

**DECISIONS OF 89TH MEETING OF MEDICAL DEVICE BOARD
HELD ON 24-04-2025**

89th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 24th April, 2025. The meeting was chaired by Dr. Muhammad Fakhr-ud-Din Amir, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1	Dr. Muhammad Fakhr-ud-Din Amir, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/ Cardiovascular Surgeon, Lahore.	Member (attended meeting through videolink)
4	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
5	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathologist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
7	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
8	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9	Wajahat Ali, Biomedical Engineer.	Member (attended meeting through videolink)
10	Hafiz Muhammad Asif Iqbal, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

The meeting commenced with the recitation of the Holy Quran. The Secretary, MDB welcomed all the participants and presented the agenda of the meeting.

REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S#	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 08-01-2025 Fee: PKR 31000/- Slip: 035538622080 Dated: 06-01-2025	Legal Manufacturer M/s Shenzhen Enmind Medical Instrument Co., Ltd. 2nd floor, Block 2#, No.14 Zhongxing road, Xiuxin community, Kengzi street Pingshan district, Shenzhen, 518122.China LOA validity: 30-12-2026 FSC validity: 18-07-2026 CE certificate: Not provided.	Brand name: Generic: Disposable Trocar Shelf Life: 03 Years Class B Model: not mentioned ISO 13485 Certificate: Valid till: 22-01-2026	Deferred for submission of brand name, CE and specific model number or apply as system under MDR 2017
2.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 20-12-2022 Fee: PKR 25000/- Slip: 291211609129 Dated: 20-12-2022	(Legal Manufacturer) M/s Zhuhai Meihua Medical Technology Limited Unit 203, Building 3 (B type Factory Building), No 1, Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China (Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	Aerobic Culture Bottle and Anaerobic Culture Bottle MD Group: Set Shelf Life: 12 months Class B Model: Aerobic Culture Bottle (CFA-01), (CFP-03), (CFL-04). Anaerobic Culture Bottle (CFN-02) ISO 13485 Certificate: Valid till: 31-03-2025	Approved subject to the clarification of Class of medical device and brand name.
3.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 20-12-2022	(Legal Manufacturer) M/s Zhuhai Meihua Medical Technology Limited Unit 203, Building 3 (B type Factory Building), No 1, Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China	Brand name: Generic: Automated Blood Culture System Shelf Life: not applicable Class A Model: (BC-32), (BC-64), (BC-128)	Approved subject to differential fee as per revised SRO for system and brand name.

	Fee: PKR 25000/- Slip: 59112977304 Dated: 14-12-2022	(Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	ISO 13485 Certificate: Valid till: 31-03-2025	
4.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 25-01-2023 Fee: PKR 25000/- Slip: 1655442803 Dated: 24-01-2023	(Legal Manufacturer) M/s Zhuhai Meihua Medical Technology Limited Unit 203, Building 3 (B type Factory Building), No 1, Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China (Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China. LOA validity: 28-09-2026 FSC (Netherlands) validity: 11-11-2027	Brand name: Generic: Enterobacteriaceae ID&AST kit, Nonfermenters ID&AST kit, Fungus ID&AST kit, Streptococcus/Enterococ cus ID&AST kit and Staphylococcus ID&AST kit Shelf Life: 12 months Class B Model: Enterobacteriaceae ID&AST kit MA-120 EB Nonfermenters ID&AST kit MA-120 NF Fungus ID&AST kit MA- 120 FG Streptococcus/Enterococ cus ID&AST kit MA-120 SE Staphylococcus ID&AST kit MA-120 SL ISO 13485 Certificate: Valid till: 31-03-2025	Approved subject to submission of Brand name.
5.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 25-01-2023	(Legal Manufacturer) M/s Zhuhai Meihua Medical Technology Limited Unit 203, Building 3 (B type Factory Building), No 1, Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China	Brand name: Generic: Microorganism Identification and Antimicrobial Susceptibility Test System Shelf Life: not applicable Class A Model: MA120	Approved subject to submission of Brand name.

