submitted

34	Kohsar Distributors, Hill View Block, Lower Basement, Block No. 516-523, Pakistan Town, Islamabad	ELI-00268	18/Oct/18	17/Oct/23	Not submitted
35	Pharmatronics Pvt Ltd, S-11.2nd, Floor, Clock Tower Shamsi Road Mardan	ELI-00270	25/Feb/19	24/Feb/24	Not submitted
36	N Z Trader, Karachi	ELI-00277	22/Oct/18	21/Oct/23	Not submitted
37	Alere Medical Pakistan (Pvt) Ltd Karachi.	ELI-00283	19/Oct/18	18/Oct/23	Not submitted
38	Nismedical, Suite No.315, 3rd Floor, Block 14, Mashriq Center, Gulshan-e - Iqbal, Karachi	ELI-00287	22/Oct/18	21/Oct/23	Not submitted
39	AB Enterprises, Plot No. C 155-156, Sector 6, F Mehran Town Karachi	ELI-00292	22/Oct/18	21/Oct/23	Not submitted
40	Sterijekt Medical Devices, 3 Shaukat Road, Near Eden Housing Society, 22-KM, Ferozpur Road, Lahore.	ELI-00297	18/Oct/18	17/Oct/23	Not submitted
41	Bio Care Medical System, 1st floor Unique Centre, 8-Shahrah-e- Taj Bagh, Taj Bagh Housing Scheme, Lahore Cantt	ELI-00300	22/Oct/18	21/Oct/23	Not submitted
42	Jam's Heart International, Lahore	ELI-00303	18/Oct/18	17/Oct/23	Not submitted
43	Ortholink, 55-4, Shadman Market, Lahore.	ELI-00312	22/Oct/18	21/Oct/23	Not submitted

44	Oscartech Pakistan, Opposite Union Council Kotla Arab Ali Khan, Tehsil Kharian, District Gujrat	ELI-00318	25/Feb/19	24/Feb/24	Not submitted
45	NSONs Group Pvt Ltd, House No CB 1-7, Lane No.7, Peshawar Road Rawalpindi.	ELI-00319	25/Feb/19	24/Feb/24	Not submitted
46	Imran & Faizan Brothers & Trading Co., 15-Patel Road Quetta	ELI-00320	25/Feb/19	24/Feb/24	Not submitted
47	Curative Pharmaceuticals Pvt Ltd, 500, 5th Floor, Plaza No 54, Block B, Civic Center, Phase-IV, Bahria Town, Rawalpindi/ Islamabad.	ELI-00330	26/Feb/19	25/Feb/24	Not submitted
48	Mira Khan & Co., H No 12/14, Swati gate (Phattok), Hakimabad, Peshawar.	ELI-00332	26/Feb/19	25/Feb/24	Not submitted
49	Safi Brothers, Room No -S-22, 2nd Floor Clock Tower Shamsi Road, Mardan, Khyber Pukhtunkhwa	ELI-00337	26/Feb/19	25/Feb/24	Not submitted
50	Unity Brands Associates Pvt Ltd, Haji Manaz Plaza, R.A Bazar Nowshera	ELI-00339	27/Feb/19	26/Feb/24	Not submitted
51	Parazelsus Pakistan Private Limited, No 201-204, 2nd Floor, Park Towers, Shahrah- e-Firdousi, Clifton, Karachi.	ELI-00340	27/Feb/19	26/Feb/24	Not submitted
52	Engltech, C-59/1 Block-B Gulshan-e-Jamal, Karachi	ELI-00341	27/Feb/19	26/Feb/24	Not submitted

53	Inventus Medical Technologies, 63/3 First Floor, Street 9, Block-C, Phase 8, DHA, Lahore	ELI-00348	27/Feb/19	26/Feb/24	Not submitted
54	AK Pharma Pvt Ltd, Building No Zone 2557 Adjacent Total Petrol Pump Firduos Market Gulberg III, Lahore	ELI-00360	27/Feb/19	26/Feb/24	Not submitted
55	Linkers Asia, 96-H-3, Johar Town Lahore	ELI-00363	27/Feb/19	26/Feb/24	Not submitted
56	Meditech Pvt Ltd, 114 G/1 M.A, Johar Town, Lahore	ELI-00366	27/Feb/19	26/Feb/24	Not submitted
57	ANZ Healthcare Technologies, 112-A, Comm. Area, Sec.-C. Bahria Town Lahore	ELI-00368	27/Feb/19	26/Feb/24	Not submitted
58	Maxims Medical, 210 2nd Floor Land Mark Plaza Jail Road Lahore	ELI-00369	27/Feb/19	26/Feb/24	Not submitted
59	Qadri Healthco, Azeem House Ground Floor, 4-A Mozang Road Lahore	ELI-00372	27/Feb/19	26/Feb/24	Not submitted
60	Votex Pharma (Pvt) Ltd, 60-A, Faisal Town Lahore	ELI-00378	23/May/19	22/May/24	Not submitted
61	Ethos Healthcare (Pvt) Ltd, 1st Floor, Plot No 18, Sector 47, Survey 86, Off main Korangi Creek Road, Karachi	ELI-00381	23/May/19	22/May/24	Not submitted
62	Elegant Health Services, Suit No.123-124, 1st Floor, SP Chamber, SITE, Karachi	ELI-00383	24/May/19	23/May/24	Not submitted

63	McPharm International (Pvt) Ltd, 219-A Lalazar Commercial Market, Raiwind Road Lahore	ELI-00388	22/May/19	21/May/24	Not submitted
64	Ruella Medical, Suit No 1002, 10th Floor, Kawish Crown Plaza, Shahra-e- Faisal,Karachi	ELI-00390	24/May/19	23/May/24	Not submitted
65	Mydent International, A-16, 4th Floor, Block 13-C, Dashtiyaar Chambers, SB 32, Gulshan-e- Iqbal, Karachi	ELI-00391	24/May/19	23/May/24	Not submitted
66	Bayer Pakistan (Pvt) Ltd., C-21,SITE, Karachi.	ELI-00399	28/May/19	27/May/24	Not submitted
67	Medilink Trading And Maintenance (Pvt) Ltd., Lahore	ELI-00400	28/May/19	27/May/24	Not submitted
68	Diabetapak (Pvt) Ltd. Showroom No 3 Ground Floor, Dadabhoy Centre, Plot ST-11 Shahrah- e- Faisal Karachi	ELI-00406	29/May/19	28/May/24	Not submitted
69	Marie Stopes Society, 21-C Commercial Area, Old Sunset Boulevard, DHA Phase 2, Karachi	ELI-00411	30/May/19	29/May/24	Not submitted
70	Creative Network Solution, G-170, G-199 Naz Plaza M.A Jinnah Road, Karachi	ELI-00417	31/May/19	30/May/24	Not submitted
71	CSM Pakistan (Gurantee) Ltd., 23-C/ Commercial Area,Old Sunset Boulevard, DHA Phase 2, Karachi	ELI-00418	31/May/19	30/May/24	Not submitted

72	S.S. Surgical Point, Building No 111-C, Mezzanine Floor, Phase II Ext DHA, Karachi	ELI-00419	31/May/19	30/May/24	Not submitted
73	Dolitso Pakistan (Pvt) Ltd., Suit No 3, Building 13C, 5th commercial Lane, Sehar commercial Area, DHA Phase 7, Karachi	ELI-00428	03/Jun/19	02/Jun/24	Not submitted
74	Sanoptech, Second Floor, D-22, Block D, North Nazimabad, Karachi	ELI-00429	10/Jun/19	09/Jun/24	Not submitted
75	Bio Medical Technologies, 407,4th Floor Madina City Mall, Abdullah Haroon Road, Karachi	ELI-00438	10/Jun/19	09/Jun/24	Not submitted
76	Platinum Corporation, F-10/7/6 Near Arfeen Masjid Barrage Colony, Sukkur	ELI-00443	10/Jun/19	09/Jun/24	Not submitted
77	Swera Pharma Distributers, House No 687, Street No 3, Ch Walayat Khan Road, Chaklala Scheme 111, Rawalpindi	ELI-00446	10/Jun/19	09/Jun/24	Not submitted
78	Cent Dix Curative Smc (Pvt) Ltd., Office No 201-03, 2nd Floor, Platinum Arcade, 11/1 Civic North Commercial, Soan Garden, Islamabad	ELI-00447	10/Jun/19	09/Jun/24	Not submitted
79	Medi Impex, Room No 109 Rehmani Chamber, Altaf Hussain Road, New Challi Karachi	ELI-00450	10/Jun/19	09/Jun/24	Not submitted

80	Haris Enterprises, 10A Karachi Market Khyber Bazar Peshawar	ELI-00452	17/Jun/19	16/Jun/24	Not submitted
81	A.J & Company, Mandviwala Chambers, Talpur Road, Karachi	ELI-00466	02/Dec/19	01/Dec/24	Not submitted
82	Sapphire Consults, Office 209, Royal Center, 106- West, AK Fazle Haq Road, Blue Area, Islamabad	ELI-00477	24/Jan/20	23/Jan/25	Not submitted
83	Safe Line, 52-D, PGSHS, Mohlanwal, Multan Road, Lahore	ELI-00478	28/Jan/20	27/Jan/25	Not submitted
84	Raheem Sons, Shop No 09-10 Nawab Plaza Shalley Velly Range Road Rawalpindi	ELI-00479	28/Jan/20	27/Jan/25	Not submitted
85	Penicon, Ground Floor, C-91, Block 10 Federal B Area, Karachi	ELI-00481	29/Jan/20	28/Jan/25	Not submitted
86	Medtech System, Suit No. 1, 3rd Floor, Abrar Business Center, 25-Main Wahdat Road, Lahore	ELI-00483	03/Feb/20	02/Feb/25	Not submitted
87	S.K. Enterprises, No. 701 7th Floor, KS Trade Tower, Shahra-e- Liaquat, Karachi	ELI-00498	07/Feb/20	06/Feb/25	Not submitted
88	Global Technical Services, Suite No. 1 & 2, 3rd Floor, Nadir House, I.I.Chandrigar Road, Karachi.	ELI-00512	07/Feb/20	06/Feb/25	Not submitted

89	Health Care Solutions, Shop No.51-52, 2nd Floor, Ghakkar Hathyal, Main Simly Dam Road, Barakahu, Islamabad	ELI-00514	06/Feb/20	05/Feb/25	Not submitted
90	DKT Pakistan (Pvt.) Limited, RJ, Building, 4th Floor, Plot No. 37-C, Stadium Lane, Comm. Area, Phase V, DHA, Karachi	ELI-00515	06/Feb/20	05/Feb/25	Not submitted
91	Mezrab, No 25-C, Commercial Area, Old Sunset Boulevard, DHA Phase-II, Karachi	ELI-00519	06/Feb/20	05/Feb/25	Not submitted
92	Apex Services, Office No. 1 & 2 First floor, Building No. 69, Al-Malik Plaza, Chour Chowk Main Peshawar Road Rawalpindi.	ELI-00522	06/Feb/20	05/Feb/25	Not submitted
93	Ultimate Step Group, Office No.5,6, Al Noor Plaza Mandi Mour, G.T Road, Haripur	ELI-00528	06/Feb/20	05/Feb/25	Not submitted
94	The Healers, 206-2, D- Block Satellite Town Rawalpindi	ELI-00535	07/Feb/20	06/Feb/25	Not submitted
95	Physionics, Suit No. 7, 40-C, Main Khayaban-e- Bukhari, Bukhari Commercial Area, Phase 6, D.H.A, Karachi	ELI-00537	07/Feb/20	06/Feb/25	Not submitted
96	Solutions For Efficient Engineered Design Pvt, Ltd, Building No 1, Civic Center, Phase-IV, Bahria Town, Islamabad	ELI-00541	07/Feb/20	06/Feb/25	Not submitted

97	Siddiqui & Company, Plot No.3-C-9/3B, Shumail Terrace, Nazimabad No.3, Karachi	ELI-00547	13/Feb/20	12/Feb/25	Not submitted
98	Medimage Services, Suite No. 5/B Peshawar Medical Centre, Shoba Bazar, Peshawar	ELI-00548	13/Feb/20	12/Feb/25	Not submitted
99	Med-n Tec Pharma,: D- 574, Shafi Street, Satellite Town Rawalpindi	ELI-00553	13/Feb/20	12/Feb/25	Not submitted
100	MedCom International,Office Number 32CC, Central Plaza, Barkat Market, Garden Town, Lahore	ELI-00557	13/Feb/20	12/Feb/25	Not submitted
101	Medimen, House No.199 P 2, St.3, G.E.C.H.S. Link Road, Model Town, Lahore	ELI-00559	13/Feb/20	12/Feb/25	Not submitted
102	CCL Pharmaceuticals (Pvt) Ltd, 65 Industrial Estate, Kot Lakhpat, Lahore	ELI-00562	17/Feb/20	16/Feb/25	Not submitted
103	Ultra Vision (Pvt) Ltd, CC-16 & 17/B, Hasan Centre, Block 16, Gulshan-e-Iqbal, Karachi	ELI-00563	01/Mar/20	28/Feb/25	Not submitted
104	Medtrade, 16-G, Al- Riaz Society, Justice Inamullah Road, Karachi	ELI-00564	01/Mar/20	28/Feb/25	Not submitted

Decision: The board observed that the above licence holder(s) have not made renewal applications 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 firm 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 firm also stands invalid/ cease to exist which requires submission of fresh applications as well.

