

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

DECISIONS OF 133rd MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 9th & 10th JUNE 2026

133rd 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 9th & 10th June 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. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary
3.	Mr. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
4.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
5.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
6.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member (attended meeting through videolink)
7.	Dr. Farid Khan, Senior Consultant Neurosurgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
10.	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)
11.	Mrs. Tazeen S Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-Opted Expert (attended meeting through videolink)
12.	Mr. Salateen Waseem Phillip, Deputy Director QC on behalf of Director QA< Division	Co-Opted Expert
13.	Mr. Shoaib Ali Khan, Deputy Director Legal Affairs Division	Co-Opted Expert

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants. The Evaluator, Mr. Khalid Mehmood, Deputy Director, MD&MC Division assisted the secretary in presenting the agenda for the meeting.

Sr.No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Ms. 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. Ammar Ashraf Awan	Deputy Director
10.	Dr. Hanif Ullah	Deputy Director
11.	Mr. Khalid Mahmood	Deputy Director
12.	Mr. Asif Jalil	Deputy Director

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

i. FRESH CASES FOR RENEWAL OF ELM:

S.No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1	M/s Asian Fiber, Office/godown: Plot No.41 and 42, Sector-25 Korangi Industrial Area, Karachi. ELM-0031	Muhammad Ali B. Pharmacy	Ms Mehvish Sarfraz Pharm D	The board observed that the operations of the firm have been ceased and premises have been sold out. Moreover, renewal of license was due on 16-07-2024 and the firm hasn't made renewal application even after lapse of more than one year of expiry of license. Therefore, the board declared the license invalid under rule 7(5) of medical devices rules 2017. The registrations/ enlistment of products held by the firm shall also become invalid/ cease to exit under medical devices rules 2017.
2	M/s Kolachee International (Pvt) Ltd, Office/godown: Plot No. C-79, Estate Avenue, Opp JS Bank SITE Branch, Karachi ELM-0017	Mr. Noor ul Amin Bs Bio medical Engineer	Mr. Hammad Hussain BS (Bio Medical Engineering)	The board observed that the operations of the firm have been ceased and its operations and the premises is observed to be nonfunctional / inoperative. Moreover, renewal of license was due on 17-03-2025 and the firm hasn't made renewal application even after lapse of more than one year of expiry of license. Therefore, the board declared the license invalid under rule 7(5) of medical devices rules 2017. The registrations/ enlistment of products held by the firm shall also become invalid/ cease to exit under medical devices rules 2017.

Item No. I(B) : 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 FDS (Pvt) Ltd., office/godown: Flat No.8, 1st Floor, Ganga Ram Mansion Shahrah-e- Quaid-e-Azam, Lahore ELI-00475	Hajrah Malik Pharm D	Mr. Changez Yusuf Mumtaz Ms. Qudsia Mumtaz	Approved. Room temp products.
2.	M/s Glow Pak International, office/godown: 129/5-M Quaid E Azam Industrial Estate, Kot Lakhapt, Lahore. ELI-00298	Mr. Sayyed Fazlullah BSc Biomedical Engineering	Mr. Muhammad Idress Qadri Mr. Shoaib Afzal Mr. Muhammad Anees Qadri	Approved. Room temp products

Item No. I(C): RENEWAL OF ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES / MANAFATURE MEDICAL DEVICES.

Renewal applications of following firms had become late, and all these firms were advised to submit late renewal fees under Rule 7(5) of Medical Drives Rules 2017 on the 28th October, 2025. The rule position 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.”

S.No	Firm Name	Renewal Due On	Renewal application Received on	Months Late
1.	M/s Sky Traders A-11, Ground Floor, Al-Hilal Co-Operative Housing Society, Block No. IV & V, KDA Scheme No. 7, Karachi. (ELI-00047).	03/08/2023	19/09/2023	2 months late fee remaining
2.	M/s Hi Tech Scientific International, 67/1 E Satelite Town, Rawalpindi (ELI-00207)	19/10/2023	03/01/2024	2 months late fee remaining
3.	M/s Oncogene Pharmaceuticals, Mezanine floor , 246-B Block 6 PECHS, Karachi, Pakistan (ELI-00013)	03/08/2023	10/01/2024	6 months late fee remaining
4.	M/s SHARIF TRADING COMPANY, ADJACENT D-691, NEELUM BLOCK, HOUSE NO.20/3A, AL-HAMD COLONY, ALLAMA IQBAL TOWN,LAHORE (ELI-00115)	03/08/2023	18/08/2023	1-month late fee remaining
5.	M/s OPTIC CLASS DISTRIBUTION NETWORK, OFFICE NUMBER 02 FIRST FLOOR SHANE ARCADE BARKAT MARKET NEW GARDEN TOWN LAHORE (ELI-00304)	18/10/2023	13/12/2023	1-month late fee remaining