	Fee: PKR 25000/- Slip: 43013723445 Dated: 24-01-2023	(Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	ISO 13485 Certificate: Valid till: 31-03-2025 LOA validity: 28-09-2026 FSC (Netherlands) validity: 11-11-2027	
6.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 20-01-2025 Fee: PKR 5000/- Slip: 778996294 Dated: 13-08-2024	(Legal Manufacturer) M/s Zhuhai Meihua Medical Technology Limited Unit 203, Building 3 (B type Factory Building), No 1, Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China (Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	Brand name: Generic: Semi-automatic Electrolyte Analyzer Shelf Life: not applicable Class A Model: (M-900) ISO 13485 Certificate: Valid till: 04-12-2026 CE Certificate validity: 19-07-2026	Approved subject to submission of Brand name.
7.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 05-11-2024 Fee: PKR 5000/- Slip: 82575543 Dated: 01-11-2024	(Legal Manufacturer) M/s E-Lab Biological Science & Technology Co Ltd, located at No.1, Kechuang Road, Yaohua Street, Qixia District, Nanjing City, Jiangsu Province, China. (Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	Brand name: Generic: Auto Hematology Analyzer Shelf Life: 08 years Class A Model: (M-900) ISO 13485 Certificate: Valid till: 04-12-2026 CE Certificate validity: Self-Declared Product, CE Declaration of Conformity Attached Date of Issuance: 21/03/2022	Approved subject to subission of clarification for the purpose of clarity and to avoid potential disputes regarding the timeline of the agreement, please Indicate whether the power is valid for a specific period or until revoked by the principal? Also mention date of agreement on the legal papers of power of attorneyf
8.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086	(Legal Manufacturer) M/s E-Lab Biological Science & Technology Co Ltd, located at No.1, Kechuang Road, Yaohua Street, Qixia District, Nanjing City, Jiangsu Province, China.	Brand name: Generic: Semi-Auto Chemistry Analyzer Shelf Life: 08 years Class A	Approved subject to subission of clarification for the purpose of clarity and to avoid potential disputes regarding the timeline of the agreement, please

	R&I 05-11-2024 Fee: PKR 5000/- Slip: 82710734 Dated: 05-11-2024	(Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	Model: (ES-101C) ISO 13485 Certificate: Valid till: 04-12-2026 CE Certificate validity: Self-Declared Product, CE Declaration of Conformity Attached Date of Issuance: 21/03/2022	Indicate whether the power is valid for a specific period or until revoked by the principal? Also mention date of agreement on the legal papers of power of attorneyf
9.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 28-08-2024 Fee: PKR 5000/- Slip: 83605357289 Dated: 05-08-2024	(Legal Manufacturer) M/s E-Lab Biological Science & Technology Co Ltd, located at No.1, Kechuang Road, Yaohua Street, Qixia District, Nanjing City, Jiangsu Province, China. (Manufacturing site) Unit 203, 301, 302, 401, Building 3, No.1 Keji 7 Road, Tangjiawan Town, Zhuhai City, Guangdong Province, China.	Brand name: Generic: Auto chemistry analyzer Shelf Life: 08 years Class A Model: Auto chemistry analyzer AS-120 (OEM Auto chemistry analyzer IVC 120) Auto chemistry analyzer AS-160 (OEM Auto chemistry analyzer IVC 160) ISO 13485 Certificate: Valid till: 04-12-2026 CE Certificate validity: Self-Declared Product, CE Declaration of Conformity Attached Date of Issuance: 21/03/2022	Approved subject to subissson of clarification for the purpose of clarity and to avoid potential disputes regarding the timeline of the agreement, please Indicate whether the power is valid for a specific period or until revoked by the principal? Also mention date of agreement on the legal papers of power of attorneyf
10.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 03-04-2023 Fee: PKR 25000/- Slip: 16581701940 Dated: 14-03-2023	(Legal Manufacturer) M/s Boditech Med Inc. (Manufacturing site) 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do 24398, KOREA.	Brand name: ichroma™ Vitamin D Neo Shelf Life: 20 MONTHS Class B Model: CFPC -133 ISO 13485 Certificate: Valid till: 31-10-2025 CE Certificate validity: Self-Declared Product, CE Declaration of Conformity Attached	Approved.