Item No. I(H): 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 Claris Medical, Office/godown: Flat No.1, Ground Floor, Rayyan Heights, gangal east, service road , Islamabad express way , Islamabad. ELI-00269 M-119	Ada Iqra nayab saleem Pharm D	Saqib Altaf Chaudhry CEO	The board provided opportunity of personal hearing to the applicant. Mr. Syed Ajwad Manager Sales of M/s Claris appeared before the board. They informed the board that they have taken corrective actions to comply with previous inspection findings and conditions of medical devices rules 2017. They also apologized for shortcomings highlighted during initial renewal inspection. The board, looking into the positive attitude of the management, decided to conduct re-inspection of the facility for renewal of license and to verify corrective measures, by the following panel. • Mr. Aleem Awan, Member MDB • Rana Ahsan ul Haq, Deputy Director, DRAP Islamabad.
2.	M/s Ahmad Care International , Office/godown: 2 nd Floor, 7 Shahrah e Taj bagh, phase 1, main market, opp unique solution girls	Syed amin abbas	Amir Ijaz butt CEO	The applicant sent a written request that they cannot attend personal hearing this time due to paucity of time therefore personal hearing may be deferred till next meeting. The board considered the request and decided to defer personal hearing till next board meeting.

	high school, Tajbagh housing scheme, Lahore. ELI-00361 M-119				
3.	M/s Mediland Pakistan (Pvt) Ltd, Office No. B-09, 2nd Floor, Masood Arcade, IJP Road, Near Saidpur Road, Rawalpindi. Proposed Godown address: Lower ground , shop B- 16, Masood arcade, IJP, road, near Saidpur road, Rawalpindi. ELI-00202 M-123	Naveed Akhtar	Naveed Akhtar	The board provided opportunity of personal hearing to the applicant. Mr. Naseem Director Mediland appeared before the board to explain their position. They informed the board that their main operational activities and head office is in Lahore therefore they have not maintained a big godown in Rawalpindi. They further informed that they have also designated a new godown in Lahore (16-Shershah Block, Garden Town Lahore) which they shall use in future for all business activities in Lahore area. They further informed that they have taken corrective actions taken as per inspection findings and could be inspected any time. They also provided proof of making a formal application and fee for additional godown in Lahore as per above details. The board took a serious note of the casual attitude shown in the past and advised the applicant to maintain and comply with all requirements of law once a license was granted by medical devices board. However, board appreciated the positive attitude of the applicant regarding improvement of shortcomings and decided to re-inspect the facility as per following details: 1. Dr. Mahmood Ahmad Member MDB and Rana Ahsan ul Haq Deputy Director DRAP, Isb to conduct inspection of additional godown 16-Shershah Block, Garden Town Lahore. 2. Rana Ahsan ul Haq Deputy Director DRAP Isb to conduct re-inspection of Rwp facility to verify improvements made by the firm in the light of initial inspection report.	

Item No. I(C): CHANGE OF QUALIFIED PERSON

The qualified person of below mentioned firms has informed that they are no more working with these companies. These firms were intimated and advised in writing to appoint a qualified person in accordance with medical devices under MDR, 2017. However, no response in this regard has been received so far.

These cases were placed before the MDB in its 125th meeting held on 16th March, 2026 and decided as mentioned below against each:-

S.#	Name of Establishment	Director/Proprietor/ partners	Name of Qualified Person	Decision
4.	M/s Health Prior (SMC-Private) Limited, 502, Flat No.03, 5 th Floor,	Muhammad Faizan	Rabia Ruby 37301-0479859-8	The board provided opportunity of personal hearing to the applicant.

	Gulberg Green, Islamabad. ELI-01006			Mr. Faizan CEO of the firm appeared before the board. He informed the board that he has already hired a qualified person (Alishba Javed, Pharm D) as per conditions of medical devices rules 2017, however he was unable to upload details and submit application using online portal due to technical reasons. The board appreciated the efforts of the applicant and advised to coordinate with MIS team to fix the technical issue in making change of qualified person application. If the applicant fails to comply with direction of MDB, final opportunity of personal hearing shall be provided failing which license may be cancelled.
5.	M/s Perfect Traders, 72 Harley Street, Lane No 2, Rawalpindi. ELI-01394	Mr. Nafees-ur-Rehman, Deputy Director, DRAP, Islamabad.	Shaiza Khan 37401-8606292-7	The board provided opportunity of personal hearing to the applicant. Mr. Ahmad Hassan CEO of the firm appeared before the board. He informed the board that he has already hired a qualified person (Athar Nawaz, Pharm D) as per conditions of medical devices rules 2017, however he was unable to upload details and submit application using online portal due to technical reasons. The board appreciated the efforts of the applicant and advised to coordinate with MIS team to fix the technical issue in making change of qualified person application. If the applicant fails to comply with direction of

				MDB, final opportunity of personal hearing shall be provided failing which license may be cancelled.

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

Fresh cases (manual Applications)

Evaluator: Rana Ahsan ul Haq attar (Deputy Director)

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Importer Audio Medics, 30-A Shan Center, Near Honda Fort Queen's Road Abid Market, Lahore. (ELI- 000--) R&I detail 24-02-2025 Fee: Rs.31,000 Slip: 43434110708/- dated 10.02.2025. Rs.21,200/- Slip No : 5764459764 Dated 06.05.2026	Legal Manufacturer: Sonova AG, Laubisrutistrasse 28 CH-8712 STAFA, SWITZERLAND Phone: +41589280101 www.sonova.com www.hear-the-world.com Manufacturing Site: Not Provided • LOA Type: copy Notarization: Notarized Validity: issue date 15.11.2024 • FSC Type: copy Issued By: swissmedic Legalization: apostille Validity: 27.11.2027 • ISO 13485 Certificate Copy Valid till 28.02.2028. • ISO 14001:2015 Certificate Valid till 05.07.2027 • FSC RRA Country	Brand name: Unitron Generic Name: Insera B-10 NW O Hearing Aids Type: ITE Applied as: Family Class: B Model/Codes/Sizes (as per FSC & Application): Product: Insera B1-10 L OM DT5 MG Insera B1-10 R OM T5 M G Insera B1-10 LPM OM DT6 PG Insera B1-10 RPM OM DT6 PG Insera B3-10 LOM DTS M G Insera B3-10 R OM DT5 MG Insera B3-10 LPM OM DT6 PG Insera B3-10 RPM OM DT6 PG Insera B5-10 L OM DT5 M G Insera B5-10 R OM DT5 M G Insera B5-10 LPM OM DT6 PG Insera B5-10 RPM OM DT6 PG Insera B7-10 L OM DT5 M G	Approved Type CIC

		Validity • CE Certificate Validity • DE Certificate Validity	Insera B7-10 R OM DT5 M G 074-5502-220057 Insera B7-10 LPM OM DT6 PG Insera B7-10 RPM OM DT6 PG Insera B9-10 L OM DT5 MG Insera B9-10 R OM DT5 MG Insera B9-10 L PM OM DT6 PG Insera B9-10 RPM OM DT6 PG Codes: 074-5501-220054 074-5502-220054 074-5503-220054 074-5504-220054 074-5501-220055 074-5502-220055 074-5503-220055 074-5504-220055 074-5501-220056 074-5502-220056 074-5503-220056 074-5504-220056 074-5501-220057 074-5503-220057 074-5504-220057 074-5501-220058 074-5502-220058 074-5503-220058 074-5504-220058 Details OM: Omnidirectional microphone PM: Push button mounted PU: Push button unmounted DT5/DT6: Magnetic switch P: Power receiver L: Left R: Right Shelf life: 5 Years	
2.	Importer Audio Medics, 30-A Shan Center, Near Honda Fort Queen's Road Abid Market, Lahore. (ELI- 000--) R&I detail 24-02-2025	Legal Manufacturer: Sonova AG, Laubisrutistrasse 28 CH- 8712 STAFA, SWITZERLAND Phone: +41589280101 www.sonova.com www.hear-the-world.com Manufacturing Site: 1. Manufacturing site:	Brand name: Unitron Generic Name: Insera B-312 NW O Hearing Aids Type: ITE Applied as: Family Class: B Model/Codes/Sizes (as per	Approved.

	Fee: Rs.31,000 Slip: 26520830/- dated 10.02.2025. Rs.21,200/- Slip No : 01065899 Dated 06.05.2026	Sonova Hearing (Suzhou) Co., Ltd. Address: No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China. 2. Sub Assembly Site Sonova Operations Center Vietnam Co., Ltd. Address: No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. • LOA Type: copy Notarization: Notarized Validity: issue date 15.11.2024 • FSC Type: copy Issued By: swissmedic Legalization: apostille Validity: 27.11.2027 • ISO 13485 Certificate Copy Valid till 28.02.2028 & 14.04.2026. • ISO 14001:2015 Certificate Valid till 05.07.2027 • FSC RRA Country Validity • CE Certificate Validity • DE Certificate Validity	FSC & Application): Product: Insera B1-312 L PU OM DT6 P Insera B1-312 R PU OM DT6 P Insera B3-312 L PU OM DT6 P Insera B3-312 R PU OM DT6 P Insera B5-312 L PU OM DT6 P Insera B5-312 R PU OM DT6 P Insera B7-312 L PU OM DT6 P Insera B7-312 R PU OM DT6 P Insera B9-312 L PU OM DT6 P Insera B9-312 R PU OM DT6 P Codes: 074-5505-260054 074-5506-260054 074-5505-260055 074-5506-260055 074-5505-260056 074-5506-260056 074-5505-260057 074-5506-260057 074-5505-260058 074-5506-260058 Details OM: Omnidirectional microphone PM: Push button mounted PU: Push button unmounted DT5/DT6: Magnetic switch P: Power receiver L: Left R: Right Shelf life: 5 Years	
3.	Importer Audio Medics, 30-A Shan Center, Near Honda Fort Queen's Road Abid Market, Lahore. (ELI- 000--) R&I detail	Legal Manufacturer: Sonova AG, Laubisrutistrasse 28 CH- 8712 STAFA, SWITZERLAND Phone: +41589280101 www.sonova.com www.hear-the-world.com Manufacturing Site:	Brand name: Unitron Generic Name: Insera B-312 Applied as: Family Class: B Model/Codes/Sizes (as per FSC & Application):	Approved.