6.	M/s Life Scan Enterprises, R-274, First Floor Railway Society, 13 D2 Sheba Akhter Road, Gulshan-e-Iqbal Karachi (ELI-00181)	22/10/2023	03/02/2024	4 months late fee remaining
7.	M/s Battla Associates, Allah wala Building Kutchi gali No1 Marriot Roads Karachi (ELI-00281)	22/10/2023	17/11/2023	1-month late fee remaining
8.	M/s SAFEMED TECHNOLOGIES, Apt.3, 2nd Floor, RETOON PALAZA, SECTOR G-15/1, ISLAMABAD (ELI-00296)	18/10/2023	21/02/2024	5 months late fee remaining
9.	M/s Matrix Medical Care, 25-B Lower Mall 2nd Floor, Lahore (ELI-00124)	03/08/2023	11/09/2023	2 months late fee remaining
10.	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan(Private) Limited, Plot No. C-5, Block 7/8 KCHSU, Shaheed-E-Millat Road, Karachi (ELI-00374)	29/02/2024	04/04/2024	2 months late fee remaining
11.	M/s Vertex Medical Pvt Ltd, 70-B 1 Gulbuge 3, Lahore (ELI-00150)	17/10/2023	13/11/2023	1-month late fee remaining
12.	M/s ENDOKARE, 14 A AIBAK BLOCK NEW GARDEN TOWN Lahore (ELI-00153)	21/02/2024	11/06/2024	4 months late fee remaining
13.	M/s Lab Line 98, National Medicine market, Arambagh Road, Karachi (ELI-00437)	09/06/2024	29/06/2024	1-month late fee remaining
14.	M/s UNITED INTERNATIONAL, GNB-F 18/A GROUND FLOOR F- BLOCK MEHER SONS ESTATE Karachi (ELI-00272)	19/10/2023	15/08/2024	10 months late fee remaining
15.	M/s S.K Surgical, 60 C, Mezzanine Floor ,11th Commercial Street, DHA Phase II Ext., Karachi, Pakistan (ELI- 00426)	26/05/2024	25/09/2024	4 months late fee remaining

16.	M/s Technology Link, Office # 4/18 Rimpia Plaza 4th Floor M.A. Jinah Road, Karachi-Pakistan. (ELI-00427)	26/05/2024	25/09/2024	4 months late fee remaining,
17.	M/s JET SERVICES INTERNATIONAL, 231 BLOCK B2 JOHAR TOWN, LAHORE (ELI-00407)	29/05/2024	22/12/2024	7 months late fee remaining. The firm submitted 5 months fee but 2 months remaining.
18.	M/s Bone Solution, Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A., Karachi, Pakistan. (ELI-00517)	05/02/2025	10/02/2025	1-month late fee remaining
19.	M/s JD Professional Health Care Services SMC PVT LTD, Office #310, 311 3rd Floor Bank Road Saddar, Rawalpindi. (ELI-00560)	12/02/2025	18/02/2025	1-month late fee remaining
20.	M/s KARACHI MEDICAL COMPANY, B-47, AL-HILAL SOCIETY, Karachi (ELI-00464)	25/11/2024	20/06/2025	7 months late fee remaining
21.	M/s Green Top Pharma, B-137, Block-D, Five Star Chowrangi, North Nazimabad, Karachi (ELI-00393)	22/05/2024		
22.	M/s Hyderabad Dental Supply Co, Flat No 104/B-36 Block 13-A, Gulshan-e-Iqbal, Karachi ELI-00545	06/02/2025	16/01/2026	7 months late fee remaining
23.	M/s The National Radio Telecommunications Corporation (Pvt) Ltd, T&T Complex, Haripur, KPK ELM-0020	08/09/2025	10/03/2026	7 months late fee remaining

Decision: The board observed that all the above licence holder(s) have failed to complete renewal applications as required under medical devices rules 2017 causing significant delays in conducting renewal inspections to verify storage conditions and to obtain updated information on management and tech staff besides others. The board therefore decided to issue show cause notice to all the above-mentioned firms for cancellation of license with the directions to appear before the board.

Item No. I(D): 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.”

S. No	Firm Name	Firm Name and Address	License No	Date Of Issuance	Validity/ Renewal Date	Date of Renewal application	Decision
1	M/s Idcot Pharmaceuticals	57, 1st floor Muslim Town 1 Sargodha Road, Faisalabad.	ELM-0003	29/10/2018	03/02/2022	Not submitted	The board observed that the firm has not made renewal application after lapse of more than one year of expiry of license. Therefore, the board declared the license invalid/cease to exist under rule 7(5) of medical devices rules 2017. The firm needs 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. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

DEFERRED CASES AGENDA:

Evaluator: HAJIRA ABID (Intern-2)

