

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

DECISIONS OF 106th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 30-10-2025 - MANUAL APPLICATIONS (PART-II)

106th 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 30th October, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

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

11.	Prof Dr M Nadeen Ahmed, Department of Radiology, Agha Khan University Hospital, Karachi.	Member (attended meeting through videolink)
12.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
13.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

Sr.No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X
10.	Mr. Hanif Ullah	Deputy Director-XI

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

(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Recommendations/ Conclusion
1.	M/s NI Healthcare Products (Pvt) Limited, Unit No. 10, Survey No. 263, Damlotte Road, District Malir, Karachi	Safder Hussain Qureshi Biomedical Engineer	Ms. Sonia Saher Naveed Pharmacist	The board considered the report of the firm and approved Establishment License to manufacture medical devices for following sections: - Packing and Sterilization of Sutures & Catguts (Absorbable, Non-Absorbable; Synthetic & Natural) and Gloves - Assembly of Silicon/PVC Medical Grade Tubing/Catheters/Disposables

Item No. I(B): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017
(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Confiance Co, Office and Godown: Plot No. 523/11, 1 st Floor, Sector 6A, Mehran Town, Karachi Korangi Industrial Area, Karachi	Ali Raza D.V.M	Approved
2.	M/s Eracos, Office and Godown: A-187, Sector 6F, Mehran Town, Korangi Industrial Area, Karachi	Laiba Khan Pharm D	Approved
3.	M/s F.A Trader, Office and Godown: House No. P-196, Street No. 2, Gulgushat Colony Near Rabani Colony Bankers, Faisalabad	Muhammad Mudassar Javed B.Sc (Hons) Microbiologist	Approved
4.	M/s Tariq Dental Services, Office and Godown: A07 Alfatah Medicine Center Main GT Road, Peshawar	Kashif Hussain Pharm D	Approved

Item No. I(C): APPLICATIONS FOR GRANT OF RENEWAL OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.
(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

(RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Amanco, 402, Marine Point, Block-9, Clifton Karachi (ELI-00261) Godown Address: Plot No. 36, Warehouse No. 3 & 4, Sector 28, Korangi Industrial Area, Karachi	Alam Khan Microbiologist	Ms. Amina Ashraf	Approved

2.	M/s Batla Impex, Shop No. 40 Centre, Cambell Street, Karachi (ELI-00170) Godown: Rehman Chamber, Medicine Street No. 2, Marriot Road, Karachi	Ms. Nusrat Saleem Pharm D	Iqbal Batla	Approved
3.	M/s Grace Pharmaceuticals, 102, 1 st Floor, Block -9, Clifton, Karachi (ELI-00254) Godown: Latif Godown, F-112, SITE, Karachi	Asia Paveen Pharm D	Shahdev Vankwani	Approved
4.	M/s Meditec Instruments Co. Office and Godown: Suit No. 202, Tahir Plaza, A-20, KCSHU Near Duty Free Shop, Karachi (ELI-00233)	Muhammad Waqar Bio Medical Engineer	Ismat Hatim Gabaji Mrs. Arwa Ms. Tasneem Hozaifa Hozaifa Hashim	Approved
5.	M/s Saru International, Office and Godown: B-194/1, Block-12, Gulistan-e-Joha,Karachi (ELI-00316)	Samia Rizwan B-Pharmacy	Saleem Iqbal	Approved
6.	M/s A.M Sales and Services, Office and Godown: A.M House, 82-L, Block -2, P.E.C.H.S, Karachi (ELI-00244)	Ms. Inshirah BS Bio Medical (Biomedical Engineer)	Anwar Habib Mrs. Karima	Approved
7.	M/s A.H Sons, Office and Godown: E-10, Naveed Bungalows, 17, Gulistan-e-Johar, Karachi (ELI-00520)	Syed Daniyal Jamal Bio Medical Engineer	Ashfaq Ahmed Asad Ashfaq Azmi Jehanzaib Ashfaq Azmi Omar Ashfaq Azmi Ashraf Ahmed Azmi	Approved
8.	M/s Medifar Impex International (Pvt) Ltd., Office and Godown: Suit No. 403-4, 4 th Floor, Mohammadia Plaza College Road, Rawalpindi (ELI-00536)	Naqeeb Ullah Pharmacist	Tanveer Iqbal Farooqi Mrs. Naila Tanveer	Approved
9.	M/s Arfi International, Office and Godown: Office No. 904, 09 th Floor, Al Rahim Tower, I.I Chundrigar Road, Karachi (ELI-00570)	Jai Kishan Pharm D	Altaf Gauhar	Approved