	24-02-2025 Fee: Rs.31,000 Slip: 1787243728/- dated 10.02.2025. Rs.21,200/- Slip No : 3777445991 Dated 06.05.2026	1. Manufacturing site: Sonova Hearing (Suzhou) Co., Ltd. Address: No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China. 2. Sub Assembly Site Sonova Operations Center Vietnam Co., Ltd. Address: No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. • LOA Type: copy Notarization: Notarized Validity: issue date 15.11.2024 • FSC Type: copy Issued By: swissmedic Legalization: apostille Validity: 27.11.2027 • ISO 13485 Certificate Copy Valid till 28.02.2028 & 14.04.2026. • ISO 14001:2015 Certificate Valid till 05.07.2027 • FSC RRA Country Validity • CE Certificate Validity • DE Certificate Validity	Product: Insera B1 312 L DV3U PM MM WHP Insera B1 312 R DV3U PM MM WHP Insera B3 312 L DV3U PM MM WH P Insera B3 312 R DV3U PM MM WH P Insera B5 312 L DV3U PM MM WH P Insera B5 312 R DV3U PM MM WH P Insera B7 312 L DV3U PM MM WH P Insera B7 312 R DV3U PM MM WHP Insera B9 312 L DV3U PM MM WH P Insera B9 312 R DV3U PM MM WHP Codes: 074-5507-260054 074-5508-260054 074-5507-260055 074-5508-260055 074-5507-260056 074-5508-260056 074-5507-260057 074-5508-260057 074-5507-260058 074-5508-260058 Details DV3U: Digital volume control (3mm) unmounted MM: Multi microphones PM: Push button mounted P: Power receiver L: Left R: Right Shelf life: 5 Years	
4.	Importer M/s New Pakistan Traders, Office No. 306/I. Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161) R&I detail 05.06.2025 Fee: -----/-	Legal Manufacturer: hanghai Kinmed Import & Export Co., Ltd. Suit L, 12th Floor, No.588 Yingkou Road, 200433 Shanghai, PEOPLE'S REPUBLIC OF CHINA Manufacturing Site:	Brand name: Comfort Care I.D. Bracelet Generic Name: Patient ID Band Applied as: Class: A Model/Codes/Sizes (as per FSC & Application):	Deferred due to followings: 1. Name of the manufacturer not mentioned in FSC Germany. 2. FSC China issued by chamber of commerce. 3. LOA not submitted.

	Slip: -----	• LOA Type: Notarization: Validity: • FSC Type: Issued By: Legalization: Validity: • ISO Certificate Valid till 20.05.2029 • FSC RRA Country Germany Validity Issue date 14.04.2024 • CE Certificate Validity Not attached. • DE Certificate Validity	Shelf life:	4. Fee challan not attached. 5. Form 7A and undertaking on stamp paper not attached. 6. shelf life not attached. 7. product label, IFU not attached. 7. valid ELI required.
5.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024) R&I detail 26.02.2025 Fee: 62,000/- Slip: 30702113	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co., Limited Add: Fourth Floor, G3, 999#, Qujia Road, Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel-mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned	Brand name: Disposable Powered Endoscopic Linear Cutter Staplers and Reloads Generic Name: Disposable Powered Endoscopic Linear Cutter Staplers and Reloads Applied as: Not mentioned Class: C Model/Codes/Sizes (as per FSC): Staplers CNEB S45, S60, M45, M60, L45, L60 CNEP S45, S60, M45, M60, L45, L60 Reloads. CNERS: A45, W45, B45, Y45, A60, W60, B60, Y60. CNERP: A45, W45, B45,	Deferred due to following: 1. FSC China not valid. 2. Firm has applied both cutters and reloads in same application. 3. codes not mentioned in application. 4. Fee for the family not submitted. 5. Brand name not mentioned. 6. grouping not mention in application. 7. copy of brochure is not readable

		• FSC Type: copy Issued By: China Legalization: Validity: 05.05.2025 • ISO Certificate Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate Validity 25.07.2024 NB confirmation letter • DE Certificate Validity	Y45, A60, W60, B60, Y60. CNERL: A45, W45, B45, Y45, A60, W60, B60, Y60. Shelf life: Stability study for endoscopic Linear cutting stapler 3 years.	
6.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024) R&I detail 26.02.2025 Fee: 62,000/- Slip: 22284794915	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co., Limited Add: Fourth Floor, G3, 999#, Qujia Road, Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel-mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned • LOA Type: copy Notarization: yes Validity: 31.12.2027 • FSC Type: copy Issued By: China Legalization: Validity: 10.05.2025 • ISO Certificate	Brand name: Disposable Endoscope Linear Cutting Staplers and Components Generic Name: Disposable Endoscope Linear Cutting Staplers and Components Applied as: Not mentioned Class: C Model/Codes/Sizes (as per FSC): Staplers CN-LCS 55W, 55B, 55G, 75B, 75Y, 75G, 100B, 100Y, 100G CN-LCD 60W, 60B, 60G, 80B, 80Y, 80G, 100B, 100Y, 100G Components. CN-LCSM 55W, 55B, 55G, 75B, 75Y, 75G, 100B, 100Y, 100G CN-LCDM 60W, 60B, 60G, 80B, 80Y, 80G, 100B, 100Y, 100G Shelf life: Stability study for Linear cutting stapler 3 years.	Deferred for the followings: 1. FSC China not valid. 2. Firm has applied both cutters and components in same application. 3. codes not mentioned in application. 4. Fee for the family not submitted. 5. Brand name not mentioned. 6. grouping not mention in application. 7. copy of brochure is not readable

		Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate Validity 25.07.2024 NB confirmation letter • DE Certificate Validity		
7.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024) R&I detail 26.02.2025 Fee: 62,000/- Slip: 08408428160	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co.,Limited Add: Fourth Floor, G3, 999#, Qujia Road, Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel-mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned • LOA Type: copy Notarization: yes Validity: 31.12.2027 • FSC Type: copy Issued By: China Legalization: Validity: 10.05.2025 • ISO Certificate Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate	Brand name: Disposable Linear Cutting Staplers and Components Generic Name: Disposable Linear Cutting Staplers and Components Applied as: Not mentioned Class: C Model/Codes/Sizes (as per FSC): Staplers Codes and sizes not mentioned in FSC Shelf life: Stability study for Linear cutting stapler 3 years.	Deferred for the followings: 1. FSC China not valid. 2. Firm has applied both cutters and components in same application. 3. codes not mentioned in application and FSC. 4. Fee for the family not submitted. 5. Brand name not mentioned. 6. grouping not mention in application. 7. copy of brochure is not readable

		Validity 25.07.2024 NB confirmation letter • DE Certificate Validity		
8.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024) R&I detail 26.02.2025 Fee: 62,000/- Slip: 2777704168	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co.,Limited Add: Fourth Floor, G3, 999#, Qujia Road, Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel-mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned • LOA Type: copy Notarization: yes Validity: 31.12.2027 • FSC Not attached. • ISO Certificate Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate Validity 25.07.2024 NB confirmation letter • DE Certificate Validity	Brand name: Disposable Abdominal Trocars Generic Name: Disposable Abdominal Trocars Applied as: Not mentioned Class: C Model/Codes/Sizes (as per FSC): Shelf life: Stability study for Linear cutting stapler 3 years.	Deferred for the followings: 1. FSC not submitted. 2. codes not mentioned in application. 3. Fee for the family not submitted. 4. Brand name not mentioned. 5. grouping not mention in application. 6. copy of brochure is not readable
9.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024)	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co.,Limited Add: Fourth Floor, G3, 999#, Qujia Road,	Brand name: Disposable Hemorrhoidal Circular Staplers Generic Name: Disposable Hemorrhoidal Circular Staplers Applied as: Not mentioned	Deferred for submission of following documents: 1. codes not mentioned in application. 2. Fee for the family not submitted.

	R&I detail 26.02.2025 Fee: 62,000/- Slip: 46612095	Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel- mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned • LOA Type: copy Notarization: yes Validity: 31.12.2027 • FSC China Valid till 10.05.2025. • ISO Certificate Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate Validity 25.07.2024 NB confirmation letter • DE Certificate Validity	Class: C Model/Codes/Sizes (as per FSC): CN-PPH, CN-PPHA, CN-PPHE, CN-PPHT, CN-PPHAT, CN-PPHET. Shelf life: Stability study for Linear cutting stapler 3 years.	3. Brand name not mentioned. 4. grouping not mention in application. 5. ISO13485 not valid
10.	Importer M/S Medives Enterprises, House No. 45-N/A, Block 6, P.E.C.H.S, Karachi. (ELI- ELI-01214, 11/03/2024) R&I detail 26.02.2025 Fee: 62,000/- Slip: 48239817740	Legal Manufacturer: Jiangsu Channel Medical Device Co., Ltd. Medchannel Device Co., Limited Add: Fourth Floor, G3, 999#, Qujia Road, Qiandeng Town, Kunshan, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Web: http://www.channel-mdi.com/ Tel: +86 512 36857161 Manufacturing Site: Not mentioned • LOA	Brand name: Disposable Circular Staplers Generic Name: Disposable Circular Staplers Applied as: Not mentioned Class: C Model/Codes/Sizes (as per FSC): CN-CS, CN-CSA, CN-CSE. Shelf life: Stability study for Linear cutting stapler 3 years.	Deferred for the followings; 1. codes not mentioned in application. 2. Fee for the family not submitted. 3. Brand name not mentioned. 4. grouping not mention in application. 5. ISO13485 not valid

		Type: copy Notarization: yes Validity: 31.12.2027 • FSC China Valid till 10.05.2025. • ISO Certificate Valid till 11.02.2026 • FSC RRA Country Not submitted Validity • CE Certificate Validity 25.07.2024 NB confirmation letter • DE Certificate Validity		
11.	Importer Kokab enterprise, A-406, Billy's Shopper's Galleria & Residency, Gulstan e Jauhar Block 18, Karachi. (ELI- 00544) Valid till 23.11.2030. R&I detail Fee: 5000/- Slip: 0819260/-	Legal Manufacturer: GASTREX a subsidiary of Medical Instrument Corporation (MIC) France, 7, Chemin de Sacuny-69530 Brignais, France. Manufacturing Site: N/A LOA Type: • Exclusive Distribution. Notarization: Not notarized. Validity: 31.12.2030 • FSC Type: copy Issued By: France CCI-Paris Legalization: Legalized Validity: Issue date 23.11.2018 • ISO Certificate Valid till 22.09.2019 • FSC RRA Country	Brand name: Pronto-Dry Generic Name: Rapid Urease Test Applied as: Set Class: A Model/Codes/Sizes (as per FSC & Application): Shelf life:	Deferred for the followings: 1. LOA issued by Medical Instrument Corporation, and not notarized. 2. Manufacturer has given exclusive distribution to M. Azam, Kokab Enterprises. Relation of M/s kokab Enterprises to M. Azam required. 3. FSC, CCI France issue date 23.11.2018. 4. the name of the device on FSC is Pronto Dry Biopsy Rapid Urease Test. 5. ISO not valid and notarized. 6. the address of the manufacturer on FSC, ISO is GATREX 27 av. Reteur Marcel Bouchard 21640, GILLY-LES-CITEAUX, France. 7. shelf life study not submitted.

		Validity • CE Certificate Validity • DE Certificate Validity		
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DEFERRED CASES AGENDA

IMPORT CASES

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN ELI-00240 Fees: Rs 62,030 Paid on 19/05/2025 Challan # 07706326549 Date of R& I 14 th April 2025	<u>Legal Manufacturer:</u> NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD <u>Manufacturing Site:</u> YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS ZONE, 315199, NINGBO, CHINA Copy of FQA valid till 23.11.2028 Copy of DEC valid till 23.11.2028 <u>Copy of LOA:</u> Sole Agency Agreement (Notarized by CCPIT, Valid till Jan. 2029) <u>Copy of FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health) REGISTRATION NUMBER: 2023YB2690 DATE OF REGISTRATION	Brand Name: YINGMED ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE Class D Shelf Life: 5 Years Codes/Sizes: S. No DESCRIPTIONGB CODE 1. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied(PGA101) 2. Thread 75cm, 90cm, 0, Needle 35mm, ½ Circle Round Bodied (PGA102) 3. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Round Bodied (PGA103) 4. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGA104) 5. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Round Bodied (PGA105) 6. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Round Bodied (PGA106) 7. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle	Approved only one code that is PGA101.

