

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

DECISIONS OF 127th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 08th APRIL 2026 (MANUAL APPLICATIONS PART-II)

127th 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 8th April 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 Neurosurgery/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 (attended meeting through videolink)
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
9.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
10.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

S.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. Ammar Ashraf Awan	Deputy Director
10.	Dr. Hanif Ullah	Deputy Director
11.	Mr. Khalid Mahmood	Deputy Director

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

Evaluator: Mr. Muhammad Amin (Deputy Director)

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

FRESH ELM CASES:

S. No	Name and Address of Establishment	Name of Production charge	of In	Name of QC In charge	Decision
1	M/s Tecno Instrument Pvt Ltd, Office/godown: 316-C small industrial Estate Sialkot.	Asad Ali Bsc Biomedical Engineering 4 Years	♦	Muhammad Awais Biomedical Engineering 1 Year	The board considered the inspection report and approved below mentioned production facilities/ sections for manufacturing of medical devices. • Monopolar & Bipolar forceps (Reusable & disposable). • Monopolar & Bipolar cables • Finger switch pencils (Reusable & disposable).

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

RENEWAL OF ELM CASES:

S. No	Name and Address of Establishment	Name of Production In charge	Name of QC In charge	Decision
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1	M/s Lasani Healthcare, Office/godown: Plot No. 29-A / R-I, Industrial Estate, Gadoon Amazai, Swabi. ELM-0036.	Mr Inayat Ullah Pharm D	Mr. Sana Ullah Pharm D Experience: 07 years	The board considered inspection report and approved renewal of establishment license to manufacture medical devices for below sections: 1. IV Cannula Section. 2. IV Set Section (Infusion & Transfusion Sets). 3. Syringe section.
2	M/s M/s Cotton Craft (Pvt) Ltd, Office/godown: Plot NO.407-408, Sunder Industrial Estate, Raiwind, Lahore. ELM-0015	Tariq Mahmood	Nuzhat Kausar Mumtaz	The board considered inspection report and approved renewal of establishment license to manufacture medical devices for below sections: • Absorbent Cotton Wool • Plaster of Paris (POP) Bandage Section • Gauze Section (Gauze Swabs (Sterile/Non-sterile)-Absorbent Gauze Ribbon • Surgical Tulle Dressing Section • Paraffin Gauze Section • Lint Section • Bandage Section • Lap sponges Section. • Cotton Crepe Bandage Section • Eye Pad Section • Gauze Roll Section

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

(FRESH RENEWAL CASES-ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Leven Medical Care, Office/godown: 8-C, Ground Floor, street No. 03, Shah jamal, Lahroe.	Hafsa Kirn Pharm D	Adeel Ur Rehman, CEO	Approved
2.	M/s Ghrasa Laboratory Supplies, Office/godown: 174-Ferozpur Road, pearl Plaza, 2nd Floor Shahjamal Stop Lahore ELI-00167	Zunaira Sarwar Pharm D	Ghulam Hussain CEO	Approved

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

(DEFERRED CASES FOR RENEWAL OF -ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Latif Instruments (Pvt) Limited, Office: 14 Commercial Buildings, Shahrah-e-Quaid-e-Azam, Lahore Godown: House No. 62, Shadman II, Lahore (ELI-00118)	Mian Amer Rashid BSc. Biomedical Engineering	Mian Tahir Rasheed Mian Khalid Rashid Mian Arif Mushtaq Mian Amer Rashid	Approved

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

Evaluator: Saadat Ali Khan (Deputy Director)

Imported products Agenda.

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Latif Instruments Pvt Limited, Lahore. (ELI-00118) Date of R&I 07-06-2021 Fee Details: Paid Fee: 5,000/- Challan No. 80434013458 Tracking X1L-LZU-EEMZ	Legal Manufacturer (as per Form-7A): Ampelos Co., Ltd., 1213, Daeryung Techno Town 8th B/D, 96, Gamasan-ro, Geumcheon-gu, Seoul 08501, Korea. Manufacturing Site (as per Form-7A): Sciencetra Co., Ltd., RM 1208-2, Daeryung Techno Town 8cha, 96 Gamasan-ro, Gcumacheon-gu, Seoul, Korea.08501 Legal Manufacturer & Manufacturing Site (as per FSC): Sciencetra Co., Ltd., RM 1208-2, Daeryung Techno Town 8cha, 96 Gamasan-ro, Gcumacheon-gu, Seoul, Korea.08501 LOA: Type: Scan copy of notarized copy. Date of Issuance: 04-05-2021 Validity: 03-05-2023 FSC Korea Type: Scan copy of notarized copy Date of Issue: 24-04-2021 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-05-2023	TSRK-1000P Auto Refractometer / Auto Ref-Keratometer Applied as. Class-A Model/Codes/Size: Shelf Life: 2 Years	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. 4. The applied product is in Class-B (as per the attached DOC) Pwhile applied in Class-A. Clarification is required along with the additional fee for Class-B. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.

		EC Certificate (Production QA): Type: Scan copy of non-notarized copy Validity: 26-05-2024		
2.	M/s WasimCo. KutchiGali No.1, Marriott Road Karachi. (ELI-00185) Date of R&I 07-03-2022 Fee Details: Paid Fee: 5,000/- Challan No. 77542828 Tracking PX4-3WP-46S5	Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China. LOA: Type: Scan copy of notarized copy. Validity: Untill-2023 FSC (Germany) Type: Scan copy of notarized copy Date of Issue: 05-06-2019 Validity: Not mentioned FSC (China) Type: Scan copy of notarized copy Validity: 24-11-2024 ISO 13485: Type: Scan copy of non-notarized copy Validity: 09-09-2024 EC Certificate (Production QA): Type: Scan copy of non-notarized copy Validity: 09-09-2023	Classic Fine Sterile Disposable Infusion Set with Needle) Applied as Family Class-B Shelf Life: 5 Years Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product.
3.	Raffay Associates. Rawalpindi (ELI-00021) Date of R&I 01-03-2024 Fee Details: Paid Fee: 50,000/- Challan No. 987353205859 Tracking M38-PDL-D5YN	Sewoon Medical Co., Ltd 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-Si, Chungcheongnaamdo, Korea. LOA: Type: Scan copy of notarized copy. Issuance date: 19-10-2023 Validity: not expiry. FSC (Korea) Type: Scan copy of notarized copy Date of Issue: 16-05-2016 Validity: Not mentioned	Bonastent Self-Expandable Metallic Colo-Rectal Un Covered Stent. Applied as Single Class-C (as per DOC) Shelf Life: 3 Years Model/Codes/Size: Un-covered	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product.

		FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 05-05-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-12-2025 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024		
4.	M Yousaf & Co, 79m Gulberg Iii Lahore ELI-00302. Date of R&I 20-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 0773891838 Tracking 2HE-GEB-DNRB	B.J.ZH.F. Panther Medical Equipment Co., Ltd Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China. LOA: Type: Scan copy of notarized copy. Issuance date: 22-09-2022 Validity: 22-09-2025 FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 29-11-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-11-2026 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024	Trocars Trocars Applied as Single Class-B Shelf Life: 3 Years Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. 4. The type of Trocars along with justification their grouping with catalog is required. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.
5.	M Yousaf & Co, 79m Gulberg Iii Lahore ELI-00302. Date of R&I 19-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 65152930 Tracking GLR-BPE-ZMEL	B.J.ZH.F. Panther Medical Equipment Co., Ltd Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China. LOA: Type: Scan copy of notarized copy. Issuance date: 22-09-2022 Validity: 22-09-2025	Endo Linear Cutter Stapler Endo Linear Cutter Stapler Applied as Single Class-B Shelf Life: Not mentioned Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid

		FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 29-11-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-11-2026 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024		notarized CE documents of the applied product. 4. Codes as per FSC with catalog is required. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.
6.	M Yousaf & Co, 79m Gulberg Iii Lahore ELI-00302. Date of R&I 19-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 87485690424 Tracking V5V-B8M-UY7M	B.J.ZH.F. Panther Medical Equipment Co., Ltd Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China. LOA: Type: Scan copy of notarized copy. Issuance date: 22-09-2022 Validity: 22-09-2025 FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 29-11-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-11-2026 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024	Linear Cutter Stapler Linear Cutter Stapler Applied as Single Class-B Shelf Life: Not mentioned Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. 4. Codes as per FSC with catalog is required. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.
7.	M Yousaf & Co, 79m Gulberg Iii Lahore ELI-00302. Date of R&I 20-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 11284802676 Tracking DMV-VQR-	B.J.ZH.F. Panther Medical Equipment Co., Ltd Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China. LOA: Type: Scan copy of notarized copy. Issuance date: 22-09-2022	Linear Stapler Linear Stapler Applied as Single Class-B Shelf Life: Not mentioned Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any

	HBZP	Validity: 22-09-2025 FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 29-11-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-11-2026 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024		reference country or valid notarized CE documents of the applied product. 4. Codes as per FSC with catalog is required. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.
8.	M Yousaf & Co, 79m Gulberg Iii Lahore ELI-00302. Date of R&I 20-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 1340405684 Tracking W7B-J49-VGQA	B.J.ZH.F. Panther Medical Equipment Co., Ltd Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China. LOA: Type: Scan copy of notarized copy. Issuance date: 22-09-2022 Validity: 22-09-2025 FSC (Belgium) Type: Scan copy of notarized copy Date of Issue: 29-11-2022 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-11-2026 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024	Cutter Stapler Cutter Stapler Applied as Single Class-B Shelf Life: Not mentioned Model/Codes/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Valid legalized Free Sale Certificate (FSC) of country of origin mentioning all the manufacturers & the applied codes of the product. 3. Valid legalized Free Sale Certificate (FSC) of any reference country or valid notarized CE documents of the applied product. 4. Codes as per FSC with catalog is required. 5. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.
9.	M/s Ejazuddin & Co., Karachi. (ELI-00078) Date of R&I 13-03-2020 Fee Details: Paid Fee: 50,000/- Challan No. 1945886 dated 10-03-	M/s Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany. LOA: Type: Scan copy of notarized copy. Validity: 12-12-2025 FSC (Germany)	Dade Innovin Dade Innovin Applied as Kit Class-C Shelf Life: 36 months Model/Codes/Size: Dade Innovin: B4212-40	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer for the applied product. 2. Justification of grouping with catalog is required along with fee for grouping if justified. 3. Shelf life evidence/study for all the applied codes/reagents/control.

	2020 Tracking R1M-4TZ-N9AZ	Type: Scan copy of notarized copy Date of Issue: 19-01-2023 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 15-08-2027	B4212-50 ORKL17 Standard Human Plasma, OPAT03 PT-Multi Calibrator, ORKE41 Control Plasma N, OUPZ17 Control Plasma P, 291070 Dade Ci-Trol 1, 291071 Dade Ci-Trol 2, 291072 Dade Ci-Trol 3, OQAA33 Imidazole Buffer Solution	
10.	Bay-G Pharma 103-A A, Block Satellite town Rawalpindi ELI-00016 Date of R&I 11-07-2025 Fee Details: Paid Fee: 62,000/- Challan No. 86320640 Tracking ME8-YPT-SX2T	Cofee Medical Technology Co., Ltd. 816 Zhenha Road, Yuhua District Changsha City, Hunan Province China. LOA: Type: Scan copy of notarized copy. Validity: 09-05-2030 FSC (China) Type: Scan copy of notarized copy Date of Issue: 02-02-2025 Validity: 26-02-2027 ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-07-2025 EC Certificate (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2025 With extension letter	Believia Blood Glucose Monitor Applied as Kit Class-C Shelf Life: 5 yrs Model/Codes/Size: Believia Model No. BG-01 Cofee Model No. CGH-210	Approved as per FSC the following code only. CGH-21
11.	M/s Ijaz Enterprises, Islamabad ELI-00016 Date of R&I 03-06-2022 Fee Details: Paid Fee: 25,000/- Challan No. 9790965736 Tracking ME8-YPT-	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	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:	Deferred for submission of the following: 1. Justification of grouping with catalog is required along with fee for grouping if justified. 2. Shelf life evidence/study. 3. Properly filled Form-7A along with all the required annexures duly signed by the authorized person.