10	M/s Biomadics, Office and Godown: Plot No. 211/B, S.M.C.H.S, Karachi (ELI-00432)	Syed Umar Jameel Pharm D	Baqi Bullah	Approved
11	M/s Chohan and Company, Office and Godown: 21 Bahadurabad, Block-3, Karachi (ELI-00344)	Tayaba Pervaz Pharm D	Abdul Waheed Chohan	Approved
12	M/s Eastern Optical Co., Lakshmi Building, M.A Jinnah Road, Karachi Godown: Suit No. 10, Lakshmi Building, M.A. Jinnah Road, Karachi	Sumaiya Aziz Bio Medical Engineer	Ms. Shahida Zulfiqar Ahsan Zulfiqar	Approved
13	M/s Greenstar Social Marketing Pakistan (Guarantee) Ltd., Ocean Towers, 8 th Floor, G-3,Block 9, KDA Scheme-5, Main Clifton Road, Karachi (ELI- 00253) Godown: Ground Floor, Plot No. F- A/A-2, Hub River Road, Shershah, S.I.T.E, Karachi	Syed Ishrat Naqi Jaffri B. Pharmacy	Dr. Syed Aziz Ur Rab Javaid Sadiq Karl William Hofman Mrs. Mahtab Akbar Rashdi Mrs. Marcie Anne Cook Douglas Foster Call	Approved
14	M/s Gulfam Brothers, Office and Godown: House No. 01-C, Green Villa, Zaildar Park, Ichra, Lahore (ELI-00028)	Dorosham Khan Pharm D	Ms. Al-Kausar Sarfaz	Approved
15	M/s Hikmat Trading & Company, Office and Godown: E-8, Naveed Bungalows, Block-17, Gulistan-e-Johar, Karachi (ELI-00551)	Mehtab Ali Pharm D	Yasir Ullah Khan	Approved
16	M/s Medica, Office and Godown: Office No. 1, Mezzanine Floor, Plot No. 57-C, 12 th Commercial Street, Phase-II (Extension), DHA, Karachi (ELI-00237)	Khalid Aziz Bio-Medical Engineer	Salman Qureshi Muahhamd Asif Dossiani	Approved

17	M/s Innovate Medical Technologies (Pvt) Ltd., Office and Godown: Plot No. C-4, Block 7, Gulshan-e-Iqbal, Karachi (ELI-00352)	Rasool Bux Leghari Pharm D	Waqas Jawaaid Maroof Ali Mohyuddin	Approved
18	M/s Jasani Scientific, Office No. 1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi (ELI-416) Godown: Office No. 2, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi	Sara Naz Pharm D	Arshad Ali Jasani	Approved
19	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-0030) Godown: 208/1, Sector 23, Korangi Industrial Area, Karachi	Muhammad Ahmed Hashmi B Pharm	Mujeeb Ali Khan Jahanzab Saeed Munaf Lakda	Approved
20	M/s Mediniche International, Office and Godown: 113, 2 nd Floor, China Town Plaza, Gordon College Road, Rawalpindi (ELI-00224)	Ms. Zainab Jamshed Pharm D	Nadeem Iqbal Khokhar	Approved
21	M/s Medtronic Pakistan (Pvt) Ltd., 21 st Floor, Ocean Mall, Main Clifton Road, Block-9 Clifton, Karachi (ELI-00273) Godown: Plot No. SI, Survey 231, Sector 2, Road No. 4000, Korangi Industrial Area, Karachi	Mubashir Hanif BE Biomedical	Shahid Manzoor Fabiano Favretto Moussa Srour	Approved
22	M/s Nassir Trading Company, Suit no. 109, 1 st Floor , Al-Rehman Trade Centre, Shahrah-e-Liaquat Opposite Sindh Madrassa, Karachi (ELI-00511) Godown: Office No. 214, 2 nd Floor, Al- Rehman Trade Centre, Shahrah-e-Liaquat Opposite Sindh Madrassa, Karachi	Tarique Hussain Pharm D	Nasir Mehmood	Approved