		STATUS: 2024 Valid Upto: Dec, 2025 <u>Copy of ISO:</u> ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026	Round Bodied (PGA107) 8. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGA108) 9. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Round Bodied (PGA109) 10. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGA110) 11. Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGA111) 12. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGA112) 13. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGA113) 14. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGA114) 15. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied (PGA201) 16. Thread 75cm, 90cm, 0, Needle 60mm, Straight Cutting (PGA202) 17. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGA203) 18. Thread 75cm, 90cm,1, Needle 35mm, ½ Circle Round Bodied (PGA204) 19. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Curved Cutting (PGA205) 20. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGA206) 21. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle	
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			Round Bodied (PGA207) 22. Thread 75cm, 90cm, 2/0, Needle 16mm, ½ Circle Curved Cutting (PGA208) 23. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Curved Cutting (PGA209) 24. Thread 75cm, 90cm, 2/0, Needle 60mm, Straight Cutting (PGA210) 25. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGA211) 26. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGA212) 27. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Curved Cutting (PGA213) 28. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGA214) 29 Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGA215) 30. Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Round Bodied (PGA216) 31. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGA217) 32. Thread 75cm, 90cm, 4/0, Needle 25mm, ½ Circle Curved Cutting (PGA218) 33. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Curved Cutting (PGA219) 34. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Curved Cutting (PGA220) 35 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle	
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			Curved Cutting (PGA221) 36 Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Curved Cutting (PGA222) 37 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGA223)	
2.	Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN ELI-00240 Fees: Rs 62,030 Paid on 19/05/2025 Challan # 89006840 Date of R& I 14th April 2025	<u>Legal Manufacturer:</u> NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD <u>Addres in FSC</u> Room 1201-9, No.456 Tai'an Middle RD, Yinzhou District, Ningbo, Zhejiang, CHINA. <u>Address in credential:</u> YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS ZONE, 315199, NINGBO, CHINA Copy of FQA valid till 23.11.2028 <u>Copy of LOA:</u> Sole Agency Agreement (Notarized by CCPIT, submitted with file): Valid till Jan. 2029 <u>FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health) Valid Upto: Dec, 2025 Copy of FQA valid till	<u>Brand Name:</u> YINGMED ABSORBABLE POLYGLACTIN SURGICAL SUTURE Class D <u>Shelf Life: 5 Years</u> <u>Codes/Sizes:</u> S. No DESCRIPTION 1. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied (PGLA101) 2. Thread 75cm, 90cm, 0, Needle 35mm, ½ Circle Round Bodied (PGLA102) 3. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Round Bodied (PGLA103) 4. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGLA104) 5. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Round Bodied (PGLA105) 6. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Round Bodied (PGLA106) 7. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGLA107) 8. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGLA108) 9. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Round Bodied (PGLA109) 10. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGLA110) 11. Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGLA111) 12. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle	Approved with name “Yingmed absorbable polyglactin 910 (PGLA)”, only one code that is PGLA101

		23.11.2028 Copy of DEC valid till 23.11.2028 <u>Copy ISO:</u> ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026	Round Bodied (PGLA112) 13. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGLA113) 14. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA114) 15. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied (PGLA201) 16. Thread 75cm, 90cm, 0, Needle 60mm, Straight Cutting (PGLA202) 17. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGLA203) 18. Thread 75cm, 90cm, 1, Needle 35mm, ½ Circle Round Bodied (PGLA204) 19. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Curved Cutting (PGLA205) 20. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGLA206) 21. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGLA207) 22. Thread 75cm, 90cm, 2/0, Needle 16mm, ½ Circle Curved Cutting (PGLA208) 23. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Curved Cutting (PGLA209) 24. Thread 75cm, 90cm, 2/0, Needle 60mm, Straight Cutting (PGLA210) 25. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGLA211) 26. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGLA212) 27. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Curved Cutting (PGLA213) 28. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGLA214) 29. Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGLA215) 30. Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Round Bodied (PGLA216)	
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			31. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA217) 32. Thread 75cm, 90cm, 4/0, Needle 25mm, ½ Circle Curved Cutting (PGLA218) 33. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Curved Cutting (PGLA219) 34. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Curved Cutting (PGLA220) 35. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Curved Cutting (PGLA221) 36. Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Curved Cutting (PGLA222) 37. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA223)	
3.	Applicant: M/s Safe Health Pakistan Bizcon. Office No. 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI- 00275) Track ID: PDS-58W-A1R8 Fee: PKR 5000/- Slip: 8401979738 Dated: 09-09-2021	(Legal Manufacturer) Name: M/S. Suzhou Yaxin Medical Products Co., Ltd. No. 12, Zhonghua Road, Mudu Town, Suzhou, Peoples Republic of China FSC Validity: 08-10-2025 Letter of authorization: Issuance date: 25-02- 2024 Expiry date: Not mentioned	Disposable Feeding Bag Venous™ 500ml,1000 ml, 1200 ml & 1500 ml Generic: Enteral Feeding set Class-A Shelf life: 05 years Storage Conditions: Room temperature	Disposed of as rejected in 101 MDB meeting.
4.	Applicant: M/s Safe Health Pakistan Bizcon. Office No. 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI- 00275) Track ID: PDS-58W-A1R8 Fee: PKR 5000/- Slip: 2043614 Dated: 06-10-2020	(Legal Manufacturer) Name: M/S. Suzhou Yaxin Medical Products Co., Ltd. No. 12, Zhonghua Road, Mudu Town, Suzhou, Peoples Republic of China FSC Validity: 08-10-2025	Disposable Chest Drainage Bottle (System) Single Chamber, Two Chambers & Three Chambers - Venous™ Class-A Letter of authorization: Issuance date: 25-02-2024 Expiry date: Not mentioned Shelf life: 05 years Storage Conditions: Room temperature	Disposed of as rejected in 101 MDB meeting.
5.	M/S. Safe Health	Legal Manufacturer:	Venous Biopsy Needle	Approved only one

	Pakistan Bizcon. Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275 R&I details 20th May 2025 Fee Rs. 30,000.00 through slip no. 511522573 Date 12-05-2025	M/S. Gangzhou Shengwei Medical Devices Co., Ltd. No 126, Gangshao Road, Aotou Town, Conghua District, Guangzhou 510945, Guangdong Province, China. LOA: Validity: 08-05-2027 FSC: Validity: 06-12-2025 ISO-13485: Validity: 10-04-2027	Class-B Shelf Life: 5 years Sizes: G-14, 16, 18, 20 & 22 Models: 121, 111, 112	code/Model 111.
6.	M/s Safe Health Pakistan Bizcon. Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan (ELI-00275) R&I Date: 10-02-2025 CMS tracking ID: XRX-454-YVVY Fee: 25,000/-	Manufacturer Name: M/S. Jiangsu Kangbao Medical Equipment Co., Ltd. Address: 78#, North Suzhong Road, Baoying 225800 Yangzhou, Peoples Republic of China. LOA Notarization: Yes Valid: 01-10-2029 • FSC Legalized: Notarized Issued by: JSMMPA, China Valid: 08-12-2025 ISO – Certificate: Notarization: No Valid till: 31-01-2026 EC Certificate: Valid till 26-05-2024	Brand Name: VENOUS Generic Name: THREE WAY STOPCOCK Applied as: Single Class: B Models/Code/sizes (as per FSC & application): Three-way valve Shelf life 5 years	Rejected as FSC is neither apostille nor legalized.
7.	M/S. Safe Health Pakistan Bizcon. Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275	Legal Manufacturer: M/S. Chamfond Biotech Co., Ltd. 2/F Building E, Sino Danish Eco Life Science Pak, Jiangbei, New Area, Nanjing Jiangsu, CN 21032, China. LOA: Issuance: 01-03-2025	Venous Disposable Biopsy Needle. Class-B Shelf Life: 5 years Sizes: G-8, 9, 11, 13, 15, 16, 18 Models:	Approved only one code BN-MAR-1/CF specification 1204.

	R&I details 9 th May 2025 Fee Rs. 30,000.00 through slip no. 851977932085 Date 12-05-2025	FSC: Validity: 11-05-2025 ISO-13485: Validity: 12-07-2027	BN, MAB, CF, CB, MA	
8.	M/S. Safe Health Pakistan Bizcon. Office No. 25, 2 nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)	<u>Legal Manufacturer:</u> M/S. Zheijiang Runqiang Medical Instruments Co., Ltd. Manufacturing Site: No. 618, Dade Road, Jiaxing Xiuzhou Distric, 314031 Jianxing City, Peoples Republic of China. FSC: Validity: Germany 14-07-2025. <u>LOA</u> Validity: 01-01-2025 <u>EC Certificate</u> Validity: 06-05-2025 <u>ISO 13485</u> Validity: 06-05-2023	Venous Extension Set (Pressure Tube) Class B Shelf Life: 05 years Codes/Sizes: As per FSC	Approved only 100cm.
9.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1121-C 23-12-2022	<u>Legal Manufacturer:</u> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo (Blood Gas analyzer, reagent pack, Test card and Control) Class-B Shelf life: not provided Codes: FSC is not provided	Approved Wondfo Blood Glucose Analyzer (BGA-102).
10.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1688-C 23-12-2022	<u>Legal Manufacturer:</u> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo Optical coagulation Analyzer Prothrombin Time kit Activated Partial Thrombin Time Reagent kit Fibrinogen Reagent kit Activated Clotting Time Reagent kit Thrombin Time Reagent kit Class-C Shelf life: Codes: FSC is not provided	Approved Wondfo Optical Coagulation Analyzer (OCG-102)..
11.	Safe Health Pakistan Bizcon Office # 18 & 19, 1st Floor, Dilkusha	Legal Manufacturer (as per FSC) Shandong Zhushi Pharmaceutical Group	Brand Name: Infusion Set For Single use With Needle Generic Name:	Disposed of as same has been registered through MDMC portal and same was

	Chambers, Marstom Road, Karachi - 74400. Pakistan, Karachi Fee: Rs 32400 /- Challan No.: 26538775407 Date of submission: 13 August 2025 Tracking ID: MDMR-20250813-00008	Co. , Ltd. Address: Fanlou South Road, Development Zone, Shan Country ISO 13485: Submitted Issue Date: 2025-05-28 Validity Date: 2028-05-27 Notarization Status: Apostille CCPIT EC Certificate: Submitted Issue Date: 2025-07-24 Validity Date: 2027-06-10 Issuing Authority: Shandong Zhushi Pharmaceutical Group Co. ,Ltd. Attestation Status: Apostille CCPIT FSC LOA: Submitted Issue Date: 2025-06-12 Validity Date: 2030-06-11 Notarization Status: Apostille CCPIT	Infusion Set For Single use With Needle Class B Device/Accessories Name: Infusion Set Shelf life/service life: 5 Years Codes/Sizes (if any): SY01 (Air Intake Type), SY02 (Non-air Intake Type)/0.36X15RWLB, 0.45X15RWLB, 0.55X20RWLB, 0.6X25TWLB, 0.7X25TWLB, 0.8X28TWLB, 0.9X28TWLB, 1.2X30TWLB Specify grouping: Family Storage condition: Room Temperature	confirmed from the firm telephonically.
12.	Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore ELI-01426 Date of R&I 18-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 3470975434	Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland Manufacturing site: Agri Bio Eco Laboratori riuniti S.r.l.via delle Albicocche 19,00071 Pomezia (Roma) Italy FSC Copy. LOA Validity: 06-05-2030 (Copy) FSC: Validity: 15-12-2026 (Copy) ISO Validity: 11-03-2027 (Copy) EU QA/ EC Certificate(copy) Validity: 26-05-2024	Brand name: JALUPRO HMW Generic Name: Jalupro HMW Class-D Shelf life: 36 MONTHS Models/ Specification	Approved as medical device on the basis of: 1. FSC (legalized) of swissmedic valid till 15.12.2026.