	SX2T	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	M000338, M000137, M000339, M000138, M000140, M000293, M000294, M000295	
12.	M.N Enterprise, Karachi. ELI-00453 Date of R&I 08-03-2024 Fee Details: Paid Fee: 25,000/- Challan No. 466664100230 Tracking XNU-TD1- Z6WR	OSTEOSYS CO., LTD. Address as per Form-7A: Room 903, 9 floor, Jnk Digital Tower Building, 111 Digital-Ro 26, Guro-Gu, Seoul, Korea. Address as per FSC: 26 Maehwasandan 3-gil, Sheung-si gyeonggi-do, Room 903, 9F, Jnk Digital Tower Building, 111 Digital-Ro. 26, Guro-Gu, Seoul, Korea. LOA: Type: Scan copy of notarized copy. Validity: 31-12-2026 FSC Type: Scan copy of notarized copy Issued by: Korea Issued Date: 16-01-2024 Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 17-11-2026 EC Certificate (FQA): Type: Scan copy of non- notarized copy Validity: 17-11-2022 With extension letter	SONOST-3000 Bone Absorptiometric Ultrasound System Applied as Class-B Shelf Life: 2 yrs Model/Codes/Size:	Approved with manufacturer address as per FSC.
13.	Kokab Enterprises Karachi (ELI-00544) Date of R&I 11-04-2022 Fee Details: Paid Fee: 50,000/- Challan No. 47313310397	Carnamedica Sp. z o. o. Address: ul. Olszynki Grochowskiej 21 lok. U6, 04-281 Warsaw Poland. Address as per FSC: Olszynki Grochowskiej 21 lok. U6, 04-281 Warszawa, Poland.	PlegiStore Histidine Tryptophan Ketoglutarate (HTK) Solution Applied as Single Class-D Shelf Life: 18 months	Approved

	Tracking LVY-9E4-3D4Y	LOA: Type: Scan copy of notarized copy. Issuance Date: 08-04-2021 Validity: Not mentioned FSC Type: Scan copy of notarized copy Issued by: Office of Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland. Issued Date: 16-01-2024 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-07-2022 EC Certificate: Type: Scan copy of non-notarized copy Validity: 02-07-2023 EC- Design Examination Certificate: Type: Scan copy of non-notarized copy Validity: 02-07-2023	Model/Codes/Size: 1000ML, 2000mL Bags (container filled with solution for perfusion or preservation of organs intended for transplantation)	
14.	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 Rs. 62000/- Slip No. 673332822185 & Rs. 141300/- Slip No. 1763331160 Date: 27-06-2025 Tracking ID: XT4-	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 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-	Safecath (Disposable Central Venous Catheter Kit) Class. D Applied as Family Shelf life: 3 Years Code/Model/Size: <u>Single Lumen, Double Lumen, Triple Lumen:8.5F/8F/7F/5F/6F</u> Codes: MMCVCBJ1-14-15 MMCVCBJY1-14-15 MMCVCBJ1-14-20 MMCVCBJY1-14-20 MMCVCBJ1-14-30	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 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.

	T8D-XYB5	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	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	
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Additional Agenda Cases:

Evaluator: Rana Ahsan-ul-Haq Athar

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	M/s Ear Technic Pvt. Ltd., Office No. 03, 2nd Floor, G.8 Square Plaza, G.8 Markaz Islamabad ELI-00956 Date of R& I 25.04.2025 Fee: Rs. `62000/ through slip no. 241458572445	Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic A.s. Universiteler mah. 1596 Cad. Safir Bloklan E Blok Ofis No. 02/03 Zemin Kat Kapi No. 6 Beytepe – Cankaya – Ankara Turkiye. LOA: Valid till: 10-03-2026 (Copy) FSC: Turkiye issue date 25.01.2024. Validity Date: 24-01-2027(Copy) ISO - Validity Date: 21-10-2027 (Copy) EC Certificate Valid till:	Brand Name: Desu Medical Shunt Valves and Catheters with accessories Generic: Total PSA (CLIA) and Total PSA (CLIA) controls Applied as: Kit Class D Shelf Life : Code/sizes: i. DECURVE adult silicon shunts high pressure (8680454740473) ii. DECURVE adult silicon shunts low pressure (8680454740275) iii. DECURVE adult silicon shunts medium pressure (8680454740374) iv. DECURVE pediatric silicon shunts medium pressure (8680454740329)	Approved.
2.	4A International ,Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 966703506	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC:	Brand Name: Detro Pro Activ Generic Name: %55 (w/w) Pentapotassium bis (peroxymonosulphate) bis (Sulphate) Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Rejected as product has common intended use such as hygiene of floor and laundry. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

		Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026		
3.	4A International,Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 098085184238	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Akaclean Rust Generic Name: Phosphoric acid, complexing agents, corrosion inhibitors Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 2 years	Rejected as product has common intended use that is cleaning rust and rust-forming residues of instruments made of stainless steel laboratory and dentistry. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
4.	4A International,Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 41181481	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026	Brand Name: Detro Aspiradent Generic Name: Nonionic active agent, amphoteric active agent, 2-aminoethanol, n-alkyl dimethyl benzyl ammonium chloride Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 2 years	Rejected as product is not used for disinfection of the medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

		ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026		
5.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 5635563313	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Matic A Generic Name: Potassium Hydroxide, Surfactants, Silicates, Complexing agents, corrosion inhibitors Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Rejected as product is not used for disinfection of the medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
6.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 3566956499	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Matic Enzym Generic Name: Enzymes (Protease, amylase, Lipase), anionic surfactant Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

7.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 17388696	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Lube Generic Name: White paraffin oils, butane, propane Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
8.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 822505514802	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Instruclean Generic Name: Non ionic surfactants, corrosion inhibitors, complexing agents. Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
9.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/İSTANBUL-TÜRKİYE	Brand Name: Detro Enzym Plus Generic Name: Enzymes, glycol, nonionic surfactant, anticorrosive materials Applied as: Single-5L	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017,

	R&I Date: 01-07-2025 Fee: 6000/- Slip #7948999495	T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Class: A Models/Code/sizes-5L (as per FSC & application 5L Shelf Life: 3 Years	disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
10.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #826733871129	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Cleanex Generic Name: Ultrasonic Cleaner Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
11.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #110186068397	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes	Brand Name: Detro Matic NS Generic Name: Citric acid, surfactant, corrosion inhibitors. Applied as: Single-5L Class: A Models/Code/sizes-5L (as per FSC & application 5L Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration

		Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A		as a medical device.)
12.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip # 896853035032	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Air Spray Generic Name: fumigation Disinfectant Applied as: Single- Class: A Models/Code/sizes (as per FSC & application 1L Shelf Life: 2 years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
13.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip # 347021365672	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Notarization: Validity: • FSC Type: Issued By: Legalization:	Brand Name: Detro Trolley Generic : Trolley with Four transport Trays Applied as: single Class: A Models/Code/sizes-single (as per FSC & application Shelf Life:	Approved.