23	M/s Sanwa Trading Corporation, Office and Godown: Office No. 88, Cricket Stadium, Rawalpindi Stadium Road, Rawalpindi (ELI-00210)	Ms. Rakhta Tasleem Pharmacist	Ajmal Masih	Approved
24	M/s Uniprom Healthcare, L-151, 2 nd Floor, Sehba Akhter Road, Block 13-D, Gulshan-e-Iqbal, Karachi (ELI-00286) Godown: A-33, Bukhari Town Block, 10-A, Gulshan-e-Iqbal, Karachi	Shanza D/o Shabbir Ahmed Qaim Khani Bio Medical Engineer	Muhammad Abid Muniar	Approved
25	M/s Otsuka Pakistan Limited, Office and Godown: 30-B SMCHS, Karachi (ELI-00243)	Ms. Qurrat Ul Ann Shahid Pharm D	Hanif	Deferred for approval of management and technical staff.
26	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Clifton Block -9, Karachi (ELI-00006) Godown: Ground Floor, Plot No. C-153, Sector 6F, Mehran Town, Karachi	Umair Saleem Khan Pharm D	Wasif Sajjad Christian Joachim Rainer Hildebrandt Andreas Walde	Deferred for approval of management and technical staff

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

Deferred Renewal Cases:

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Intek Corporation Office 517, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000. Godown 1: 25-A , Nagi Road, Westridge 1, Rawalpindi Godown 2:	Muhammad Farrukh Tariq Pharmacist (Godown 1) Adnan Maqsood Pharm D (Godown 2)	Irfan ul Azeem Arain	Approved

	22-C, Green Wood Homes, New Muslim Town, Lahore ELI-00794			
2.	M/s Surgi World, Office and Godown: 303, Muhammdia Plaza, College Road, Rawalpindi (ELI-00212)	Old Technical person: Muhammad Yasir New Technical Person: Maria Murtaza Pharm-D	Muhammad Saeed Iqbal	Approved

Item No. I (F): CORRECTION OF ADDRESS – RENEWAL OF ELI

Correction in the address of following firm (Renewal of ELI) is required that was approved in 103rd meeting of Medical Devices Board. The firm has submitted relevant documents and fee for the change of godown address. The case is placed before the board for consideration.

S.No	Name and address of firm in 103 rd meeting	Name and Address of the firm with correct address	Decision
1.	M/s Easha Enterprises, No. 376, Khaleej Centre, Saidpur Road, Near Rasheed Nursing Home, Rawalpindi (ELI-00203),	M/s Easha Enterprises Building No. 5, Street No. 9, Usman Block Jeddah Town, Main G.T Road, Islamabad (ELI-00203),	The board decided to approve the address of the premises as per recommendation of the panel in its inspection report for renewal as below: <i>M/s Easha Enterprises Building No. 5, Street No. 9, Usman Block Jeddah Town, Main G.T Road, Islamabad (ELI-00203)</i>

Agenda Item No.II. ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Mr. Ammar Ashraf Awan (Deputy Director-X)