		(expired) Design Examination certificate, expired (copy) Validity: 26-05-2024		
13.	Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore ELI-01426 Date of R&I 18-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 898446811424	Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland Copy of LOA PROVIDED FSC: Apostilled Validity: 15-12-2026 (Original) ISO Validity: 11-03-2027 (Colored copy) EC Certificate (colored copy) validity: 26-05-2024 Design Examination certificate (colored copy) validity: 26-05-2024	Brand name: JALUPRO SUPER HYDRO Generic Name: Jalupro Super Hydro Class-D Shelf life: 36 months Models/ Specification	Approved as medical device on the basis of: 1. FSC (legalized) of swissmedic valid till 15.12.2026.
14.	Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore ELI-01426 Date of R&I 18-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 943450949312	Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland Manufacturing site: Agri-Bio-Eco Laboratori riuniti S.r.l.via delle Albicoche 19,00071 Pomezia (Roma)-Italy LOA Validity: 05-05-2030 (Copy) FSC: apostille Validity: 15-12-2026 (Copy) ISO Validity: 11-03-2027 (Copy) EU QA/ EC Certificate (copy)	Brand name: JALUPRO YOUNG EYE Generic Name: Jalupro young eye Class-D Shelf life: 36 MONTHS Models/ Specification	Approved as medical device on the basis of: 1. FSC (legalized) of swissmedic valid till 15.12.2026.

		Validity: 26-05-2024 (expired) Design Examination Certificate (copy) validity: 26-5-2024 (Expired)		
15.	La Vie Pvt. Ltd., 450 G/3, Gohar Town, Lahore ELI: 00113 R&I Date: 29.05.2025 Fee: 31000/- Slip #77290818984	Name of Manufacturer: Zhejiang haichuang Medical Device Co., Ltd. Address: #3 Building No. 146, East Chaofeng Road, Linping District, Hangzhou China LOA1: (Zhejiang haichuang Medical Device Co., Ltd.) has authorized Joy Beyond Health Limited, China) Type: copy Notarization: No Issue date: 13.09.2024 Validity: 12.09.2027 LOA2: (Joy Beyond Health Limited, China has authorized La Vie Pvt. Ltd., 450 G/3, Gohar Town, Lahore) Type: copy Notarization: No Issue date: 01.08.2024 Validity: 31.08.2027 FSC Type: Copy Issued By: Zhejiang Medical Product Administration Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce) Apostilled the notarization. Validity: 20.09.2025 ISO – Certificate: Type: Copy Legalization: Notarized (China council for the Promotion of International Trade China Chamber of	Brand Name: Bi-fix Generic Name: Surgical incision closure set Applied as: Set Class: B Models/Code/sizes (as per FSC & application: 5HWH-2, 5HWH-4, 5HWH- 6, 5HWH-8, 5HWH-10, 5HWH-12, 5HWH-16, 5HWH-20, (5HWH-24 applied but not mentioned in FSC) Shelf Life: 36 months	Rejected due to following reasons: 1. copy of the FSC China valid till 20.09.2025 with their reply on 18.10.2025. 2. Firm has not responded to query that is The firm has mentioned new application as well as proposed changes in the Form-7A. Clarification is required. 3. The address both Joy Beyond Health Limited & La-Via (Private) Limited not mentioned in LOA. 4. the codes mentioned in FSC are 5HWH-2A, 5HWH-4A, 5HWH- 6A, 5HWH-8A, 5HWH-10A, 5HWH-12A, 5HWH-14A, 5HWH-16A, 5HWH-18A, 5HWH-20A, 5HLS. 5. the code 5HLS not mentioned in DOC. 6. The codes 5HWH- 14A, 5HWH-18A, 5HWH-20A, not mentioned CABs extension letter. <i>copy of the accelerated shelf life study and claimed shelf life tentative from 24-30 months and in conclusion for 36 months.</i>

		International Commerce) Apostilled the notarization. Validity: 10.09.2027 CE certificate: Type: Copy Validity: 27.05.2024 Extension for Ila class: 31.12.2028		
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LOCAL PRODUCTS AGENDA

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM- 0084 valid till 27-10-2029) R&I date 03-06-2025 [1064-L] Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage,	Venus Non Sterile Disposable Examination Gloves Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 28734006 Sizes: Xs, S, M, L,XL	Deferred for the product specific inspection by the following panel, stability studies and fee for the family. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore

	Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section		
2.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1065-L] R&I date 03-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three-way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section	Venus Sterile Light Powdered Examination Gloves Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 35990270 Sizes: 6.5, 7.0, 7.5, 8, 8.5,9 & 9.5 Inches.	Deferred for the product specific inspection by the following panel, stability studies and fee for the family. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore
3.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1066-L] R&I date 03-06-2025	Venus Transducer Kit Double Chamber Transducer Kit Double Chamber Class: B	Deferred for the product specific inspection by the following panel, and submission of stability studies. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy

	Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section	Shelf Life: 5 Years Fee: 25000 Fee Slip No. 46783894	Director DRAP Lahore
4.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1068-L] R&I date 03-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section.	Venus Transducer Kit Single Chamber Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 84205617848	Deferred for the product specific inspection by the following panel, and submission of stability studies. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore

	6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section		
5.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1067-L] R&I date 03-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes,	Venus Surgical Tape Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 8069885302	Approved.

	Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section		
6.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1069-L] R&I date 20-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).	Venus Multi Filament Sutures Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1458891805	Deferred for the product specific inspection by the following panel, and submission of stability studies and fee for fsmly. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore

	13. Lap sponges with X-Ray Threads Section		
7.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1070-L] R&I date 20-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section.	Venus MonoFilament Sutures Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 13257895435	Deferred for the product specific inspection by the following panel, and submission of stability studies and fee for family. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore
8.	Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1071-L] R&I date 20-06-2025 Approved Sections:	Venus Non-Absorbable Sutures Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 0226046112	Deferred for the product specific inspection by the following panel, and submission of stability studies and fee for family. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore

	1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section.		
9.	Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084) [1072-L] R&I date 20-06-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic fistula, scalp	Venus Absorbable Sutures Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 700032499	Deferred for the product specific inspection by the following panel, and submission of stability studies and fee for family. 1. Dr. Mehmood Ahmad, Member MDB; 2. Sheikh Rasheed, Deputy Director DRAP Lahore

	vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section.		
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Item No. III:

PERSONAL HEARING AGENDA OF PORTAL CASES

Evaluator: Ghayour Ahmad (Deputy Director)

Subject: - **REGISTRATION/ENLISTMENT OF MEDICAL DEVICES TO IMPORT –PERSONAL HEARING NOTICE THEREOF.**

S.#	Name of Firm	Manufacturer's detail	Name of Medical Device	Decision of MDB
1.	Pharma Consultant Pakistan Pvt. Ltd. Suit No. 207, 207A, Khan Tower, DHA Square, Walton Road, Lahore Cantt, Lahore Fee Paid: Rs 104500 /- Challan No.: 916803691 Date of submission: 13 October 2025 Total Challans Fee Paid: Rs 104500 /- ELI no: ELI-00176 Tracking ID: MDMR-20251013-16665 - D-108	Legal Manufacturer (as per FSC) BIOMET, INC. also known as Biomet Orthopedics Address: 56 EAST BELL DR. P.O. BOX 587 WARSAW, IN USA 46581 ISO 13485: Submitted Issue Date: 2018-11-27 Validity Date: 2027-10-10 Notarization Status: Notarized EC Certificate FSC LOA: Submitted Issue Date: 2025-04-29 Validity Date: 2028-04-29 Notarization Status: Notarized	Brand Name: Vanguard Knee System Generic Name: Knee System Class D	<u>Decision of M-122.</u> <u>Proceedings:</u> <u>Personal Hearing of M/s Rech International:</u> Mr. Noman Ahmed Aftab (CNIC No. 42101-5831420-9), Strategy & Business Lead and Ms. Moomal Akbar (CNIC No. 44103-3170326-8), Regulatory Affairs Manager, appeared before the Board on behalf of M/s Rech International, Karachi. They presented copies of the following orders of VIIIth Senior Civil Judge, Karachi, in civil suit no 3266/2025 before the Board; Order of the civil suit 3266/2025 Dated 07-05-2025: <i>“In view of the submissions made and in the interest of justice, the operation of the termination letter dated 29-01-2024 is hereby suspended till the next date of hearing. The defendant is also restrained from appointing any new distributor in place of the plaintiff in violation of the agreement dated 03-05-2017. Let fresh summons be issued to the defendants through all permissible modes of service. To come up for further orders on 28-05-2025.”</i> Order of the civil suit 3266/2025 Dated 09-02-2026: <i>“Case called. Counsel for plaintiff is present. Counsel for defendant is present. Associate Counsel for plaintiff received the copy of Affidavit in re-joinder to C/A to appl. u/o VII Rule-11 CPC of defendant, Counsel for defendant submitted statement stating therein that the defendant is a foreign company based in USA and rejoinder to counter affidavit is filed and submitted scanned copy thereof and further undertake that he shall submit the original of the same on the next date after receiving of courier,</i>

				which is kept on record. W/S did not submit by defendant. Status-quo extended till next date. Put off to 23-02-2026 for filing W/S by defendant as last chance. For filing C/A by defendant on appl. u/o 1 Rule-10 CPC for Hg on appl U/O 7 Rule 11 R/W Sec 151 CPC.” They further requested the Board to maintain and continue the product authorization in favor of RECH International until the legal proceedings are conclusively decided as Hon’ble Civil Court has restrained Zimmer from appointing any new distributor in place of RECH International and the matter being sub-judice. The Board observed that the copies of the court orders were not certified true copies. The Board directed representatives of M/s Rech International, Karachi to submit certified true copies of court orders. They submitted that they have applied for issuance of certified true copies. <u>Personal Hearing of Pharma Consultant Pakistan Pvt. Ltd.</u> Mr. Muhammad Kashif Saleem (CNIC No. CNIC: 35200-1418611-5), Chief Executive Officer and Ms. Romesa Khan (CNIC No. 35202-0167327-0), Regulatory Affairs Officer appeared before the Board on behalf of M/s Pharma Consultant Pakistan Pvt. Ltd., Lahore. They contested that they have been issued a valid Letter of Authorization (LOA) by the manufacturer (Zimmer), appointing their company as the authorized importer/distributor. They further added that the manufacturer has also formally cancelled the previous authorization granted to RECH International, and the written cancellation letter is available on record. They further debated that referenced court order contains no explicit direction restraining the manufacturer from cancelling the previous LOA or requiring continuation of RECH
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				International's authorization and It also does not include any instruction to DRAP to maintain or recognize the earlier LOA. The issue appears to be a commercial dispute between private parties, with no specific directive issued to DRAP. Furthermore, there is no written legal basis for any objection raised against their authorization. In light of the valid LOA and the formal cancellation of the previous authorization, they requested to proceed on the basis of the legally issued and currently valid authorization documents submitted. <u>Decision:</u> The Board observed that the matter is sub-judice in the court. Keeping in view of the decision of the court the Board unanimously decided to defer the application till the conclusive decision of the Hon'ble Court regarding authorization of the product. Furthermore, the Board directed the parties to apprise the Medical Device Board regarding the final outcome of the court case without failure for further processing into the matter.
2.	Pharma Consultant Pakistan Pvt. Ltd. Suit No. 207, 207A, Khan Tower, DHA Square, Walton Road, Lahore Cantt, Lahore Fee Paid: Rs 104500 /- Challan No.: 58146668858 Date of submission: 03 September 2025 Total Challans Fee Paid: Rs 104500 /- ELI no: ELI-00176	Legal Manufacturer (as per FSC) ZIMMER, INC. Address: 1800 West Center Street WARSAW, INDIANA 46580 USA Manufacturing Site (as per FSC) ZIMMER MANUFACTURING B.V. Address: ROUTE 1, KM. 123.4, BLDG. 2 TURPEAUX INDUSTRIAL PARK MERCEDITA, PR USA 00715	Brand Name: PERSONA® The Personalized Knee System Generic Name: The Personalized Knee System Class D Codes applied	Decision of M-123. Personal hearing for the same matter in two other product of the same firms were considered in the 122nd meeting of the MDB. The Board decided to adopt the same decision in this case as well, as the same two companies are involved regarding the issue of authorization and cancellation. Therefore, the decision of the 122nd MDB is reproduced herer as under. Proceedings: Personal Hearing of M/s Rech International: Mr. Noman Ahmed Aftab (CNIC No. 42101-5831420-9), Strategy & Business Lead and Ms. Moomal Akbar (CNIC No. 44103-3170326-8), Regulatory Affairs Manager, appeared before the Board on behalf of M/s Rech International, Karachi.