			Date of Issuance: 20/05/2022 LOA validity: 31-12-2025 FSC (Korea) Issued: 20-05-2022	
11.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 28-08-2024 Fee: PKR 25000/- Slip: 002624880996 Dated: 28-08-2024	(Legal Manufacturer) M/s Boditech Med Inc. (Manufacturing site) 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do 24398, KOREA.	Brand name: ichroma™ Calprotectin Shelf Life: 20 MONTHS Class B Model: CFPC-83 ISO 13485 Certificate: Valid till: 31-10-2025 FSC (Belgium) Issued: 22-10-2024 LOA validity: 31-12-2025 FSC (Korea) Issued: 20-05-2022	Approved.
12.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 06-12-2022 Fee: PKR 25000/- Slip: 0831647172 Dated: 06-12-2022	(Legal Manufacturer) M/s Boditech Med Inc. (Manufacturing site) 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do 24398, KOREA. LOA validity: 31-12-2025 FSC (Korea) Issued: 20-05-2022 FSC (Belgium) Issued: 22-10-2024	Brand name: ichroma™ H. pylori Stool Antigen Shelf Life: 20 MONTHS Class B Model: CFPC -81 ISO 13485 Certificate: Valid till: 31-10-2025	Approved.
13.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 06-12-2022	(Legal Manufacturer) M/s Boditech Med Inc. (Manufacturing site) 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do 24398, KOREA. LOA validity:	Brand name: ichroma™ Total IgE Shelf Life: 20 MONTHS Class B Model: CFPC -91 ISO 13485 Certificate: Valid till: 31-10-2025	Approved.

	Fee: PKR 25000/- Slip: 67350661 Dated: 06-12-2022	31-12-2025 FSC (Korea) Issued: 20-05-2022 FSC (Belgium) Issued: 23-5-2022		
14.	M/s Global Health Care. Address: Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 R&I 06-12-2022 Fee: PKR 25000/- Slip: 6149178979 Dated: 06-12-2022	(Legal Manufacturer) M/s Boditech Med Inc. (Manufacturing site) 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do 24398, KOREA. LOA validity: 31-12-2025 FSC (Korea) Issued: 20-05-2022 FSC (Belgium) Issued: 23-5-2022	Brand name: ichroma™ AMH Shelf Life: 20 MONTHS Class B Model: CFPC -89 ISO 13485 Certificate: Valid till: 31-10-2025	Approved.
15.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 5543462807 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: UNIQUE Air Cushion Shelf Life: 05 years Class A Model: RUBBER WITH PUMP. PVC WITH PUMP LOA validity: 30-10-2034	Approved. For Rubber model registration letter shall be issued. For PVC with pump model, upon submission of separate form 6-A along with prescribed fee.
16.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 0384623169 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Aneroid Sphygmomanometer Accessories Shelf Life: 05 years Class A Model: Bp latex bladder, Bp PVC bladder, Bp bladder with cotton cuff Bp bladder with PVC cuff Bp PVC bulb Bp latex bulb	Approved subject to submission of fee for each accessory.