Sr no	Importer name	Manufacture details	Name of MD/Class/Code/ Shelf life/etc	Decision
1.	M/s Ijaz Enterprises, Islamabad ELI-00016 Date of R&I 03-06-2022 Fee Details: Paid Fee: 25,000/- Challan No. 9790965736 Paid Fee: 7430/- Challan No. 6353499619 Tracking ME8-YPT-SX2T	Exias Medical GmbH Kratkystra Be 2 8020 Graz Austria. LOA: Type: Scan copy of notarized copy. Validity: 31-03-2027 FSC Type: Scan copy of notarized copy Issued by: Austrian Federal Office for Safety in Health Care BASG Validity: 18-09-2026 ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-02-2027	EXIAS e I 1 Cartridge (150, 300,600) EXIAS e I 1 Cartridge QC (150,300,600) Applied as Kit Class-B Shelf Life: 5 yrs. Model/Codes/Size: M000338, M000339, M000137, M000138, M000139, M000140, M000293, M000322 M000295	Approved
2	M/s Muller & Phipps, Uzma Court, Main Clifton Road Karachi ELI-00030 R&I Details 19-06-2020. Fee of Rs. 5,000/- Fee Challan No. 0808822 dated 13-06-2020	Legal Manufacturer (as per Form-7A): ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK. Manufacturing Site (as per Form-7A): ConvaTec Dominican Re-Public, Inc. Carretera Sanchez, Km. 18.5, Parque Industrial Itabo, S.A. Dominican Republic. Manufacturer Name as	ConvaTec- Straight Tail Closures Tail Closure Class A Applied as Single. Shelf life: 5 years Code/sizes: 175635	Rejected on following grounds: Firm has provided an Invalid Fee challan form, no.0808822 which is not verifiable.

		per FSC (UK): ConvaTec Limited Letter of Authorization: Type: Scan copy of notarized copy. Date of issuance: 29-07-2024 Validity: 28-01-2026 FSC Type: Scan copy of notarized copy Issued by: MHRA, UK Date of Issuance: 14-05-2015 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 03-01-2026,		
3	Safeway Systems Pakistan Rawalpindi ELI-00308 Date of R&I: 18-02-2025 Fee Details: Paid Fee: 31,000/- Challan No. 8204420417 Tracking ID XXY-H7J-BJ73	Disposet Tıbbi Ürünler Sanayi ve Ticaret. A.Ş. Site Address as per FSc: Bati Sitesi Mah. Gersan Sanayi Sitesi Cd. 2307 Sok. No,92/ YENİMAHALLE ANKARA. Site Address as per Form-7A: Alcı Osb Mah. 2000 Cad. No:20 Sincan/Ankara, Turkey Site Address as per CE: Susuz Mahollesi 3795, Codde Dempa Sanayi Sitesi No:6 Yenimahalle Ar-İKA.RA / TURKEY. LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2026 FSC	Disposet Vascular Tourniquet Set Vascular Tourniquet sets Applied as Single. Class-B Service Life: 3 Yrs. Model/Codes/Size: 959 300 001- Adult Vascular Tourniquet Set, Single 959 300 101- Pediatric Vascular Tourniquet Set, Single 959 300 002- Adult Vascular Tourniquet Set, Double 959 300 102- Pediatric Vascular Tourniquet Set, Double 959 300 003- Adult Vascular Tourniquet Set, Triple 959 300 103- Pediatric Vascular	Approved Product Adult Vascular Tourniquet Set, Double 959 300 002.

		Type: Scan copy of non-notarized copy Issued By: Turkey. Validity: 13-11-2027 ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-02-2025 & 13-05-2028 CE (Production QA): Type: Scan copy of non-notarized copy Validity: 27-05-2024	Tourniquet Set, Triple 959 300 005- Adult Vascular Tourniquet Set, Five 959 300 105- Pediatric Vascular Tourniquet Set, Five 959 300 011- Adult Vascular Tourniquet Set, Single 959 300 111- Pediatric Vascular Tourniquet Set, Single 959 300 012- Adult Vascular Tourniquet Set, Double 959 300 112- Pediatric Vascular Tourniquet Set, Double 959 300 013- Adult Vascular Tourniquet Set, Triple 959 300 113- Pediatric Vascular Tourniquet Set, Triple 959 300 015- Adult Vascular Tourniquet Set, Five 959 300 115- Pediatric Vascular Tourniquet Set, Five 959 300 016- Vascular Tourniquet Set, 2 Snare, 4 Red, 2 Blue, 2 Transparent 959 300 017- Vascular Tourniquet Set, 2 Snare, 1 Red, 2 Blue, 5 Transparent 959 300 018- Vascular Tourniquet Set, 1 Snare, 5 Red 959 300 019- Vascular Tourniquet Set, 2 Snare, 2 Red, 2 Blue, 4 Transparent 959 300 020- Vascular Tourniquet Set, 1 Snare, 3 Transparent 959 300 021- Vascular Tourniquet Set, 1 Snare, 3 Transparent 959 300 022- Vascular Tourniquet Set, 1 Snare, 5 Tubes 959 300 023- Vascular Tourniquet Set, 1 Snare, 4 Tubes 959 300 024- Vascular Tourniquet Set, 2 Snare, 8 Tubes	
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			959 300 025- Vascular Tourniquet Set, 1 Snare, 6 Tubes (stainless steel snare) 959 300 026- Vascular Tourniquet Set, 5 Tubes, 2 Red, 2 Blue, 1 Transparent 959 300 027- Vascular Tourniquet Set, 2- Piece Dacron/Polyester Band	
4	Safeway Systems Pakistan Rawalpindi ELI-00308 Date of R&I: 13-12-2024 Fee Details: Paid Fee: 31,000/- Challan No. 1844797531 for Shunmei Shun Route Disposable Pressure Transducer (DPT) kit Tracking ID YY5-BTS-ST5Q	M/s Shunmei Medical Co. Ltd, located at Address as per FSC & Form-7A: R301 and R401, Building B, Shenchanggang Investment Co., Ltd., No. 8, Jinlong First Road, Baolong Community, Baolong, Street, Longgang District, Shenzhen, 518116 Guangdong, P.R. China. Site No.2: Huizhou Branch, Shunmei Medical Co., Ltd Address: Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China. LOA Type: Scan copy of non- notarized copy. Validity: 23-09-2027 FSC Type: Scan copy of non- notarized copy Issued by: China. Validity: 27-02-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 14-02-2025 CE: Type: Scan copy of non- notarized copy	Shun Route Disposable Pressure Transducers Applied as Single. Class-B Service Life: 3 Yrs Model/Codes/Size: DPT-C DPT-01 DPT-02	Approved code DPT-01