		Validity: • ISO – Certificate: Type: Notarization: Validity:		
14.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #05314022	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Enzym Generic Name: Enzymes (amilase, protease, lipase, cellulase), glycol, nonionic surfactant, quaternary ammonium compounds Applied as: Single Class: A Models/Code/sizes- (as per FSC & application Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
15.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #05314022	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Enzym Generic Name: Enzymes (amilase, protease, lipase, cellulase), glycol, nonionic surfactant, quaternary ammonium compounds Applied as: Single Class: A Models/Code/sizes- (as per FSC & application Shelf Life: 3 Years	Disposed off without any decision as Repeated. Same at serial No 14.

16.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #554368765	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Ultrasound Gel Generic : Deionized water, carbomer, triethanol amine, monopropylene glycol, Applied as: Single Class: A Models/Code/sizes-single (as per FSC & application Shelf Life: 3 years	Approved.
17.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip # 07529979079	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: original Notarization: Yes Validity: 02-01-2030 • FSC Type: Original Issued By: Chamber of commerce Istanbul turkey Legalization: Legalized Validity: 31-01-2030 • ISO – Certificate: Type: original Notarization: Notarized Validity: 15-11-2026 CE certificate: Original Notarized submitted	Brand Name: Detro PAA 2200 Generic Name: Peracetic Acid Applied as: Single- Class: C Models/Code/sizes- (as per FSC & application 5L Shelf Life: 18 Months	Approved.
18.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel	Brand Name: Detro San Air Forte Generic Name: 12% Hydrogen peroxide,	Rejected as product is not used for disinfection of medical devices.

	(ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #90667002956	Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	colloidal silver. Applied as: Single-1L Class: A Models/Code/sizes (as per FSC & application 1L) Shelf Life: 3 years	(As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
19.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip # 6633702691	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Akaspray Generic Name: Alcohol Based Spray Disinfectant Applied as: Single-1L Class: B Models/Code/sizes- (as per FSC & application 1L) Shelf Life: 2 years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
20.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/-	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762	Brand Name: Detro San SFC Generic: Bis (3-aminopropyl) dodecylamine, dedecyldimethylammonium chloride, benzalkonium chloride	Approved.

	Slip #234652883004	http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Applied as: Single Class: B Models/Code/sizes- (as per FSC & application 1L-5L Shelf Life: 2 years	
21.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #2568252336	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Enzym Plus DW Generic Name: Enzymes, glycol, nonionic surfactant, anticorrosive materials Applied as: Single-5L Class: A Models/Code/sizes-5L (as per FSC & application 5L Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
22.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip #40781042268	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030	Brand Name: Detro San AF Wipes Generic Name: Alcohol-Free Disinfection Wipes for Medical Devices and Equipment Applied as: Single- Class: B Models/Code/sizes- (as per FSC & application AF wipes Shelf Life: 2 years	Approved.

		• FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted		
23.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip #5975040972	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro San HP Spray Generic : Hydrogen Peroxide Based Rapid Surface Disinfection for Medical Devices and Equipment Applied as: Single-1 L Class: B Models/Code/sizes-1L (as per FSC & application 1L Shelf Life: 2 years	Approved
24.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip #606384272193	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of	Brand Name: Detro PAA 1500 Generic Name: Peracetic Acid Applied as: Single-5L Class: C Models/Code/sizes-5L (as per FSC & application 5L Shelf Life: 18 month	Approved.

		Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted		
25.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #5291141310	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Matic NF Generic Name: Phosphoric acid,surfactant, corrosion inhibitors. Applied as: Single-5L Class: A Models/Code/sizes-5L (as per FSC & application 5L Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
26.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #9448509714	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030	Brand Name: Detro San HP Generic : %14 Hydrogen peroxide, %2.9 carboxylic acid, auxiliary materials. Applied as: Family 1L-5 L Class: A Models/Code/sizes- (as per FSC & application 1L, 5L Shelf Life: 3 years	Rejected as product is used as floor disinfectant and is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

		• ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A		
27.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip # 541503599	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Dent Generic Name: Phosphoric acid, nonionic surfactant, corrosion inhibitor. Applied as: Single- Class: A Models/Code/sizes- (as per FSC & application 2L, 5L Shelf Life: 3 Years	Rejected as product is corrosion inhibitor. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
28.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip # 523722410369	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Enzym Foam Generic Name: Enzymes (amylase, protease, lipase, cellulase), surfactant Applied as: Single-1L Class: A Models/Code/sizes-1L (as per FSC & application 1L Shelf Life: 2 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

29.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #106850703861	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro Storage Generic : Drying and Storage Cabinet for Flexible Endoscopes Applied as: Single Class: A Models/Code/sizes- (as per FSC & application DSC-601, DSC-602, DSC- 603, DSC-1201, , DSC- 1202, , DSC-1203 Shelf Life:	Approved.
30.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #3939854553	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	Brand Name: Detro San Chlor Generic : Sodium dichloroisocyanurate 55% as active ingredient, effervescent base 22.5% as auxiliary substance Applied as: Single- Class: A Models/Code/sizes- (as per FSC & application DT Shelf Life: 3 years	Rejected as product has common intended purpose and is not used for disinfection of the medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
31.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/	Brand Name: Detro San HP Wipes Generic : Hydrogen Peroxide Based Rapid Surface Disinfection for	Deferred with final opportunity for submission of evidence/ justification of use of

	R&I Date: 01-07-2025 Fee: 31000/- Slip #71879844243	İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Medical Devices and Equipment Applied as: Single- Class: B Models/Code/sizes- (as per FSC & application Shelf Life: 2 years	salicylic acid as disinfectant.
32.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip # 103443776922	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro Akadent Ready Generic Name: Bis (3- aminopropyl) dodecylamine, didecyldimethyl ammonium chloride, benzalconium chloride, Applied as: single Class: C Models/Code/sizes-5L (as per FSC & application Shelf Life: 2 Years	Approved.
33.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/-	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762	Brand Name: Detro Cid Activ Generic Name: Peracetic Acid Applied as: Single100grm Class: C Models/Code/sizes- (as per FSC & application	Approved.