I. APPLICATIONS SUBMITTED ON CASE MANAGEMENT SYSTEM:

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s. Alsons Technology (Pvt.) Ltd , Plot # 8-C, Old Sunset Boulevard, Commercial Street, Phase 2 DHA Karachi-75000, Pakistan. (ELI-01322) R&I Date: 25-04-2025 Fee: 31,000/- Slip #3303836016	Name of Manufacturer: GE Medical Systems (China) Co. Ltd. Address: No 19. Changjiang Road, Wuxi National Hi-Tech Dev. Zone, 214028, Jiangsu, China. LOA Type: Copy Notarization: Yes Issue date: 24-09-2024 • FSC Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 22-11-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-05-2026 CE certificate: Notarized copy of EU certificate submitted	Brand Name: Vivid T8 Generic Name: Cardiovascular Ultrasound Imaging System Applied as: Singl Class: B Models/Code/sizes (as per FSC & application) Vivid T8 Shelf Life: N/A	Approved
2.	M/s. Alsons Technology (Pvt.) Ltd , Plot # 8-C, Old Sunset Boulevard, Commercial Street, Phase 2 DHA Karachi-75000, Pakistan. (ELI-01322) R&I Date: 25-04-2025 Fee: 31,000/- Slip #406941327574	Name of Manufacturer: GE Medical Systems (China) Co. Ltd. Address: No 19. Changjiang Road, Wuxi National Hi-Tech Dev. Zone, 214028, Jiangsu, China. LOA Type: Copy Notarization: Yes Issue date: 24-09-2024 • FSC Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 25-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes	Brand Name: Versana Active Generic Name: General-purpose ultrasound imaging system Applied as: Singl Class: B Models/Code/sizes (as per FSC & application) Versana Active Shelf Life: N/A	Approved. Firm shall submit valid FSC and CE certificate before issuance of enlistment letter

		Validity: 07-05-2026 CE certificate: Notarized copy of EC certificate valid till 26-05-2024 submitted		
3.	M/s. Alsons Technology (Pvt.) Ltd , Plot # 8-C, Old Sunset Boulevard, Commercial Street, Phase 2 DHA Karachi-75000, Pakistan. (ELI-01322) R&I Date: 25-04-2025 Fee: 31,000/- Slip #01670860890	Name of Manufacturer: GE Medical Systems (China) Co. Ltd. Address: No 19. Changjiang Road, Wuxi National Hi-Tech Dev. Zone, 214028, Jiangsu, China. LOA Type: Copy Notarization: Yes Issue date: 24-09-2024 • FSC Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 22-11-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-05-2026 CE certificate: Notarized copy of EU certificate submitted	Brand Name: Vivid T9 Generic Name: Cardiovascular Ultrasound Imaging System Applied as: Singl Class: B Models/Code/sizes (as per FSC & application) Vivid T8 Shelf Life: N/A	Approved
4.	M/s. Royal Enterprise Karachi Address of Importer SH5, Karimji Building, Opp HBL North Napier Road, Karachi, Pakistan (ELI-00062) R&I Date: 22-05-2025 Fee: 31,000/- Slip #7283596149	Name of Manufacturer: M/s FOSHAN HONGFENG CO., LTD Address: NO.4-2 LEQIANG ROAD, LEPING, SANSHUI, FOSHAN, GUANGDONG PROVINCE, CHINA LOA Type: Copy Notarization: Yes Issue date: 01-04-2025 • FSC Type: Copy Issued By: Provincial supersion body Legalization: Apostille Validity: 11-10-2026 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 13-06-2026 CE certificate: Notarized copy of EU certificate submitted	Brand Name: Nebicare+ Generic Name: Compressor Nebulizer (All sizes) Applied as: Family Class: B Models/Code/sizes (as per FSC & application) 规格型号: HIF-BC6800S, BC6800G, BC6800S, BC6403, BC6403-B, HIF-BC68001, BC68001, BC68002, BC68002-C, BRT, BC6403-D, BC6800S-FS, BC6800S-FT Model: HIF-BC6800S, BC6800G, BC6800S, BC6403, BC6403-B, HIF-BC68001, BC68001, BC68002, BC68002-C, BRT, BC6403-D, BC6800S-FS, BC6800S-FT Shelf Life: N/A	Approved. Firm shall select one model/size