		Validity: 26-05-2024		
5	Coral Pharmaceuticals, A - 85 S.M.C.H.S, Karachi. Lic. No.: ELI-00065. Date of R&I 13-09-2021 Fee Details: Paid Fee: 25,000/- Challan No. 499322168 Challan No. 75124195360 Paid Fee: 50000/- Challan No. 615847858772 Paid Fee: 14800/-	Dyneke Pty Ltd 9 Circuit Drive, Hendon, SA 5014, Australia. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued by: TGA Australia Issuance Date: 24-11-2021 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 19-04-2025.	Dysilk Silk Applied as. Class-C Service Life: 5 yrs Model/Codes/Size:	Approved product Dysilk Silk model 13910
6	Coral Pharmaceuticals, A-85 SMCHS, Karachi (ELI-00065) Evaluator: AD-VI R&I Date 06-01-2026	Legal Manufacturer: Dyneke Pty Ltd. 9 Circuit Drive, Hendon, SA 5014 Australia FSC: Australia Issued: 27-8-2018	BIOVEK Suture. (Polyglycolic Acid) Class: D Shelf Life: 03-Years 044805 / 21-11-2021	Approved product BIOVEK Suture. (Polyglycolic Acid) code 13908
7	Future Scientific, FS House, Opposite Street # 04, Main Road Shaheen Town, Gangaal West, Post Office, Fazaia Colony, Post Code 46330 Rawalpindi, Pakistan. ELI-00209 1228-P 5,000/-	Legal Manufacturer: DIESSE Diagnostica Senese S.p.A, Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy. FSC: Italy. Validity: 29-11-2022.	Mini-Cube Cube 30 Touch VES-Matic 5 VES-Matic Original VES-Matic Cube Track Class-A Shelf Life: N/A Codes: MINI-CUBE 10392 1	Rejected on following grounds: Firm documented that they have applied as cluster but fee for the cluster not submitted. Under MDR 2017 rules it belongs to class B IVD not Class A

			Analyzer CUBE 30 TOUCH 103951 Analyzer VES-MATIC 5 103601 Analyzer VES-MATIC ORIGINAL 103401 Analyzer VES-MATIC CUBE TRACK 103851 Analyzer	Clarification of brand name and generic name not provided .
8	Future Scientific, FS House, Opposite Street # 04, Main Road Shaheen Town, Gangaal West, Post Office, Fazaia Colony, Post Code 46330 Rawalpindi, Pakistan. ELI-00209 1227-P 5,000/-	<u>Legal Manufacturer:</u> DIESSE Diagnostica Senese S.p.A, Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy. FSC: Italy. Validity: 29-11-2022.	VACU-Tec VACU-Tec Cuvette-L VES-Tec Bulk VES-Tec Cuvette-L Class-A Shelf Life: 10 to14 Month Codes: VACU-TEC 10200 100 Tubes VACU- TEC CUVETTE-L 10208 200 Tubes VES-TEC BULK 10212 1500 Tubes VES-TEC CUVETTE-L 10214 200 Tubes	Rejected on following grounds: Firm documented that they have applied as cluster but fee for the cluster not submitted. Under MDR 2017 rules it belongs to class B IVD not Class A Clarification of brand name and generic name not provided. Relevant description of products not provided
9	Future Scientific, FS House, Opposite Street # 04, Main Road Shaheen Town, Gangaal West, Post Office, Fazaia Colony, Post Code 46330 Rawalpindi,	<u>Legal Manufacturer:</u> DIESSE Diagnostica Senese S.p.A, Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy. FSC: Italy. Validity: 29-11-2022.	Chorus Trio Chorus Trio Ras Chorus Autosampler Chorus Autosampler Upgrade Kit Chorus Expander Upgrade Kit Class-A Shelf Life: N/A	Rejected on following grounds: Firm documented that they have applied as cluster but fee