	Tracking ID: MDMR- 20250903-14751 - D-104	Manufacturing Site (as per FSC) Zimmer Orthopedic Mfg Ltd Address: Building No 2 East Park Shannon Industrial Estate Shannon, Clare IRELAND 00000000 Manufacturing Site (as per FSC) Zimmer Orthopedics Manufacturing Limited-Galway Address: Deerpark Industrial Estate Oranmore, Galway IRELAND Galway ISO 13485: Submitted Issue Date: 2024- 08-22 Validity Date: 2027-08-21 Notarization Status: Notarized EC Certificate FSC LOA: Submitted Issue Date: 2025- 04-29 Validity Date: 2028-04-28 Notarization Status: Notarized		They presented copies of the following orders of VIIIth Senior Civil Judge, Karachi, in civil suit no 3266/2025 before the Board; Order of the civil suit 3266/2025 Dated 07-05-2025: <i>“In view of the submissions made and in the interest of justice, the operation of the termination letter dated 29-01-2024 is hereby suspended till the next date of hearing. The defendant is also restrained from appointing any new distributor in place of the plaintiff in violation of the agreement dated 03-05-2017. Let fresh summons be issued to the defendants through all permissible modes of service. To come up for further orders on 28-05-2025.”</i> Order of the civil suit 3266/2025 Dated 09-02-2026: <i>“Case called. Counsel for plaintiff is present. Counsel for defendant is present. Associate Counsel for plaintiff received the copy of Affidavit in re-joinder to C/A to appl. u/o VII Rule-11 CPC of defendant, Counsel for defendant submitted statement stating therein that the defendant is a foreign company based in USA and rejoinder to counter affidavit is filed and submitted scanned copy thereof and further undertake that he shall submit the original of the same on the next date after receiving of courier, which is kept on record. W/S did not submit by defendant. Status-quo extended till next date. Put off to 23-02-2026 for filing W/S by defendant as last chance. For filing C/A by defendant on appl. u/o 1 Rule-10 CPC for Hg on appl U/O 7 Rule 11 R/W Sec 151 CPC.”</i> They further requested the Board to maintain and continue the product authorization in favor of RECH International until the legal proceedings are conclusively decided as Hon’ble Civil Court has restrained Zimmer from appointing any new distributor in place of RECH International and the matter being sub-judice.
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				The Board observed that the copies of the court orders were not certified true copies. The Board directed representatives of M/s Rech International, Karachi to submit certified true copies of court orders. They submitted that they have applied for issuance of certified true copies. Personal Hearing of Pharma Consultant Pakistan Pvt. Ltd. Mr. Muhammad Kashif Saleem (CNIC No. CNIC: 35200-1418611-5), Chief Executive Officer and Ms. Romesa Khan (CNIC No. 35202-0167327-0), Regulatory Affairs Officer appeared before the Board on behalf of M/s Pharma Consultant Pakistan Pvt. Ltd., Lahore. They contested that they have been issued a valid Letter of Authorization (LOA) by the manufacturer (Zimmer), appointing their company as the authorized importer/distributor. They further added that the manufacturer has also formally cancelled the previous authorization granted to RECH International, and the written cancellation letter is available on record. They further debated that referenced court order contains no explicit direction restraining the manufacturer from cancelling the previous LOA or requiring continuation of RECH International's authorization and It also does not include any instruction to DRAP to maintain or recognize the earlier LOA. The issue appears to be a commercial dispute between private parties, with no specific directive issued to DRAP. Furthermore, there is no written legal basis for any objection raised against their authorization. In light of the valid LOA and the formal cancellation of the previous authorization, they requested to proceed on the basis of the legally issued and currently valid authorization documents submitted. Decision:
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				The Board observed that the matter is sub-judice in the court. Keeping in view of the decision of the court the Board unanimously decided to defer the application till the conclusive decision of the Hon'ble Court regarding authorization of the product. Furthermore, the Board directed the parties to apprise the Medical Device Board regarding the final outcome of the court case without failure for further processing into the matter. Submit the applicable fee for all product codes as per the new SRO notified on 1st August 2025. Provide documentary evidence clarifying whether these codes are intended to be used with any other device/system or otherwise
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Decision:

The Board observed that the matter is sub-judice in the court. Keeping in view of the decision of the court the Board unanimously decided to defer the application till the conclusive decision of the Hon'ble Court regarding authorization of the product. Furthermore, the Board directed the parties to apprise the Medical Device Board regarding the final outcome of the court case without failure for further processing into the matter.

CURRENT APPLICATION OF M/S PHARMA CONSULTANT REGARDING THE INSTANT COURT MATTER

M/S Pharma Consultant ha submitted an application regarding vacation of Interim Stay in Civil Suit No. 3266/2025 which is reproduced as under.

Respected Sir.

This is in continuation to our previous correspondence dated March 24, 2026 (acknowledged by your office on March 25, 2026), regarding the issuance of Certificates of Enlistment/Registration for import of Zimmer Biomet Medical Devices in favour of Pharma Consultant Pakistan (Pvt.) Limited.

We are writing to apprise the Drug Regulatory Authority of Pakistan (the Authority) of a decisive development in the litigation initiated by Rech International, before the Hon'ble Court of VIIth Senior Civil Judge, Karachi South

Rech International had previously relied on an interim stay order dated May 7, 2025, to argue that, the Authority should defer the transfer of licenses in favour of Pharma Consultant Pakistan (Pvt.) Limited ("PCP"). The said interim order has been vacated by the court by order dated April 1, 2026.

We enclose herewith the certified copy of the Order dated April 1, 2026. The court was pleased to observe that the interim order stands vacated since Rech International has failed to make even a prima facie case. This clearly establishes the frivolity of the case pleaded by Rech International before the Court as well as before the Authority

Without prejudice to the fact that the previously issued interim order was of no relevance to the subject matter before the Authority, as of April 1, 2026, there exists no judicial bar, injunction, or restraining order of any nature that prevents the Authority from exercising its statutory mandates.. Consequently, any further deferment would lack a valid legal basis and would inadvertently facilitate a private commercial entity's attempt to obstruct regulatory processes.

In light of the above and the urgent need to ensure the availability of critical medical devices, we earnestly request the Authority to kindly:

- to immediately issue Certificates of Enlistment/Registration for Zimmer Biomet products in the name of Pharma Consultant Pakistan (Pvt.) Limited.
- Grant us a brief audience to address any residual procedural queries and present any clarification as may be required

We trust the Authority will treat this matter with the utmost urgency and proceed with immediate issuance of the registration certificates in our favour.

If any other information or clarification is required, kindly grant us a brief audience to address any residual procedural queries and present any clarification as may be required.

The court orders in Civil Suit No. 3266/2025 is reproduced as under.

Suit called. Learned counsel for the plaintiff as well as learned counsel for the defendant are present. Today, the matter is fixed for orders on the application filed by the defendant under Order VII Rule 11 CPC. At this stage, learned counsel for the plaintiff has filed an application under Order XXIII Rule 1(2) CPC read with Section 151 CPC, seeking withdrawal of the present suit with liberty to file a fresh suit on the same cause of action. Copy of the said application has been received by the learned counsel for the defendant in Court today. Upon receipt of the same, learned counsel for the defendant seeks time to file a counter affidavit/reply. Prayer is allowed in the interest of justice. Accordingly, notice of the withdrawal application is issued to the defendant. The defendant is directed to file counter affidavit/reply to the said application on or before the next date of hearing, with advance copy to the opposite side.

Further, learned counsel for the plaintiff has also moved an application under Section 151 CPC seeking extension of the interim order till the disposal of the application under Order XXXIX Rules 1 and 2 CPC. After hearing, the said application is dismissed, as the interim order dated 07.05.2025 stands vacated as no sufficient ground has been shown for its extension. List the matter on & 3.04.2026 for filing of CA on the withdrawal application and meanwhile for orders. Ordered accordingly.”

Submitted for consideration of MDB, please.

Decision.

The MDB, after thorough review of the court order in Civil Suit No. 3266/2025 dated 1st April 2026 submitted by M/s Pharma Consultant, Lahore, observed that neither M/s Pharma Consultant is a party to the said suit nor final court orders received from the Court.

Therefore, the MDB decided that the latest updates regarding the matter shall be obtained from the plaintiff to ascertain the outcome of the instant court proceedings to decide the matter.

Evaluator: Saadat Ali Khan (Deputy Director)

Personal Hearing

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

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision
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/- 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 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	Celox RAPID Gauze Hemostatic Gauze Class: D [Size & Codes] FG08839021 MDIR-0000307 Applied as: Single Shelf life: 5 Years	The Board decided to grant final opportunity of personal hearing to M/s Healthline Pharmaceuticals Pvt. Limited, Lahore in the matter, to determine whether they agree to the transfer/surrender of registration of the applied products from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore, to M/s Sind Medical Stores, Karachi. Otherwise prove their authorization of the applied product by producing Updated Valid Notarized Letter of Authorization of the above mentioned Products.
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:	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	Celox Granules 15g Hemostatic Granules Class: D MD group: Single Shelf life: 5 Years [Size & Codes] FG08830181 MDIR-0000308	The Board decided to grant final opportunity of personal hearing to M/s Healthline Pharmaceuticals Pvt. Limited, Lahore in the matter, to determine whether they agree to the transfer/surrender of registration of the applied products from M/s Healthline Pharmaceuticals Pvt.

22-05-2024 BGE-MRH-AUGH	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		Limited, Lahore, to M/s Sind Medical Stores, Karachi. Otherwise prove their authorization of the applied product by producing Updated Valid Notarized Letter of Authorization of the above mentioned Products.
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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. The operative part of the decision is reproduced 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 Euroclinic ENT Unit.	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: 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	Otocompact Otocompact professional Otocompact professional EVO Otocompact professional TS Otocompact STEEL Otoplus ENT Unit Applied as Family Class-B Product code: Otocompact Professional	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 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

		Validity: without expiry date ISO 13485 not provided Instead copy of ISO 9001:2015 attached.	Otocompact Professional Evo Otocompact Steel OtoPlus Otocompact Plus Shelf life: N/A	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: Maquet GmbH 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: 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 th 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 Validity: 14-04-2028	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.
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 MANUFACTURER) M/s Livetec Ingenieurbüro Marie-Curie-Strasse 8 79539 Lorrach, Germany. FSC Germany Issuance 16-10-2023 (Original & attested) LOA valid till 31-12-2026 (Original and notarized)	Pace T10 External Cardiac Pacemaker Class C Codes/ sizes/models: 103721(T10)	Deferred in 69 th 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.