	Slip # 307069795679	http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	100gm Shelf Life: 3 years	
34.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip #33370764	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro Wash Generic : Endoscope Washer & Disinfector Applied as: Single Class: C Models/Code/sizes- DW-5001, DW-5002, DW-5003, DW-5004, DW-5005, DW-6001, DW-6002, DW-6003, DW-6004, DW-6005, DW-7001, DW-7002, DW-7003, DW-7004, DW-7005, DW-8001, DW-8002, DW-8003, DW-8004, DW-8005 (as per FSC & application) Shelf Life:	Rejected as applied model/sizes not found in FSC.
35.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip #5715731625	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes	Brand Name: Detro San AF Generic Name: Alcohol-Free Disinfection Wipes for Medical Devices and Equipment Applied as: Single-1L Class: B Models/Code/sizes-1L (as per FSC & application 1L	Approved.

		Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Shelf Life: 2 years	
36.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip # 11062308	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Akadent Extra Generic Name: Bis (3-aminopropyl) dodecylamine, didecyldimethyl ammonium chloride, benzalconium chloride, Applied as: Single Class: C Models/Code/sizes- (as per FSC & application 5L,2L Shelf Life: 2 years	Approved
37.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip # 11062308	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy	Brand Name: Akadent Extra Generic Name: Bis (3-aminopropyl) dodecylamine, didecyldimethyl ammonium chloride, benzalconium chloride, Applied as: Single Class: C Models/Code/sizes- (as per FSC & application 5L,2L Shelf Life: 2 years	Disposed of as rejected due to repetitions of the same at serial no 36.

		Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted		
38.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #731616145423	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro Lube Spray Generic Name: white paraffin oils, butane, propane Applied as: Single-500ml Class: A Models/Code/sizes-500ml (as per FSC & application 500ml Shelf Life: 5 Years	Rejected due to common intended uses.
39.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip # 85397967098	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized	Brand Name: Akaspray Tucher Generic Name: Alcohol Based Disinfection Wipes for Surface Applied as: Single- Class: B Models/Code/sizes- (as per FSC & application Shelf Life: 2 year	Rejected due to common intended uses and is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)

		Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted		
40.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip #3513993067	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro Plus PAA DW Generic Name: Peracetic Acid Applied as: Single-5L Class: C Models/Code/sizes- (as per FSC & application 5L Shelf Life: 18 month	Approved.
41.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip #43696335	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate:	Brand Name: Detro Plus PAA Generic Name: Peracetic Acid Applied as: Single-5L Class: C Models/Code/sizes (as per FSC & application 5L Shelf Life: 18 month	Approved.

		Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted		
42.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #278051583	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S. Atatürk Mah. Cemal Gürsel Cad. No:8/3 Esenyurt/ İSTANBUL-TÜRKİYE T: +902126597762, F: +902126597762 http://www.detrox.com.tr LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC Type: Copy Issued By: Chamber of Commerce Istanbul Legalization: Legalized Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	Brand Name: Detro Hemo plus Citra Generic Name: Citric Acid 50% Applied as: Single-5L Class: A Models/Code/sizes (as per FSC & application 5L Shelf Life: 3 Years	Rejected as product is not used for disinfection of medical devices. (As per Medical Devices Rules, 2017, disinfectants only for “disinfection of Medical Devices” may be considered for enlistment/registration as a medical device.)
43.	Healer International, Off # 13, 7i/A 3 rd Floor, Satellite Shopping Center A Block 6th Road, Rawalpindi, Pakistan ELI-01167 R&I Date: 28.10.2024 Fee: 6000/- Slip # 682594462 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 8BA- W22-TMTY	Legal Manufacturer: Torch Avenue, Fengcheng High-tech Park, Yichun City, Jiangxi Province, China LOA Type: Copy Notarization: Yes Validity: 01.10.2029 • FSC Type: NIL Issued by: NIL Legalization: No Issue date: NIL ISO – Certificate: Type: Copy Notarization: Yes, CCPIT Validity: 28.12.2025 CE certificate: Type: Copy Notarization: Yes, CCPIT	Brand Name: Hawkmed Generic Name: Disposable High-Pressure Angiographic Syringes Applied as: Family Class: B Models/Code/sizes (as per FSC & application NIL Shelf Life: 3 years	Rejected due to following reasons: 1. Fee for the family of class B not submitted. 2. Application Form with the complete name of the manufacturer not submitted. 3. The name of the device as per submitted FSC is The fluid suction, tool, connecting tubes and high pressure injectors are mentioned in FSC. 4. The FSC is issued by the Municipal Administration. 5. Stability studies not submitted.

		Validity: 30.04.2024 Extended till 31.12.2028		
44.	Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore. ELI-00045 5163-P Copy of Fee challan Rs 50,000 submitted vide slip no. 71858435572 dated 30.08.2024	Legal Manufacturer: Simedice Biotechnologies Inc., 251 Little Falls, Drive, Wilmington, Delaware 19808, USA. FSC: Germany issuance 27-10-2021 Manufacturing site M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China.	Simedice (Hydrophobic Aspheric Preloaded Foldable IOL's) Class-C Shelf life: 5 years Models: AS-P22, AS1-P22, AS2-P22, AS3-P22	Rejected due to following reasons: 1. the requisite documents as per decision of MDB in its 77 meeting not provided. 2. The firm informed that they will apply on line once documents are received.
45.	M/s New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161) R&I Date: 05-06-2025 Fee: 6,000/- Slip # 349346986	Name of Manufacturer: Shanghai Kinmed Import & Export Co., Ltd., Address: Suit L, 12th Floor, NO. 588 Yingkou Road, Shanghai, China LOA: Type: Copy Notarization: No Issue Date: 22-11-2024 Validity: 21-11-2029 -- FSC: Type: Copy Issued By: Not mentioned Legalization: Legalized Validity: 19-12-2025 ISO – Certificate: Copy valid till 26-09-2027 has been submitted	Brand Name: Green Disposable PE Apron Generic Name: Disposable PE Apron Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Size: WIDTH 60-100CM, LENGTH: 100-160CM Shelf Life: 5 years	Rejected due to following reasons: 1. The brand names mentioned in the FSC are Green, KBM, Comfort and K&K. 2. The name of the manufacturer not mentioned in the FSC Germany. 3. The sizes and codes not mentioned in the FSC. 4. The FCS China issued by the chamber of commerce instead of relevant Health Regulatory Authority.
46.	M/s New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161)	Name of Manufacturer: Shanghai Kinmed Import & Export Co., Ltd., Address: Suit L, 12th Floor, NO. 588 Yingkou Road, Shanghai, China LOA:	Brand Name: Comfort Care Disposable PE Gloves Generic Name: Disposable PE Gloves Applied as: Single Class: A Models/Code/sizes (as per FSC & application)	Rejected due to following reasons: 1. The brand names mentioned in the FSC are Green, KBM, Comfort and K&K. 2. The name of the manufacturer not