	Pakistan. ELI-00209 1225-P 5,000/-		Codes: CHORUS TRIO 81200 1Analyzer CHORUS AUTOSAMPLE R 81210 1Analyzer AUTOSAMPLE R UPGRADE KIT 81215 01 kit CHORUS TRIO RAS 81220 1Analyzer CHORUS EXPANDER UPGRADE KIT 88600 01 kit	for the cluster not submitted. Under MDR 2017 rules it belongs to class B IVD not Class A Relevant description of products not provided
10	Future Scientific, FS House, Opposite Street # 04, Main Road Shaheen Town, Gangaal West, Post Office, Fazaia Colony, Post Code 46330 Rawalpindi, Pakistan. ELI-00209 1226-P 5,000/-	<u>Legal Manufacturer:</u> DIESSE Diagnostica Senese S.p.A, Strada dei Laghi 39, 53035, Monteriggioni (SI), Italy. FSC: Italy. Validity: 29-11-2022.	ESR Control ESR Control Cube Class-A Shelf Life: 18 Month Codes as per FSC ESR Control 10430 4x9ml ESR Control 10434 2x9ml ESR Control Cube 10435 4x9ml ESR Control Cube 10436 2x9ml	Rejected on following grounds: Firm documented that they have applied as cluster but fee for the cluster not submitted. Under MDR 2017 rules it belongs to class B IVD not Class A clarification of brand name and generic name not provided. Relevant description of products not provided
11	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic	Hip Prosthesis System (Acetabular cup Mental cup) Class-D Shelf life: 5years	Rejected on the ground that the firm has applied two different devices under one application

		Development Zone, Beijing China. Legalized FSC issued by China validity dated 16.04.2027. ISO 13485 Valid till 01.03.2027	Applied as family Sizes: 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72	and fee for family has not been paid.
12	Arfi International, Suit # 903 & 904, 9th Floor Al-Rahim Suite Tower I.I. Chandigarh Road, Karachi	Valmed SrL Via Dell'Industria 3 23030 Tovo di Sant'Agata (SO) - Italy	Parenteral Nutrition Bags Parenteral Nutrition Bag with Filling set Class B Self-life 5 years As kit Model; VM0594BP Sacca NPT EVA 500ml set a 3 vie - DEHP free VM0110BP TPN EVA Bag with 3 way filling set - DEHP free - 1000ml VMJ111BP TPN EVA Bag 2000ml with 3 way filling set - DEHP free VM0239BP TPN EVA Bag 3000ml with 3 way filling set - DEHP free VM0113BP TPN EVA Bag 4000ml with 3 way filling set - DEHP free	Deferred for submission of product brochure and justification of applying as kit. Clarification of “filling set” is also required.
13	M/s Global Biotech Medical Devices (Pvt) Ltd., First Floor, Plot No. 35- N/3, PECHS Block -6, Near Rohail Khund Society Karachi ELI-01292	<u>Legal Manufacturer:</u> Quanta System Spa vid Acquedotto, 109 21017 - Samarate (VA) - Italy Market Authorization Holder: AngioDynamics, 603 Queensbury Ave QBY NY USA	Venacure 1470 Pro Laser Diode Laser System Class C Shelf Life: 5 Years	Deferred with final opportunity for submission of fee for System as per revised SRO

	Date of R& I 20-05-2025 Fee: Rs.62000/ through slip no. 223235619455	LOA: Valid till: 09-04-2027 FSC: Italy Issue Date: 29-04-2022 (Copy) ISO - Validity Date: 09-03-2027 (Copy) EC Certificate Valid till: 26-05-2024 (Copy)		
14	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) Date of R& I 12-05-2025 Fee: PKR 31,000/- Slip # 33407296245	Legal Manufacturer & Manufacturing Site: M/s AngioDynamics, 603 Queensbury Avenue, Queensbury, NY 12804, USA Notified Body Name and Address: BSI Group the Netherlands B.V Say Building, John M Keynesplein 91066 EP Amsterdam LOA Validity: 09-04-2027 FSC: USA Validity: 14-01-2027 ISO Validity: 10-05-2027 EU QA /CE Certificate Validity: 01-06-2027	Brand name: VenaCure EVLT NeverTouch Direct Procedure Kit Generic Name: Never Touch Direct Procedure Kit Class-B Shelf life: 3 years Models/ Specification: H787114031015 H787165100011	Approved Model only H787114031015
15	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)	Legal Manufacturer & Manufacturing Site: M/s AngioDynamics, 603 Queensbury Avenue, Queensbury, NY 12804, USA Notified Body Name and Address: BSI Group the Netherlands B.V Say Building, John M	Brand name: VenaCure EVLT NeverTouch –FRS Procedure Kit Generic Name: VenaCure EVLT NeverTouch –FRS Procedure Kit Class-B Shelf life: 3 years	Approved Model only H787114030010