II. HARD COPY CASES

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
5.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #7948999495	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 Generic Name: Enzymes, glycol, nonionic surfactant, anticorrosive materials Applied as: Single-5L Class: A Models/Code/sizes- 5L (as per FSC & application) Shelf Life: 3 Years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
6.	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	Brand Name: Detro Cleanex Generic Name: Ultrasonic Cleaner Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 Years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

		Validity: 15-11-2026 CE certificate: N/A		
7.	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 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 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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
8.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

9.	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: Validity: • ISO – Certificate: Type: Notarization: Validity:	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:	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
10.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
11.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro Enzym Generic Name: Enzymes (amilase,	Deferred for submission of Original legalized FSC issued by the

	R&I Date: 01-07-2025 Fee: 6000/- Slip #05314022	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	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	relevant regulatory authority of country of origin along with details of model
12.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin along with details of model/size
13.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro PAA 2200 Generic Name: Peracetic Acid Applied as: Single-	Deferred for submission of Original legalized FSC issued by the relevant regulatory

	R&I Date: 01-07-2025 Fee: 62000/- Slip # 07529979079	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	Class: C Models/Code/sizes- (as per FSC & application 5L Shelf Life: 18 Months	authority of country of origin
14.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip # 90667002956	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 Air Forte Generic Name: 12% Hydrogen peroxide, colloidal silver. Applied as: Single- 1L Class: A Models/Code/sizes (as per FSC & application 1L Shelf Life: 3 years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
15.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Akaspray	Deferred for submission of Original legalized FSC issued by the

	R&I Date: 01-07-2025 Fee: 31000/- Slip # 6633702691	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	Generic Name: Alcohol Based Spray Disinfectant Applied as: Single- 1L Class: B Models/Code/sizes- (as per FSC & application 1L Shelf Life: 2 years	relevant regulatory authority of country of origin
16.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 31000/- Slip # 234652883004	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 SFC Generic: Bis (3- aminopropyl) dodecylamine, dedecyldimethylamm onium chloride, benzalkonium chloride Applied as: Single Class: B Models/Code/sizes- (as per FSC & application 1L-5L Shelf Life: 2 years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
17.	M/s. 4A International Plot 7, Street 11, Lawyers	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro Enzym Plus DW	Deferred for submission of Original legalized

	Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #2568252336	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	Generic Name: Enzymes, glycol, nonionic surfactant, anticorrosive materials Applied as: Single-5L Class: A Models/Code/sizes- 5L (as per FSC & application) Shelf Life: 3 Years	FSC issued by the relevant regulatory authority of country of origin
18.	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 • 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 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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
19.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro San HP Spray Generic : Hydrogen Peroxide Based Rapid	Deferred for submission of Original legalized FSC issued by the

	R&I Date: 01-07-2025 Fee: 31000/- Slip #5975040972	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	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	relevant regulatory authority of country of origin
20.	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 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 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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
21.	M/s. 4A International Plot 7, Street 11, Lawyers	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro Matic NF	Deferred for submission of Original legalized

	Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 6000/- Slip #5291141310	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	Generic Name: Phosphoric acid,surfactant, corrosion inhibitors. Applied as: Single-5L Class: A Models/Code/sizes-5L (as per FSC & application Shelf Life: 3 Years	FSC issued by the relevant regulatory authority of country of origin
22.	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 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: N/A	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 Shelf Life: 3 years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin Differential fee for family of different sizes shall be submitted
23.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro Dent Generic Name: Phosphoric acid,	Deferred for submission of Original legalized FSC issued by the relevant regulatory