	R&I Date: 05-06-2025 Fee: 6,000/- Slip # 16479030159	Type: Copy Notarization: No Issue Date: 22-11-2024 Validity: 21-11-2029 -- FSC: Type: Copy Issued By: Not mentioned Legalization: Legalized Validity: 19-12-2025 ISO – Certificate: Not submitted	Model: Size: Shelf Life: 5 years	mentioned in the FSC Germany. 3. The sizes and codes not mentioned in the FSC. 4. The FCS China issued by the chamber of commerce instead of relevant Health Regulatory Authority.
47.	M/s New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00161) R&I Date: 05-06-2025 Fee: 6,000/- Slip # 75888717988	Name of Manufacturer: Danyang Airtech Co., Ltd., Address: No. 8, Electromechanical Industrial Park, Situ Town, Danyang City, China LOA: Type: Copy Notarization: No Issue Date: 25-04-2025 Validity: 24-04-2035 -- FSC: Type: Copy Issued By: Jiangsu Medical Products Administration Legalization: Legalized Validity: 15-07-2026 ISO – Certificate: Copy valid till 24-03-2027 has been submitted	Brand Name: Comfort Care Medical Oxygen Regulator/Flow meter Generic Name: Medical Oxygen Regulator/Flowmeter Applied as: Single Class: A Models/Code/sizes (as per FSC & application Size: ATQX1 (0-1L/min) ATQX5(0-5L/min) ATQX10(0-10L/min) ATQX15(0-15L/min) ATQX25(0-25L/min) ATQX30(0-30L/min) ATQX70(0-70L/min) ATWH(0-15L/min) Shelf Life: 5 years	Approved Regulator (code AT-10 1-10L/min). Firm will apply through online application for enlistment/registration of Flow Meter.
48.	Applicant Name: A&E Medical 323- ATA TURK BLOCK NEW GARDEN TOWN LAHORE (ELI-00023) Date of R&I 17-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 16568829 Dated: 10-04-2025	Name of Manufacturer: Sunny Medical Device (Shenzhen) Co, Ltd located at 1F and 401, Zhongtianxin Building, Longgang District, 518000, Shenzhen, Peoples Republic of China LOA Validity: 04-09-2027 FSC: Spain Issuance 03-11-2023 ISO Validity: 18.10.2027 EU QA Certificate Validity: 26-04-2028	SUNMED Inflation Device Kit Class-B Shelf life: 03 years Models/ Specification 1-SM-ID-S3030HC14-TB 2-SM-ID-S3030HP14-TB 3-SM-ID-S3030HS14-TB 4-SM-ID-S3030HC42-TB	Deferred for submission of fee challan mentioning the name of applied product as per SRO 1399(I)/ 2025 dated 1 st August, 2025. Furthermore, for personal Hearing of both the firms i.e. the Applicant & M/S Healthcare International for confirmation of LOA.

49.	M/s A & E Medical, 323-Ata Turk Block, New Garden Town, Lahore. ELI-00023 Date of R & I 05-06-2025 Fee: 62,000/- Slip # 8307284031	Name of Manufacturer: FIAB S.p.A., Via P, Costoli 4, 50039 Vicchio (FI), Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC Type: Copy of legalized Issued By: MOH Legalization: Legalized Issue Date: 19-09-2023 Validity: Not mentioned • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 31-07-2027	Brand name: Easypace with Accessories Generic Name: External Cardiac Stimulator Applied as: Single Class: C Code/sizes (as per FSC, Application): 4427 Service Life: Not Mentioned	Approved
50.	A&E Medical 323- ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 976-C Submission date: 27/12/2022 Evaluator: DD-III	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy FSC: Italy Issued on: 16/01/2019	Disposable Sterile Hand Switch Electrosurgical Pencils Codes & Sizes: As per FSC Class-C Shelf Life: 4 years	Approved Disposable sterile pencil for electrosurgery. Models F4797/A&E
51.	A&E Medical 323- ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 977-C Submission date: 27/12/2022 Evaluator: DD-III	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy FSC: Italy Issued on: 16/01/2019	Disposable Electrosurgical Grounding plates with connection cable Codes & Sizes: As per FSC Class-C Shelf Life: 4 years	Approved Disposable split electrosurgical grounding plates with connection cable. Models F7820W/V/A&E.
52.	MOODY Global Services Office address: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad Licence No. ELI- 00926 Date of issue:	Etiometry Inc., Address: 280 Summer Street, Fourth Floor Boston, MA, USA FSC: UK Validity: 28-02-2028 LOA Validity: 30-06-2029	Etiometry Platform software Generic Name; Clinical Decision Support Software Class A Shelf Life: NA. Stability studies do not apply to software because software does not degrade	The Board decided to defer the case as: 1. Firm has submitted Expired Challans and Fee submission not verifiable from B&A Division of DRAP in other six cases. Therefore, MBD advised the division to check all the challans of the firm previously submitted and

	17-05-2022	ISO 13485 Validity: 28-02-2027.	over time like physical products. Model name and its version: (As per FSC) T3 Platform Software: DAV5.4 RAE 10.0	challans used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
53.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. (ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 633177309 Dated:	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 24-09- 2022 Letter of authorization: 10-10-2028 ISO 13485 Certificate validity: EC Certificate validity: DOC:	Brand name: Maccura Generic: Thyroid Profile Model: Total T3: IM4405051, IM4401051 IM4402051, IM4406051 IM4404051, IM4403051 Total T4: IM4405053, IM4401053 IM4402053, IM4406053 IM4404053, IM4403053 FT3: IM4405052, IM4401052 IM4402052, IM4406052 IM4404052, IM4403052 FT4: IM4405054, IM4401054 IM4402054, IM4406054 IM4404054, IM4403054 TSH: IM4405055, IM4401055 IM4402055, IM4406055 IM4404055, IM4403055 Class- B Shelf life: 12 months	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not verified from B&A Division of DRAP. 2. codes are not mentioned in FSC. 3. Only single page of ISO attached. MBD further advised the division to check all the challans of the firm previously submitted and challans used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
54.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Chalan No. 498137388334	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC (Germany) Issuance date: 06-11-2024 Valid till 05-11-29.	Cobas Phosphate (Inorganic) PHOS2 Class: B Product Name: 1. PHOS2 CAT #: 08058610214 Pack size: 750 Tests Shelf life: 18 months at 2 - 8°C	Approved.