		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		
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Decision: 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 say that below mentioned application(s) by M/s Iqbal and Company Alfalah Manzil, Opp. National Police Foundation, Street#26, Sector, E-11/4, Islamabad, for transfer of registration of medical device from M/s Moody Global Service, Islamabad to their name were discuss by the Medical Device Board in its 127th meeting held on 8th April, 2026. The operative part of the decision is reproduced below against each: -

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision of 127 th Meeting of MDB
1.	Iqbal and Company Alfalah Manzil, Opp. National Police Foundation, Street#26, Sector, E- 11/4, Islamabad, Pakistan ELI-00117 R&I Submission Date: 02-07-2025 Fee Submitted: Rs. 203,300	Beijing Target Medical Technologies Inc. No.60, Shunren Rd. Shunyi District, 101300, Beijing, P.R. China LOA: Type: Scan copy of notarized copy. Validity Date: 14-01-2027 FSC Type: Scan copy of notarized copy	Safecath (Disposable Central Venous Catheter Kit) Class. D Applied as Family Shelf life: 3 Years Code/Model/Size: Single Lumen, Double Lumen, Triple Lumen:8.5F/8F/7F/5F/6F Codes: MMCVCBJ1-14-15 MMCVCBJY1-14-15	Deferred for submission of the following: 1. Justification of grouping with catalog is required along with fee for grouping if justified. 2. Copy of previous Registration letter along with any PRVs & renewal evidence (if applicable) Furthermore, both parties shall be called upon for a personal hearing in the matter, to

Rs. 62000/- Slip No. 673332822185 & Rs. 141300/- Slip No. 1763331160 Date: 27-06-2025 Tracking ID: XT4-T8D-XYB5	Issuance Date: 23-01-2025 Validity: 21-11-2026 FSC (RRA) Type: Scan copy of notarized copy. Issued by: The Netherlands Issuance Date: 13-02-2025 Validity: 11-09-2027 ISO 13485: Type: Original, notarized. Validity Date: 31-03-2028 NOC from MOODY Global Services Type: Scan copy Issuance Date: 15-01-2026 Transfer of Registration letter from Beijing Target Medical Technologies, Inc. Type: Scan copy of notarized copy. Issuance Date: 15-01-2026	MMCVCBJ1-14-20 MMCVCBJY1-14-20 MMCVCBJ1-14-30 MMCVCBJY1-14-30 MMCVCBJ1-16-15 MMCVCBJY1-16-15 MMCVCBJ1-16-20 MMCVCBJY1-16-20 MMCVCBJ1-16-30 MMCVCBJY1-16-30 MMCVCBJY1-18-15 MMCVCBJY1-18-20 MMCVCBJY1-18-30 MMCVCBJY1-20-13 MMCVCBJY1-16-30 MMCVCBJY2-40-05 MMCVCBJY2-40-08 MMCVCBJY2-40-13 MMCVCBJY2-50-08 MMCVCBJY2-50-13 MMCVCBJY2-50-20 MMCVCBJ2-70-15 MMCVCBJY2-70-15 MMCVCBJ2-70-20 MMCVCBJY2-70-20 MMCVCBJ2-70-30 MMCVCBJY2-70-30 MMCVCBJ2-70-50 MMCVCBJY2-70-50 MMCVCBJY3-55-08 MMCVCBJY3-55-13 MMCVCBJ3-70-15 MMCVCBJY3-70-15 MMCVCBJ3-70-20 MMCVCBJY3-70-20 MMCVCBJ3-70-30 MMCVCBJY3-70-30	determine whether they agree to the transfer of registration of the applied products from Moody Global Services ELI-00926., to M/s Iqbal and Company, Islamabad.
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Decision: The Board decide to grant final opportunity of personal hearing to M/s Moody Global Service, Islamabad to determine whether they agree to the transfer of registration of the applied products. Otherwise prove their authorization of the applied product by producing Updated Valid Notarized Letter of Authorization of the above-mentioned Products.

Furthermore, the case of Iqbal and Company Alfalah Manzil, Opp. National Police Foundation, Street#26, Sector, E-11/4, Islamabad is deferred for provision of

1. Justification of grouping with catalog is required along with fee for grouping if justified.
2. Copy of previous Registration letter along with any PRVs & renewal evidence (if applicable)

Case No:05: 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. The operative part of the decision is reproduced 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

[illegible]

	25,000/- Challan No.: 705185019	Mars Enterprises, Shelf life: 5 Years Termination Letter Scan copy of [Size & Codes] notarized copy. (With filter, Date of issuance: 22-01-2024 Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi dated 15-08-2023. SSC Cance: 22-01- Type: Scan copy of Copy of NOC Issued by: NMPA - Registration of Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 ECQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	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	Amhui Easyway I Care Sterile Insulin Medical Supplies Co. Disposable Syringe for single use ISD Supplies CO., Sterile (Blood, 1ml) Address: No.737, East MDIR-0002351 Andher Road, Set for MDIR group: Single Nan Chang City, Anh use Class: B Pinghu Road, (With filter, life: 5 Years PT. Ronghui City, with of Size & Codes] LAOAI Province, without 0.5ml, 1ml Type: Scan copy of (needle) notarized copy. (MDIR- Validity: 22-01-2024 002349) Termination letter MD group: notarized copy (Single Validity: 22-01-2024 Class: B 01-2029 Shelf life: 5 Termination Copy of Years notarized copy. [Size & Codes] Date of issuance: 22-01-2024 (With filter, 2024 orter (M/s without Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi on its letter dated 15-08-2023. SSC of Type: Scan copy of notarized copy.	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

		ISO 13485 by NOMPA - China transfer of Validity: 19-06-2025 ISO 13485 by Type: Scan copy of notarized copy. Validity: 06-07-2026 EC-QA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024		
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 Supplies Co., Ltd. ISD Supplies CO., Address: No.737, East Chang Road, Nanzhang City, Anhui Province, China Type: Scan copy of notarized copy. Validity: 22-01-2024 Termination letter notarized copy Validity: 22-01-2024 Type: Scan copy of notarized copy. Date of issuance: 27-01-2024 Copy of NOC for transfer of products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. Type: Scan copy of notarized copy. ISO 13485 by NOMPA - China transfer of Validity: 19-06-2025 ISO 13485 by Type: Scan copy of notarized copy. Validity: 06-07-2026 EC-QA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Syringe for single use (Blind 10ml, 20ml) Sterile (MDIR-0002352) Set for MD group: Single Class: B (With shelf life: 5 Years [Size & Codes] without 10ml, 10ml, 20ml (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

	25,000/- Challan No.: 705185019	Mars Enterprises, Shelf life: 5 Years Termination Letter Scan copy of [Size & Codes] notarized copy. (With filter, Date of issuance: 22-01-2024 Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi on its letter dated 15-08-2023. SSCance: 22-01- Type: Scan copy of Copy of NOC Issued by: NMPA - Registration of Validity: 06-07-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 ECQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	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 I Care Disposable Sterile Medical Supplies Co., Disposable Intravenous Needle for ISD Supplies CO., Sterile High Use Address: No.737, East Street, MDLR-0002355 Andher Road, Set for MDL group: Single Nanjing City, Anhui Province, Class: B Pianjiang Road, (With filter, shelf life: 5 Years PT. R. CHHAI City, with [Size & Codes] LAOUI Province, without (with wings) – (0.4mm, Type: Scan copy of needle) 0.45mm, 0.5mm, 0.55mm, LAOUI Azed copy. (MDLR-0.6mm, 0.7mm, 0.8mm, Validity: 22-01-2024 MDLR-0.9mm, 1.1mm, 1.2mm) Termination letter MD group: notarized copy (Single Validity: 22-01-2024 Class: B Shelf life: 5 Termination copy of Years notarized copy. [Size & Codes] Date of issuance: 22-01-2024 Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi on its letter dated 15-08-2023. SSC of Type: Scan copy of notarized copy.	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

		ISO 13485 by NOMPA - China transfer of Validity: 19-06-2025 ISO 13485 by Type: Scan copy of notarized copy. Validity: 06-07-2026 EC-QA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024		
9	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 Supplies Co., ISIP, Supplies CO., Address: No.737, East Jianhe Road, Nanzhang City, Anhui Province, China Type: Scan copy of notarized copy. Validity: 22-01-2024 Termination letter notarized copy Validity: 22-01-2024 Type: Scan copy of notarized copy. Date of issuance: 27-01-2024 Copy of NOC for transfer of products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. Type: Scan copy of notarized copy. ISO 13485 by NOMPA - China transfer of Validity: 19-06-2025 ISO 13485 by Type: Scan copy of notarized copy. Validity: 06-07-2026 EC-QA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Connecting Extension Tubes Sterile for single use MDIR-0002356 Set for MD group: Single Class: B (With shelf life: 5 Years with or without filter, without needle) MD group: Single Class: B Shelf life: 5 [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

	25,000/- Challan No.: 705185019	Mars Enterprises, Shelf life: 5 Years Termination Letter Scan copy of [Size & Codes] notarized copy. (With filter, Date of issuance: 22-01-2024 Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi on its letter dated 15-08-2023. HSN of Type: Scan copy of notarized copy. Validity: 26-05-2024	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 I Care Disposable Sterile Medical Supplies Co., Disposable Syringe for single use ISDPLIES CO., Sterile MDIR-0002359 Address: No.737, East Main Road, Set for Single B and He Road, use Shelf life: 5 Years Nan Zhang City, Anhui Province, (With filter, & Codes] Piaohe Road, with 30ml, 50ml, 60ml, 100ml PT. RICHING City, without LAOAI Province, (needle) Type: Scan copy of notarized copy. (MDIR- Validity: 22-01-2024 Termination letter MD group: notarized copy (Single Validity: 22-01-2024 Type: Scan copy of notarized copy. [Size & Codes] Date of issuance: 22-01-2024 Copy of NOC for needle) transferee Registration of type: Products by M/s Mars Enterprises, Karachi on its letter dated 15-08-2023. HSN of Type: Scan copy of notarized copy.	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

		ISO 13485 by NOMPA - China transfer of Validity: 19-06-2025 ISO 13485 by Type: Scan copy of notarized copy. Validity: 06-07-2026 EC-QA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024		
13	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 Supplies Co., ISIP, Supplies CO., Address: No.737, East Jianhe Road, Nanzhang City, Anhui Province, P.R.China Lic. No. ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	I Care Disposable Sterile Infusing and Feeding Sterile Blonges for single use MDIR-0002360 Set for MD group: Single Class: B (With shelf life: 5 Years without filter, 100ml, 10ml, 20ml, 50ml, 60ml, 150ml, 200ml, 250ml, 300ml, 350ml, 500ml (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

14	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 Supplies CO., Ltd. Address: No.737, East Chang East City, Anhui Province, China Type: Scan copy of notarized copy. Validity: 22-01-2024 Termination letter provided by M/s Mars Enterprises, Karachi dated 08-2023. HSC of Dispense 22-01-2024 Issued by NMMPA - China Transfer of Validity: 19-06-2025 ISO 13485 by M/s Mars Enterprises. 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 Blood Transfusion Set for Single Use MDIR-0002824 MD group: Single Class: B (With filter, life: 5 Years with or without filter) TS-01, TS-02, TS-03, TS-04, TS-05, TS-06 (MDIR-2002349) 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
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Decision: The Board decided to grant final opportunity of personal hearing to M/s Mars Enterprises, Karachi to determine whether they agree to the transfer/surrender of registration of the applied products. Otherwise prove their authorization of the applied product by producing Updated Valid Notarized Letter of Authorization of the above-mentioned Products.

Furthermore, the case of M/s Hospital Services & Sales, 13-C Annexe, Block 6, PECHS, Karachi is deferred for provision of the following:

1. Evidence of submission of renewal Application by the Registration Holder (M/s Mars Enterprises, Karachi).
2. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.

POST LICENSE VARIATION

Case No.01: CHANGE OF MANAGEMENT

S. No.	Name of Establishment	Existing Details of ELI	Proposed Details for ELI	Decision
1.	M/s Al Hamd Enterprises, FL-11/1/1 , Block- 6, Gulshan-e-Iqbal , Karachi ELI-00285 issued on 22-10-2018 Change of management (Directors/Partners)	Existing Management/ Proprietors Mr. Aslam Ullah Khan, Nouse No.FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. CNIC: 42101-3645836-9	Proposed Management/ Proprietors Mr. Imran Khan, C-93, Block-15,tan-e-Johar, Karachi. CNIC:42101-0997924-9 Ms. Sundus Imran, C-93, Block-15,tan-e-Johar, Karachi. CNIC:42201-6331046-6 Mr. Aslam Ullah Khan, Nouse No.FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. CNIC: 42101-3645836-9	The board on the statement of Mr. Aslam Ullah Khan that he is transferring the shares to other partners with his own will and submitted undertaking, approved the change of management.

Item No. IV:

ADDITIONAL AGENDA FOR 129TH MEETING OF MDB

MR. ASIF JALIL (DEPUTY DIRECTOR)

Agenda Item No.1. CANCELLATION OF REGSITARTION OF 2-5ML SIZES/VOLUME OF CONVENTIONAL SYRINGES FOR IMPORT ALREADY BANNED BY MINISTRY OF COMMERCE AND FEDERAL GOVERNMENT.