	R&I Date: 01-07-2025 Fee: 6000/- Slip # 541503599	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	nonionic surfactant, corrosion inhibitor. Applied as: Single- Class: A Models/Code/sizes- (as per FSC & application 2L, 5L Shelf Life: 3 Years	authority of country of origin Differential fee for family of different sizes shall be submitted
24.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
25.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro Storage Generic : Drying and Storage Cabinet for Flexible Endoscopes	Deferred for submission of Original legalized FSC issued by the relevant regulatory

	R&I Date: 01-07-2025 Fee: 6000/- Slip #106850703861	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	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:	authority of country of origin Differential fee for family of different sizes shall be submitted
26.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
27.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099)	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S.	Brand Name: Detro San HP Wipes Generic : Hydrogen Peroxide Based Rapid Surface Disinfection	Deferred for submission of Original legalized FSC issued by the relevant regulatory

	R&I Date: 01-07-2025 Fee: 31000/- Slip #71879844243	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	for Medical Devices and Equipment Applied as: Single- Class: B Models/Code/sizes- (as per FSC & application Shelf Life: 2 years	authority of country of origin along with details of intended model/sizes
28.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

29.	M/s. 4A International Plot 7, Street 11, Lawyers Society, Chaklala, Rawalpindi (ELI-00099) R&I Date: 01-07-2025 Fee: 62000/- Slip # 307069795679	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 Cid Activ Generic Name: Peracetic Acid Applied as: Single 100gm Class: C Models/Code/sizes- (as per FSC & application) 100gm Shelf Life: 3 years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
30.	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:	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin Differential fee for family of different models shall be submitted

31.	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 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 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 Shelf Life: 2 years	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
32.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin Differential fee for family of different sizes shall be submitted.

33.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin Differential fee for family of different sizes shall be submitted
34.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

35.	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 Validity: 01-01-2030 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin along with details of intended models/sizes
36.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

37.	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: Type: Copy Notarization: Yes Validity: 15-11-2026 CE certificate: Notarized Copy submitted	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin
38.	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	Deferred for submission of Original legalized FSC issued by the relevant regulatory authority of country of origin