	Dated: 09-04-25 R&I Date 30-09-2025.	LOA Validity: 17-01-2028 EU QMS Certificate: 14-12-25 ISO 13485: RDG ISO Validity: 29-06-2027 Suzhou ISO Validity: 20-10-2025		
55.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan 0970518400 Dated. 11-04-25 R&I Date 30-09-2025.	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: Validity: 05-11-2029 LOA Validity: 17-01-2028 EU QMS Certificate: 14-12-25 ISO 13485: RDG ISO Validity: 29-06-2027 Suzhou ISO Validity: 20-10-2025	Cobas Triglycerides TRIGL Class: B Product Name: 1. TRIGL CAT #: 08058687214 Pack size: 1000 Tests Shelf life: 15 months at 2 - 8°C	Approved.
56.	Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 16/05/2025 Fees: 62,000/- Challan No.317702431211 R&I Date 30-09-2025.	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: 11-02-2030 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027	Tina-quant Hemoglobin A1CX4 Class: C Product Name: 1. A1CX4 CAT #: 09529721190 Pack size: 500 Tests Shelf life: 15 months at 2-8°C 1. A1CX4 CAT #: 09529705190 Pack size: 200 Tests Shelf life: 15 months at 2-8°C 1. A1CX4 CAT #: 09529713190 Pack size: 500 Tests Shelf life: 15 months at 2-8°C	Approved.

57.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan No. 14894324125 Dated: 11-04-25 R&I Date 30-09-2025.	Legal Manufacturer: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA Manufacturing Site: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA FSC: Validity: 20-08-2026 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 03-11-2026 ISO 13485: Validity: 19-08-2027	Confirm anti-Total cMET (SP44) Rabbit Monoclonal Primary Antibody Class: B Product Name: 1. Confirm anti-Total cMET (SP44) Rabbit Monoclonal Primary Antibody CAT #: 05571219001 Pack size: 50 Tests Shelf life: 24 months at 2-8°C	Approved.
58.	M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. ELI-00009 Date of R& I 14-05-2025 Fee: PKR 31,000/- Slip # 9596259802 R&I Date 30-09-2025.	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 17-03-2025 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-10-2025 • EU QMS Certificate: Not Submitted	Brand Name: Elecsys Anti-Tg Generic Name: Anti-Tg Applied as: Single Class: B Code/sizes: 09005021214 Shelf Life: 15 Months (2-8°C)	Approved.
59.	M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.	Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany	Brand Name: Elecsys Calcitonin Generic Name: Elecsys Calcitonin	Approved.

	ELI-00009 Date of R& I 14-05-2025 Fee: PKR 62,000/- Slip # 71996124 Dated: 10-04-2025 R&I Date 30-09-2025.	Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 17-03-2025 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-10-2025 • EU QMS Certificate: Not Submitted	Applied as: Kit Class: C Code/sizes: 09005676214 Shelf Life: 18 Months (2-8°C)	
60.	M/s. Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail 19-06-2025 Fee: 6,000/- Slip: 761959153215 R&I Date 30-09-2025.	Legal Manufacturer: M/s Roche Molecular Systems Inc., 1080 US Highway 202 South Branchburg, NJ 08876 USA. Manufacturing Site: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination • FSC (Germany) Type: Original Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 30-06-2027	Brand name: Cobas® 6800 Generic Name: PCR based molecular diagnostic system Applied as: Single Class: A Model/Codes/Sizes: 09575154001 Shelf life: Not mentioned.	Rejected as the case has already been deferred but firm has replied with reference to 97th MDB meeting and has not clarified about the manufacturing site in the Switzerland.

61.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. (ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 14132561668 Dated: R&I Dated: 25-09-2025.	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 26-11-2024 Letter of authorization: 10-10-2028	Brand name: Maccura Generic: Hematology Analyzer Reticulocyte Control Model: Level 1: 3.0mL × 1 3.0mL × 2 3.0mL × 3 3.0mL × 6 2.5mL × 1 2.5mL × 2 2.5mL × 3 2.5mL × 6 Level 2: 3.0mL × 1 3.0mL × 2 3.0mL × 3 3.0mL × 6 2.5mL × 1 2.5mL × 2 2.5mL × 3 2.5mL × 6 Level 3: 3.0mL × 1 3.0mL × 2 3.0mL × 3 3.0mL × 6 2.5mL × 1 2.5mL × 2 2.5mL × 3 2.5mL × 6 Level 1~3: 3.0mL × 3 Level 1~3: 2.5mL × 3 Class- B Shelf life: 90 days ISO 13485 Certificate validity:	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not verified from accounts Division of DRAP. 2. FSC not attached. 3. Only single page of ISO attached. 4. DOC of Urine Strip attached. MBD further advised the division to check all the challans of the firm previously submitted and challans used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
62.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan.	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 26-11-2024	Brand name: Maccura Generic: Automatic Hematology Analyzer Model: Part No: F560 F580	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not verified from accounts Division of DRAP. 2. EC certificate issued by CMC

	(ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 15037594862 Dated: R&I Dated: 25-09-2025.	Letter of authorization: 10-10-2028	Class- B Shelf life: 05 years ISO 13485 Certificate validity:	Medical Devices & Drugs S.L. that is consultancy Firm instead of CAB. 3. Name & address of the manufacturer in FSC is different from the name & address mentioned in application. 4. models/codes mentioned in the FSC China are F580, F580L and F580S. 5. the ISO13485 valid till 09.02.2026. MBD further advised the division to check all the challans of the firm previously submitted and challans used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
63.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. (ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 14276538 Dated: R&I Dated: 25-09-2025.	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 26-11-2024 Letter of authorization: 10-10-2028	Brand name: Maccura Generic: Hs-CRP Chemiluminescent Immunoassay Kit Model: IM4402303, IM4406303 IM4403303 Class- B Shelf life: 18 months ISO 13485 Certificate validity:	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not verified from accounts Division of DRAP. 2. codes and sizes not mentioned in the FSC. 3. Only single page of ISO attached. 4. CE certificate or FSC RRA not submitted MBD further advised the division to check all the challans of the firm previously submitted and challan used for the

				enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
64.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. (ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 36929968495 Dated: R&I Dated: 25-09-2025	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu, PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 26-11-2024 Letter of authorization: 10-10-2028	Brand name: Maccura Generic: Automatic Hematology Analyzer Model: Part No: F800 F810 F880 Class- B Shelf life: 05 years ISO 13485 Certificate validity:	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not verified from accounts Division of DRAP. 2. EC certificate issued by CMC Medical Devices & Drugs S.L. that is consultancy Firm instead of CAB. 3. Name & address of the manufacturer in FSC is different from the name & address mentioned in application. 4. the ISO13485 valid till 09.02.2026 . MBD further advised the division to check all the challans of the firm previously submitted and challan used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
65.	Applicant: M/s Moody Global Services. Address: Office No. 14, 2 nd	(Legal Manufacturer) Name: M/s Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech zone, 611731 Chengdu,	Brand name: Maccura Generic: Thyroglobulin (Tg) Model: IM4401059, IM4402059	Rejected due to following: 1. Firm has submitted Expired Challan and Fee submission not

	Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. (ELI-000926) Fee details: Amount paid: PKR 5000/- Paid Slip / challan No.: 2297552630 Dated: R&I Dated: 25-09-2025	PEOPLES REPUBLIC OF CHINA. Free Sale Certificate Valid till: 24-09- 2022 Letter of authorization: 10-10-2028 ISO 13485 Certificate validity: EC Certificate validity: DOC:	IM4403059, IM4404059 IM4405059, IM4406059 IM4407059, IM4408059 Class- B Shelf life: 12 months	verified from accounts Division of DRAP. 2. EC certificate issued by CMC Medical Devices & Drugs S.L. that is consultancy Firm instead of CAB. 3. Name & address of the manufacturer in FSC is different from the name & address mentioned in application. 4. models/codes are not mentioned in FSC. 5. the name of device is Tg (CLIA) in DOC. 6. CE certificate of FSC RRA not submitted. MBD further advised the division to check all the challans of the firm previously submitted and challan used for the enlisted/registered devices. Furthermore, the board decided to verify the storage of cold chain products by the following panel: 1. Muhammad Amin, DD(MD), 2. Dr. Ghayour Ahmad, DD(MD)
66.	Name Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) R&I Date: 17-10-2024 CMS tracking ID: V18-QUW-HG7G Fee: 62,000/-	Legal Manufacturer: M/s KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI Address: Atakent Mah. 221 Sk. No: 3A Rota Office A Blok Kat:14 D:82-83, 34200 Küçükçekmece, Turkey. Telephone Number: +90 212 471 42 00 Manufacturing Site: KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI. Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey	Brand Name: Wancare Generic Name: WANCARE ONESEPT GA 2% Glutaraldehyde Applied as: Single Class: C Models/Code/sizes (as per FSC & application): KAF G23 Pack Size: 5L with Activator 100 ml Accessory: Test Strips	Approved Model Model KAF G23 (barkod 8682079003474).

		LOA Notarization: Yes valid: 31-12-2029 • FSC Legalized: No Issued by: MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE Valid: 26-03-2027 ISO – Certificate: Notarization: Yes Valid till: 04-03-2025 EC Certificate: Valid till 26-05-2024	Shelf life 2 years	
67.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	EUROLINE Anti-TO.R.C.H. Profile (IgM) DN 2410-1601-4 M, DN 2410-5001-4 M, DN 2410-6401-4 M Class C Shelf life 12 months Fee 50000/-	Approved subject to verification of fee.
68.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024.	Anti-Hepatitis E Virus (HEV) ELISA (IgM) EI 2525-9601 M Class C Shelf life 12 months Fee 50000/-	Approved subject to verification of fee.

		Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025		
69.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Cardiolipin ELISA (IgG) EA 1621-9601 G Class C Shelf life 12 months Fee 50000/-	Approved subject to verification of fee.
70.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Dengue Virus Type 1-4 ELISA (IgM) EI 266a-9601-1 M Class C Shelf life 15 months Fee Rs 50000/-	Approved subject to verification of fee.
71.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site:	Dengue Virus NS1 ELISA EQ 266a-9601-1 Class C Shelf life 12 months Fee Rs 50000/-	Approved subject to verification of fee.

	R&I Date 18-04-2025.	EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025		
72.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Cardiolipin ELISA (IgM) EA 1621-9601 M Class C Shelf life 12 months Fee 50000/-	Approved subject to verification of fee.
73.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Dengue Virus Type 1-4 ELISA (IgG) EI 266a-9601-1 G Class C Shelf life 15 months Fee 50000/-	Approved subject to verification of fee.

74.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of expired FSc of Germany issued on 19.03.2019 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-EBV-CA ELISA (IgG) EI 2791-9601-1 G Class C Shelf life 12 months Fee Rs 50000/-	Approved Anti-EBV- CA ELISA (IgG) EI 2791-9601 G subject to verification of fee.
75.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-Cardiolipin ELISA (IgA) EA 1621-9601 A Class C Shelf life 12 months Fee Rs 50000/-	Approved subject to verification of fee.
76.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued	Anti-Chikungunya Virus ELISA (IgG) EI 293a-9601 G Class C Shelf life 15 months Fee Rs 50000/-	Approved subject to verification of fee.

		on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025		
77.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-β2-Glycoprotien 1 ELISA (IgG) EA 1632- 9601 G Class C Shelf life 12 months Fee Rs 50000/-	Approved subject to verification of fee.
78.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 13.03.2019 Notarized LOA valid till 31.12.2024. Notarized ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Anti-VZV ELISA (IgG) EI 2650-9601 G Class C Shelf life 12 months Fee Rs 50000/-	Approved subject to verification of fee.
79.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e	Legal Manufacturer: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck	Anti-β2-Glycoprotien 1 ELISA (IgM) EA 1632-9601 M	Approved subject to verification of fee.

	Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105 R&I Date 18-04-2025.	Seekamp 31, 23560 Lubeck Germany. Manufacturing Site: EUROIMMUN Medizinische Labordiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany Copy of FSc of Germany issued on 19.03.2024 Notarsied LOA valid till 31.12.2024. Notasried ISO valid till 18.05.2026 Copy of FQA valid till 26.05.2025	Class C Shelf life 12 months Fee Rs 50000/-	
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