	Date of R& I 12-05-2025 Fee: PKR 31,000/- Slip # 62572429897	Keynesplein 91066 EP Amsterdam LOA Validity: 09-04-2027 FSC: USA Validity: 14-01-2027 ISO Validity: 10-05-2027 EU QA /CE Certificate Validity: 01-06-2027	Models/ Specification: H787114030010 H787114030020 H787114030030 H787114030040 H787114030050 H787114030060 H787114030070 H787114030120 H787114030130 H787114033015 H787114033025	
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Case No:01: DISPUTE OF LETTER OF AUTHORIZATION

S. #	Importer Name	Manufacturer Name	Medical Device Name	Decision
1.	Applicant Name: M/s Sadqain Healthcare Pvt. Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi ELI-00020 Date of R&I 14-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 3662459837	Name of Manufacturer: Insightra Medical, Inc, 2543 Madison Street #105, Clarksville, TN, 37043 United States of America Contract Manufacturing: Done at Dolphin life science LLC Block No 133 Village Dhamdod NR . Hotel Supreme .ta .Mangrol Surat , Gujrat , India . LOA Validity: 16-03-2028 (Copy) FSC: USA Validity: 06-06-2026 (Original) ISO Validity: 23-04-2027(copy) EU QA/ EC Certificate Not given	Brand name: Ultra IABP Catheter kit Generic Name: Ultra aortic Balloon Catheter kit Class-D Shelf life: 5 years Models/ Specification Ultra IABP 7Fr Catheter Kit, System, Balloon, Intra Aortic and Control IMU7F-20 System, Balloon, Intra Aortic and Control IMU7F-25 System, Balloon, Intra Aortic and Control IMU7F-30 System, Balloon, Intra Aortic and Control IMU7F-35 System, Balloon, Intra Aortic and Control IMU7F-40 System, Balloon, Intra Aortic and Control	In light of the valid CFG issued in the name of Insightra Medical, Inc., USA as the legal manufacturer of the applied product and valid Apostilled LOA from legal manufacturer abroad, the Board approved the grant of registration the applied product to M/s Sadqain Healthcare (Pvt) Limited.

EVALUATOR: MINAHIL JAVED (intern I)

S.No	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc	Decision
1.	JF International 4th Floor, 10-C, 6th sunset commercial Lane Phase 2 EXT DHA Karachi Pakistan (ELI-00246) Evaluator: AD-VI	CONTEC MEDICAL Systems., Ltd. No. 112 Qinhuang West Street, Economic & Technical Devolpment Zone, Qinhuangdao, 066004, Hebei Province China FSC: China Valid Till: 26-8-2020	CONTEC Electrocardiograph ECG 1200G. Class: C Shelf Life: Codes & Sizes as per FSC	Approved
2.	M/s Sadqain Healthcare Pvt.Ltd. ELI -00020 R&I Receiving: 15-08-2022 Fee: Rs. 25000/- Fee challan no. 32636790428 Challan Date 12/8/2022	Legal Manufacturer M/s. Intersurgical Limited. Crane House ,MollyMillars Lane, Wokingha,Berkshire,United Kingdom Manufacturing site: UAB Intersurgical Arnioniu60, Pabrade, LT-18170, Lithuania Non notarized copy of LOA: Validity: 1-3-2026 FSC Type: Scan copy of notarized copy. Issued by: MHRA UK Validity: 30-6-2029 ISO 13485: Type: Scan copy of notarized copy. Validity: 26-11-2023	10mm flex tube single heated wire breathing system with neo water trap monitor line and limb > 1.6m Generic name BREATHING SYSTEM Applied as system Class-B Product code: 4506850 Shelf life : 5 years	Approved

3.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad. ELI-01125 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 64967856353 Fee:21,230/- Slip: 1726461764 Total fee paid: 52,230	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier) • FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023 Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)	Brand name: Clarinet Generic Name: Middle Ear Analyzer/Tympanometry Applied as: Family Class: B Code/sizes (as per DOC, Application & Labels): 10517 (Clarinet Basic) 10542 (Clarinet Plus) Service Life: 10 Years	Deferred for submission of evidence of applied codes. Also select one model.
4.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20097; 07-Jul-2025 Fee: 100,000/- Slip # 5584121690	Name of Manufacturer: BTL Industries Ltd. Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-785F Generic Name: Non-invasis RF Technology Machine Applied as: System Class: C Models/Code/sizes (as per FSC & application Model): EMFACE, EXION and EMFEMME 1. BTL-785F 2. EXION Body applicator BTL- 785-1 3. EXION Body applicator tip BTL-785-1-1 4. EXION Face applicator BTL- 785-2 5. EXION Face applicator tip BTL- 785-2-1 6. EMFEMME applicator BTL- 785-3	Approved as emaface BTL-785F Along its EMFACE Controller – BTL-785-7 EMFACE Forehead Applicator – BTL-785-7-1 EMFACE Cheek Applicator – BTL-785-7-2 EMFACE Eye applicator BTL-785-7-11 EMFACE Neck applicator BTL-785-7-10 EMFACE Submentum applicator BTL-785-7-9