DEFERRED 106th MEETING AGENDA

DEFERRED IMPORT CASES

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision																												
1.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: 62,000/- Slip No. 169920796831 Fee: 42,500/- Slip No. 27224060	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfelden-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	Brand name: Enova Generic Name: Hydrophobic Intraocular Lense Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><th>Model</th><th>Model No.</th></tr><tr><td>ENOVA GF3</td><td>M055G</td></tr><tr><td>ENOVA T GF3</td><td>M085G</td></tr><tr><td>ENOVA ADC</td><td>M088G</td></tr><tr><td>ENOVA T ADC</td><td>M089G</td></tr><tr><td>ENOVA MAESTRO C</td><td>M0109G</td></tr><tr><td>ENOVA MAESTRO T C</td><td>M0110G</td></tr><tr><td colspan="2">Preloaded</td></tr><tr><td>ENOVA PGF3</td><td>M059G</td></tr><tr><td>ENOVA T PGF3</td><td>M0115G</td></tr><tr><td>ENOVA PADC</td><td>M0119G</td></tr><tr><td>ENOVA T PADC</td><td>M0120G</td></tr><tr><td>ENOVA MAESTRO CP</td><td>M0131G</td></tr><tr><td>ENOVA MAESTRO T CP</td><td>M0132G</td></tr></table> Applied as: Family Shelf life: 4 Years	Model	Model No.	ENOVA GF3	M055G	ENOVA T GF3	M085G	ENOVA ADC	M088G	ENOVA T ADC	M089G	ENOVA MAESTRO C	M0109G	ENOVA MAESTRO T C	M0110G	Preloaded		ENOVA PGF3	M059G	ENOVA T PGF3	M0115G	ENOVA PADC	M0119G	ENOVA T PADC	M0120G	ENOVA MAESTRO CP	M0131G	ENOVA MAESTRO T CP	M0132G	Approved.
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2.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: 62,000/- Slip No. 4974244278 Fee: 42,500/- Slip No. 61620350132	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfelden-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	Brand name: Acryva Generic Name: Hydrophobic Intraocular Lens Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><th>Model</th><th>Model No.</th></tr><tr><td>ACRIVA UD 613</td><td>M003G</td></tr><tr><td>ACRIVA BB UD 613</td><td>M025G</td></tr><tr><td>ACRIVA BB UDM 611</td><td>M031G</td></tr><tr><td>ACRIVA BB T UDM 611</td><td>M029G</td></tr><tr><td>ACRIVA TRINOVA PRO</td><td>M0220G</td></tr><tr><td>ACRIVA TRINOVA PRO TORIC</td><td>M0221G</td></tr><tr><td>ACRIVA TRINOVA PRO C</td><td>M077G</td></tr></table> Applied as: Family Shelf life: <table><tr><th>Model</th><th>Shelf life.</th></tr><tr><td>ACRIVA UD 613</td><td>5 Years</td></tr><tr><td>ACRIVA BB UD 613</td><td>3 Years</td></tr><tr><td>ACRIVA BB UDM 611</td><td>3 Years</td></tr><tr><td>ACRIVA BB T UDM 611</td><td></td></tr><tr><td>ACRIVA TRINOVA PRO</td><td></td></tr></table>	Model	Model No.	ACRIVA UD 613	M003G	ACRIVA BB UD 613	M025G	ACRIVA BB UDM 611	M031G	ACRIVA BB T UDM 611	M029G	ACRIVA TRINOVA PRO	M0220G	ACRIVA TRINOVA PRO TORIC	M0221G	ACRIVA TRINOVA PRO C	M077G	Model	Shelf life.	ACRIVA UD 613	5 Years	ACRIVA BB UD 613	3 Years	ACRIVA BB UDM 611	3 Years	ACRIVA BB T UDM 611		ACRIVA TRINOVA PRO		Approved
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			ACRIVA TRINOVA PRO C	5 Years	
3.	M/s. Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. (ELI- 00091) R&I detail 05-06-2025 Fee: 31,000/- Slip: 41793247	Legal Manufacturer: ACON Laboratories, Inc., 5850 Oberlin Drive, # 340 San Diego, CA USA 92121. Manufacturing Site: ACON Biotech (Hangzhou) Co., Ltd., No. 210 Zheuzhoug Road West Lake District Hangzhou, Zhejiang, China 310030 • LOA Type: Copy of Notarized Notarization: Notarized Validity: 10-03-2029 • FSC Type: Copy Issued By: US FDA Legalization: Not legalized Validity: 16-07-2025 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-09-2025	Brand name: On-Call® Lancing Device Generic Name: Lancing Device Applied as: Single Class: B Model/Codes/Sizes (as per application): G124-11A G124-17A Service life: Not mentioned.	Approved On-Call Lancing Device as per FSC.	
4.	M/s. Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. (ELI- 00091) R&I detail 30-06-2025 Fee: 62,000/- Slip: 63386793256	Legal Manufacturer: ACON Laboratories, Inc., 5850 Oberlin Drive, # 340 San Diego, CA USA 92121. Manufacturing Site: ACON Biotech (Hangzhou) Co., Ltd., No. 210 Zheuzhoug Road West Lake District Hangzhou, Zhejiang, China 310030	Brand name: On-Call® GK Dual BGMS Generic Name: Blood Glucose/Ketone Monitoring System Applied as: Single Class: C Model/Codes/Sizes (as per application): GK114-13B	Deferred for submission of legalized FSC of RRA or CE marking certificate and shelf life study.	