Pakistan is facing multitude of public health crises due to rapidly rising burden of blood borne infections like Hepatitis-c, AIDS etc. There are many causes of spreading of blood borne infections including un-screened blood transfusions or organ transplants from an infected donor, infected mother to her infant during pregnancy, childbirth, or breastfeeding, re-use of single use syringes, etc. In order to holistically review the situation and to suggest the viable solution to the problem of blood borne diseases in Pakistan, M/o NHS,R&C constituted National Task Force on Injection Safety in November, 2019. The task force closely worked with all the stakeholders including manufacturers, importers and healthcare providers and after thorough deliberations finally recommended the replacement of conventional syringes to auto-disable /re-use prevention syringes. On the recommendation of National Task Force on Injection Safety, M/o NHS,R&C forwarded summary for imposing ban on import and manufacturing of conventional syringes for the sizes/volume of 2ml, 2.5ml, 3ml, 5ml w.e.f 01-04-2021 and 01-08-2021 respectively. The Economic Coordination Committee of the Cabinet approved the summary vide Case No. ECC-64/7/2021 dated 10-03-2021.

Accordingly, Ban was imposed by Ministry of commerce on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml) vide SRO 483(I)/2021 dated 16-04-2021. The MDB in its 36th meeting also cancelled registrations of 24 locally manufactured conventional syringes (2ml, 2.5ml, 3ml, 5ml). Thereafter, as per aforesaid policy, import and manufacturing of conventional syringes (2ml, 2.5ml, 3ml, 5ml) are banned till date while other sizes/volume of conventional syringes (1ml, 10ml, 20ml, 30ml, 50ml,) and all types of re-use prevention syringes (auto-disable, self- Destructive, Retractable syringes etc) are allowed to be imported and manufactured locally.

It is further submitted that although ban has already been imposed by Ministry of commerce on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml) vide SRO 483(I)/2021 dated 16-04-2021, it is proposed that the registration of these sizes/volumes may also be cancelled by the MDB. Following conventional syringes having sizes/volume from 2ml to 5ml for import were registered since 2018 under MDR, 2017 with details as mentioned in table below. The current status of registrations along with reply of firms is also mentioned against each for consideration of MDB. Accordingly the board decided each case as mentioned in last column of following table:

Sr. No	Importer Name	Manufacturer Name	Medical Device Name	Reg.No.	Decision of MDB
1	M/s IBL Health Care First Floor N.I.C.L Building Abbasi Shaheed Road. Karachi Godown Address : F-2 Q, PTC Factory SITE Karachi	Manufacturer: M/s Shandong Weigao Group Medical Polymer Co., Ltd. No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China	WEGO Disposable Syringes for Single Use (1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml)	MDIR-0000004	As the Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml) and on the request of firm to discontinue 2ml, 2.5ml, 3ml, 5ml, the MDB decided to cancel the registration of 2ml, 2.5ml, 3ml, 5ml.
2	M/s Matrix Medical Care Flat No.55/5, First Floor, Shadman Market, Lahore	Manufacturer: M/s Zibo Qray International Co., Ltd. No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China	Qraymed Sterile Hypodermic Syringes for single use QR06-0201, QR06-0202, QR06-0203, QR06-0204, QR06-0205, QR06-0206, QR06-0207, QR06-0301, QR06-0302, QR06-0303, QR06-0304, QR06-	MDIR-0000067	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement that due to the termination of their collaboration with the manufacturer, they did not proceed with the renewal of product registration within due date and the registration of the product ceased to exist

			0305, QR06-0306, QR06-0307, QR06-0308, QR06-0309, QR06-0310		since 22-02-2025. Therefore, the MDB decided to cancel the registration of Qraymed Sterile Hypodermic Syringes for single use for all sizes/variants having Reg. No MDIR-0000067.
3	M/s Nasir Brothers, Office No 22B, 2nd Floor, Zeenat Medicine Market, North Napier Road, Karachi. Godown Address: Plot No 149 150, Ground Floor , Block 7/8, Memon Cooperative Housing Society Karachi	M/s Changzhou Jinlong Medical Plastic Appliance Co. Ltd., Zhennan Road, Zhenglu Town, Changzhou City, Diangsu Province, China	VCARE Sterile Syringes for single use (with needle) 1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL	MDIR-0000418	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has not submitted renewal of registration within due time and therefore under Rule 16(5) of the MDR 2017, the registration of the product ceased to exist since 30-05-2025. Therefore, the MDB decided to cancel the registration of VCARE Sterile Syringes for single use (with needle) for all sizes/variants having Reg. No MDIR-0000418.
4	M/s Unique Pharma House No 1775/21, Street No.1, Tariqabad , MDA Road, Multan	M/s. Shanghai Kindly Enterprise Development Group Co., Ltd. 658, Gaochao Road, Shanghai, 201803, China	Easy Pro Disposable Syringe 1ml,2ml,2.5ml,3ml, 5ml, 10ml,20ml,25ml,30 ml,35ml,50ml,60ml	MDIR-0000499	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement that due to discontinuation of their commercial arrangement with the manufacturer/supplier and other business considerations, they have not applied for renewal of the following-mentioned registrations within the stipulated time and accordingly, these registrations may be treated as lapsed/ expired. Therefore, the registration of these products ceased to exist since 08-07-2025. Accordingly, the MDB decided to cancel the registrations of following

					medical devices for all sizes/ variants: <table><tr><td>S R N o.</td><td>Produ ct Name</td><td>Registr ation Numbe r</td></tr><tr><td>1</td><td>Easy Pro Dispos able Syring e</td><td>MDIR- 00004 99</td></tr><tr><td>2</td><td>Hypod ermic Needl es</td><td>MDIR- 00005 00</td></tr><tr><td>3</td><td>Uni- Set Infusi on Set</td><td>MDIR- 00005 01</td></tr><tr><td>4</td><td>Uni- Set Infusi on Set with Burett e</td><td>MDIR- 00005 02</td></tr></table>	S R N o.	Produ ct Name	Registr ation Numbe r	1	Easy Pro Dispos able Syring e	MDIR- 00004 99	2	Hypod ermic Needl es	MDIR- 00005 00	3	Uni- Set Infusi on Set	MDIR- 00005 01	4	Uni- Set Infusi on Set with Burett e	MDIR- 00005 02
S R N o.	Produ ct Name	Registr ation Numbe r																		
1	Easy Pro Dispos able Syring e	MDIR- 00004 99																		
2	Hypod ermic Needl es	MDIR- 00005 00																		
3	Uni- Set Infusi on Set	MDIR- 00005 01																		
4	Uni- Set Infusi on Set with Burett e	MDIR- 00005 02																		
5	M/s Searle Company Limited First Floor N.I.C.L Building Abbasi Shaheed Road. Karachi. Godown Address : F-2/Q SITE Karachi.	M/s Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE	Medeco Inject Single use Syringe 2ml, 3ml & 5ml	MDIR- 0000741	As the Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml) and on the request of firm to discontinue 2ml, 3ml, 5ml, the MDB decided to cancel the registration of Medeco Inject Single use Syringe (2ml, 3ml & 5ml) having Reg. No MDIR-0000741.															
6	M/s Lab Link Enterprises M-203, Block 2, P.E.C.H.S Opp Ghousiya Masjid, Karachi. B-40, S.I.T.E, Karachi	M/s PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta Jl. Surya Utama Kav. I-22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia.	Nipro Disposable Syringe (with needle) 1ml, 3ml, 5ml, 10ml, 20ml	MDIR- 0001101	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement that that they have not submitted renewal of registration of 3ml and 5ml within stipulated time and discontinued these sizes/variants. Therefore, the MDB															

					decided to cancel the registration of 3ml and 5ml sizes/variants.
7	M/s Wasim Co. Medicine Centre, 2nd Floor, Kachi Gali No 1, Marriot Road, Karachi. Godown Address: Sadaf Center SR- - 3/22 Serial Road, 2nd Floor No.15 & 26, Karachi.	M/s Changzhou Yuandong Medical Equipments Co., Ltd Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China	Classic Fine Disposable Syringes Sterile, With needle [1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml]	MDIR-0001118	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement that they request for the withdrawal of 3ml and 5ml from already registered medical device. Therefore, the MDB decided to cancel the registration of 3ml and 5ml sizes/variants.
8	M/s Mars Enterprises, Office No 4, Jason Center, 2nd floor, BC-8, Block 9, Clifton, Karachi	M/s Anhui Easyway Medical Supplies Co., Ltd., No. 737 East Jianshe Road, Tianchang City, Anhui Province, China.	I care Disposable Sterile Irrigating and Feeding Syringes for Single Use 5ml, 10ml, 20ml, 50ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 500ml	MDIR-0002360	As the Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Therefore, the MDB decided to cancel the registration of 5ml.
9	M/s MSB Medical F-2, 1st Floor, 51-1/C, Block-6, P.E.C.H.S, Karachi	M/s Jung Rim Medical Industrial Co. Ltd., 187, Jinkwange RO, Iwol-myeon, Jincheon gun, chungbuk, Republic of Korea	Jung Rim Disposable Syringe (Disposable Syringe with needle) [1ml, 5ml, 10ml, 20ml]	MDIR-0003919	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement that they have discontinued 5ml size and requested for the withdrawal of 5ml from already registered medical device. Therefore, the MDB decided to cancel the registration of 5ml.
10	M/s B.N Trading Company Office No. 207, 2nd Floor Makka Tower, Namak Mandi, Peshawar	M/S JIANGSU WEBEST MEDICAL PRODUCTS CO., LTD Adress no,5, ying Chun Road, industrial Park.21700 Xuyi, Jiangsu Province, Peoples	BESTLIFE Sterile Syringes with Needle for Single Use [1ml/2ml/3ml/5ml/10ml/20ml/50ml Needle Size: 0.3/0.33/0.4/0.45/0.5 /0 .55/0.6/0.7/0.8/0.9/1.2 mm]	MDIR-0007504	The MDB thoroughly discussed that ban has already been imposed by Federal Government and accordingly by Ministry of Commerce on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml) vide SRO 483(I)/2021 dated 16-04-2021. Therefore, the MDB decided to issue show cause

		Republic of China Mfg.site: M/S JIANGSU WEBEST MEDICAL PRODUCTS CO., LTD No,18, ying Chun East Road, Industrial Park,211700 Xuyi, Jiangsu Province, Peoples Republic of China			notice/ personal hearing to the firm under Medical Devices Rules, 2017 for cancellation of 2ml, 3ml and 5ml sizes/ variants.
11	United Healthcare Plot No.330/B, 2nd Floor DMCH, Bahadurabad, Karachi.	M/s Hebei ZOJE Medical Equipment Co., Ltd. No.19, Zhuming north street, Xincheng Industrial Park, Linzhang County 056600 Handan City, Hebei Province, P.R. China	Star Care Sterile Syringe with Needle for Single Use Straight Plug middle head type (Z) 1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml	MDIR-0008816	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement with request to cancel 2ml and 5ml from already registered medical device. Therefore, the MDB decided to cancel the registration of 2ml and 5ml.
12	United Healthcare Plot No.330/B, 2nd Floor DMCH, Bahadurabad, Karachi.	M/s Jiangsu Webest Medical Product Co., Ltd. No.5 Yingchun Rd. Industrial Park 211700 Xuyi, Jiangsu PEOPLE'S REPUBLIC OF CHINA	Starmed Sterile Syringe with Needle for Single Use 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml 0.3mm, 0.33mm, 0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.2mm	MDIR-0008833	The Federal Government and Ministry of Commerce has imposed ban on import of conventional syringes (2ml, 2.5ml, 3ml, 5ml). Furthermore, the firm has submitted written statement with request to cancel 2ml, 3ml and 5ml from already registered medical device. Therefore, the MDB decided to cancel the registration of 2ml, 3ml and 5ml.

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