			7. EMFEMME V tip BTL-785-3-1 8. EMFEMME V24 tip BTL-785- 3-2 9. EMFEMME V30 tip BTL-785- 3-3 10. EXION Fractional RF applicator BTL-785-4 11. EMFACE controller BTL-785-7 12. EMFACE forehead applicator BTL-785-7-1 13. EMFACE cheek applicator BTL-785-7-2 Shelf Life: 5 years	
5.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20096; 07-Jul-2025 Fee: 31,000/- Slip # 9109518754	Name of Manufacturer: Legal Manufacturer: ♦ BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaia 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized ♦ Validity: 08-04-2027	Brand Name: Exomind Generic Name: Transcranial Magnetic Stimulation (TMS) Applied as: System Class: B Models/Code/sizes (as per FSC & application Model: Exomind Exomind Applicator (BTL-699-AP-M-2) Shelf Life: 5 years	Deferred for submission of differential fee of system.

6.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20100; 07-Jul-2025 Fee: 31,000/- Slip # 4261667609 Fee: 21,230 Slip:846364156066 Total fee paid 52200	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-Emsella Generic Name: High-Intensity Focused Electromagnetic (HIFEM) Technology Applied as: system Class: B Models/Code/sizes (as per FSC & application Model: BTL Emsella BTL Chair Applicator BTL 299-3 Esmella Chair Applicator BTL-299-3 Esmella Chair applicator BTL-899-AP-M-3 Shelf Life: 5 years	Approved as BTL Emsella Chair Applicator
7.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20092; 07-Jul-2025 Fee: 50,000/- Slip # 0098508976	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-Emsculpt NEO Generic Name: High Intensity Focused Electromagnetic (HIFEM) technology combined with radiofrequency (RF) Applied as: System Class: B Models/Code/sizes (as per FSC & application Model: Emsculpt NEO 1. Large applicator 899-AP-C-1 2. Small applicator 899-AP-C-2 3. Edge applicator 899-AP-C-4 4. Edge applicator 899-AP-C-5 5. Patient Switch 899-ACC-1 Shelf Life: 5 years	Approved as BTL-Emsculpt NEO (A899 .101) along its applicator 1. Large applicator 899-AP-C-1 2.Small applicator 899-AP-C-2 3. Edge applicator 899-AP-C-4 4. Edge applicator 899-AP-C-5
8.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd.	Brand Name: BTL-4000 Smart /4000 Premium (Combined	Approved as BTL-4000 Smart /4000 Premium (Combined

	Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20102; 07-Jul-2025 Fee: 100,000/- Slip # 39390659959	Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Therapy) Generic Name: Physiotherapy Devices: combination of therapies, including ultrasound, Electrotherapy, Magnetotherapy and laser therapy Applied as: System Class: C Models/Code/sizes (as per FSC & application Model: BTL-4000 Smart_/4000 Premium [Combination Therapy)" (Models: 1. BTIL -4820S Smart 2. BTL-4820S Premium 3. BTL 4825S Smart 4. BTL-4825S Premium 5. BTL-4820L Smart 6. BTL 48201 Premium 7. BTL-4825L Smart 8. BTL- 4825L Premium 9. BTL-4800SL Smart 10. BTL-4800SL Premium 11. BTL 4820SL Smart 12. BTL-4820SL Premium 13. BTL-4825SL Smart 14. BTL-4825SL Premium 15. BTL-4800LM2 Smart 16. BTL-4800LM2 Premium 17. BTL-4820M² Smart 18. BTL 4820M² Premium 19. BTL-4825M² Smart 20. BTL-4825M² Premium 21. BTL-4820M4 Smart 22. BTL-4820M4 Premium 23. BTL-4825M4 Smart 24. BTL-4825M4 Premium 25. BTL-4820LM2 Smart 26. BTL-4820LM2 Premium 27. BTL-4825LM2 Smart 28. and 29. BTL- 4825LM2 Premium) Shelf Life: 5 years	Therapy) Electrotherapy Ultrasound therapy BTIL -4820S Smart, BTL-4820S Premium BTL-4825S SMART, BTL-4825S PREMIUM
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9.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I. Chandrigar Road, Karachi (ELI-00282) R&I Date: 30-06-2025 Fee: 31,000/- Slip # 747783338602. Fee: 21,000/- Slip: 11937386310 Total fee paid: 52,0000	Name of Manufacturer: Tianchang HengSheng Medical Devices Co.,Ltd Address: Qinlan Industrial Park Tianchang City, Anhui Province, China. LOA: Type: Copy Notarization: Notarized Validity: 29-04-2030 FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 04-05-2027 Copy of Free Sale certificate issued by German Authority has also been submitted issued dated 15-06-2023 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-04-2026 Notarized copy of EC certificate also submitted	Brand Name: LifeCare Generic Name: Disposable Latex Surgical Gloves, powder free, sterile Applied as: family Class: B Models/Code/sizes (as per FSC & application) Model: Size: 6.0#, 6.5#, 7.0#, 7.5#,8.0#,8.5#,9.0# Shelf life: 5 years	Approved
10.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I. Chandrigar Road, Karachi (ELI-00282) R&I Date: 30-06-2025 Fee: 31,000/- Slip # 86512482957. Slip:11937386310 Fee:21000/- Total 52000	Name of Manufacturer: Tianchang HengSheng Medical Devices Co.,Ltd Address: Qinlan Industrial Park Tianchang City, Anhui Province, China. LOA: Type: Original Notarization: Notarized Validity: 29-04-2030 FSC: Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 04-05-2027	Brand Name: LifeCare Generic Name: Disposable Latex Surgical Gloves, Powdered, Sterile Applied as: family Class: B Models/Code/sizes (as per FSC & application) Model: Size: 6.0#, 6.5#, 7.0#, 7.5#,8.0#,8.5#,9.0# Shelf life: 5 years	Approved