		• LOA Type: Copy of Notarized Notarization: Notarized Validity: 10-03-2029 • FSC Type: Copy Issued By: US FDA Legalization: Not legalized Validity: 16-07-2025 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-09-2025	GK134-10A GK134-11A GK124-12A G124-11A4 G124-13A4 Service life: Not mentioned.	
5.	M/s. Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. (ELI- 00091) R&I detail 30-06-2025 Fee: 62,000/- Slip: 77858380503	Legal Manufacturer: ACON Laboratories, Inc., 5850 Oberlin Drive, # 340 San Diego, CA USA 92121. Manufacturing Site: ACON Biotech (Hangzhou) Co., Ltd., No. 210 Zheuzhoug Road West Lake District Hangzhou, Zhejiang, China 310030 • LOA Type: Copy of Notarized Notarization: Notarized Validity: 10-03-2029 • FSC Type: Copy Issued By: US FDA Legalization: Not legalized Validity: 16-07-2025 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-09-2025	Brand name: On-Call® Sure Generic Name: Blood Glucose Monitoring System Applied as: Single Class: C Model/Codes/Sizes (as per application): G115-10U G115-11U G115-12U G115-13U G115-10W G115-11W G115-12W G115-13W G135-10U G135-11U G125-12U G124-10A G124-11A Service life: Not mentioned.	Approved On-Call Sure Blood Glucose Meter as per FSC.
6.	Health Tec, Pakistan H.No 10-B, Valley road, Westridge 1, Rawalpindi Pakistan.	Legal Manufacturer: Translumina GmBH Neue Rottenburger Strasse 50,	Yukon Chrome PC Sirolimus Eluting Coronary Stent System.	Approved and MDB authorized the chairman

	(ELI- 00046) R& I Date: (16/01/2025) Fee details: Amount paid: PKR 62,030/- Paid Slip/ challan No:459137472 Dated: (16/01/2025)	D-72379 Hechingen Germany Tel: ++49 (0) 7471 9894 0 Fax:++49 (0) 7471 9894 380 Website: www.translumina.com Free Sale Certificate Dated: 22-02-2024 ISO 13485 certificate validity:(01/03/2025) EC certificate Validity: (27/05/2024) Confirmation validity:26/05/2026 Letter of authorization: Validity: 07/11/2026	Class-D Shelf life: 2 years Models / Sizes: T-CMG-2008PC, T-CMG- 2012PC, T-CMG-2016PC, T- CMG-2018PC, T-CMG-2021PC, T-CMG-2024PC, T-CMG- 2024PC, T-CMG-2028PC, T- CMG-2032PC, T-CMG- 22508PC, T-CMG-22512PC, T- CMG-22516PC, T-CMG- 22518PC, T-CMG-22521PC, T- CMG-22524PC, T-CMG- 22528PC, T-CMG-22532PC, T- CMG-2508PC, T-CMG-2512PC, T-CMG-2516PC, T-CMG- 2518PC, T-CMG-2521PC, T- CMG-2524PC, T-CMG-2528PC, T-CMG-2532PC, T-CMG- 274508PC, T-CMG- T-CMG- 27512PC, T-CMG-27516PC, T- CMG- 57518PC, T-CMG- 27521PC, T-CMG-27524PC, T- CMG-27528PC, T-CMG- 27532PC, T-CMG-27540PC, T- CMG-3008PC, T-CMG-3012PC, T-CMG-3016PC, T-CMG- 3018PC, T-CMG-3021PC, T- CMG-3024PC, T-CMG-3028PC, T-CMG-3032PC, T-CMG- 3040PC, T-CMG-3508PC, T- CMG-3512PC, T-CMG-3516PC, T-CMG-3518PC, T-CMG- 3521PC, T-CMG-3524PC, T- CMG-3528PC, T-CMG- 3532PC, T-CMG-3540PC, T-CMG- 4008PC, T-CMG-4012PC, T- CMG-4016PC, T-CMG-4018PC, T-CMG-4021PC, T-CMG- 4024PC, T-CMG-4028PC, T- CMG-4032PC, T-CMG-4040	and Secretary MDB to give personal hearing to M/s Trans Angio System for verification of NOC for transfer of registration.
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