		ISO – Certificate: Type: Original Notarization: Notarized Validity: 11-04-2026 Notarized copy of EC certificate also submitted		
11.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad. ELI-01125 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 1847571099	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier) • FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023 Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)	Brand name: Timpani Generic Name: Audiometer/Middle Ear Analyzer Applied as: Family Class: B Code/sizes (as per DOC, Application & Lables): 11440 Service Life: 10 Years	Deferred for submission of evidence of code 11440.
12.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad. ELI-01125 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 91278885380 Fee: 21,230 Slip:	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier) • FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023	Brand name: Flute Model Generic Name: Middle Ear Analyzer/Tympanometer Applied as: Family Class: B Code/sizes (as per DOC, Application & Lables): 10337 (Flute Basic) 10340 (Flute Plus)	Deferred for submission of evidence of applied codes. Also select one model.

	6904930032 Total fee paid: 52,230	Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)	10409 (Flute HF) Service Life: 10 Years	
13.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad. ELI-01125 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 217120507 Fee:21,230 Slip:02061297354 Total fee paid: 52230	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier) • FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023 Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)	Brand name: Harp Generic Name: Audiometer Applied as: Family Class: B Code/sizes (as per DOC, Application & Lables): 10145 (Harp Basic) 10146 (Harp Plus) Service Life: 10 Years	Deferred for submission of evidence of applied codes. Also select one model.

14.	M/s AMB HK Enterprises (Pvt.) Ltd., 2nd Floor Plaza 60, Commercial Block-K Phase-1, DHA, Lahore. ELI-00863 Date of R& I 27-06-2025 Fee: 31,000/- Slip # 890337484355 Fee: 21,000 Slip: 891703785725 Total fee paid: 52,200	Name of Manufacturer: Rong Jia Medical Science and Technology Group Ltd., Yuziang Industrial Park, Yuziang Yingtian City, Jiangxi 335200, China. • LOA: Not submitted. • FSC Type: Copy Issued By: MPA Legalization: Not Legalized Validity: 11-11-2025 • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 26-10-2027 • EU QMS Certificate: Type: Copy Notarization: Not Notarized Validity: 23-03-2030	Brand name: Sure-Guard Generic Name: Disposable IV Set Applied as: Single Class: B Code/sizes (as per FSC & Application): A1, A2, V1, V2 Shelf Life: 3 Years	Approved As A1
15.	Tech Zone Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore ELI- 00040 Date of R&I 26-06-2024 Slip No.: 8433902103: Fee :5000/- Fee: 107500/- Slip: 9120003038 Fee: 97500/- Slip: 8480099720 Total fee paid: 210000/-	Zhejiang Longterm Medical Technology Co., Ltd., Shuang Shan Road 277, Fuxi Subdistrict, Deqing County, 313200 Huzhou City, Zhejiang Province, People's Republic of China LOA Type: Scan copy of notarized copy. Validity date: 21-10-2028. • FSC Not attached • ISO 13485: Type: Scan copy of notarized copy Validity: 31-03-2025 EU Quality Assurance Certificate (MDR) Type: Scan copy of notarized copy Validity: 10-04-2028	INNOMED Hydrocolloid Dressing Applied as Cluster: Class-A Shelf life: 3 Years Codes/Model/Sizes: 5cm×5cm、 5cm×10cm、 5cm×15cm、 5cm×20cm、 6cm×7.6cm、 7.5cm×7.5cm、 8 cm×12cm 、 10cm×10cm 、 10cm×11cm 、 10cm×12cm 、 10cm×15cm 、 10cm×20cm 、 10cm×25cm 、 10cm×30cm 、	Approved

			10cm×35cm 、 12cm×14cm、 14.3cm×15.6cm、 15cm×15cm、 15cm×18cm 、 15cm×20cm 、 20cm×20cm 、 20cm×25cm、 20cm×30cm	
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