			LOA validity: 30-10-2034	
17.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 27936358 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Manual Breast Pump Shelf Life: N/A Class A Model: JI-150, JI-180, JI-240, JI-300 LOA validity: 30-10-2034	Approved subject to submission of fee as per revised SRO for Family.
18.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 27936358 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Ear Bulb Sucker Shelf Life: N/A Class A Model: RUBBER, PVC JI-90ML, JI-60ML, JI-30ML, JI-15ML LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved. Registration letter shall be issued for Rubber Model subject to submission of fee as per revised SRO for Family. For PVC model, registration letter shall be issued after submission of separate application on prescribed form along with fee.
19.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 60746176610 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Hot and Cold Patch, Cooling Fever Gel Patch Shelf Life: 03 years Class A Model: JI-201, JI-202, JI-203, JI-204, JI-205, JI-206, JI-207, JI-208 LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved subject to submission of fee as per revised SRO for Family.
20.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 19999268317	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Hot Water Bag Shelf Life: 03 years Class A Model: RUBBER, PVC LOA validity:	Approved. Registration letter shall be issued for Rubber Model. For PVC model, registration letter shall be issued after submission of separate application on prescribed form

	Dated: 02-01-2025		30-10-2034 FSC (China) Issued: 24-03-2027	along with fee.
21.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 19999268317 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Hot Water Bag Shelf Life: 03 years Class A Model: RUBBER, PVC LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved. Registration letter shall be issued for Rubber Model. For PVC model, registration letter shall be issued after submission of separate application on prescribed form along with fee.
22.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 3614529339 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Medical Latex Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI- 676, JI-677, JI-678, JI-679 LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved subject to clarification of type of gloves whether powdered or non- powdered.
23.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 50866997283 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Medical PE Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI- 676, JI-677, JI-678, JI-679 LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved subject to clarification of type of gloves whether powdered or non- powdered.
24.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/-	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New	Brand name: Unique Medical PVC Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI- 676, JI-677, JI-678, JI-679 LOA validity: 30-10-2034	Approved subject to clarification of type of gloves whether powdered or non- powdered.

	Slip: 0051403774 Dated: 02-01-2025	District, Zhengzhou, Hanan, China.	FSC (China) Issued: 24-03-2027	
25.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 454821344729 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Medical Vinyl Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI-676, JI-677, JI-678, JI-679 LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved subject to clarification of type of gloves whether powdered or non- powdered.
26.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 298986853 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Tourniquet Shelf Life: 03 years Class A Model: Buckle style, Self-action style, Self-suction style, Type-A, Type-B, Type-C, Type-D, Type-E LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved. Registration letter shall be issued for buckle style. For self-action style & self-suction style models, registration letter shall be issued after submission of separate applications on forms along with fees.
27.	M/s Battla Brothers Shop No.12, H.J Center Kutchi Gali No. 2 Marriot Road Karachi. ELI-00441 R&I 09-01-2025 Fee: PKR 6000/- Slip: 13759053 Dated: 02-01-2025	(Legal Manufacturer) M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: Unique Wooden Tongue Depressor Shelf Life: 05 years Class A Model: JI-701, JI-702, JI-703, JI-704 LOA validity: 30-10-2034 FSC (China) Issued: 24-03-2027	Approved subject to submission of fee as per revised SRO for Family.
28.	M/s Fresenius Medical Care Pakistan Pvt. Ltd. TAMC, First Floor, 27- C III, M.M. Alam Road Gulberg III, Lahore. ELI-00441 R&I 07/12/2022	(Legal Manufacturer) M/s Fresenius Medical Care AG & Co. KGaA. 61346 Bad Homburg Germany. Manufacturing Site: Nova Med GmbH	Brand name: HD – Bloodlines sterilized by irradiation (e-beam) Model: AV-Set ONLINEplus BVM Paed 5008- R (F00001068) Shelf Life: 02 years	Approved.

	Fee: PKR 25000/- Slip: 140551076 Dated: 22-11-2022	Address: Antalya Serbest Bölgesi Merkez Subesi No:16, Liman Serbest Bölgesi Mahallesi 07070 Antalya, Turkey	Class B LOA validity: 18-12- 2025 FSC (Germany) Issued: 12-03-2020	
29.	M/s M/s Bio-Tech Services, 746- Shadman-1, Lahore. ELI-00715 R&I 29-03-2025 Fee: PKR 31000/- Slip: 8470651550 Dated: 29-03-2025	Legal Manufacturer: EDAN Instrument Inc. Manufacturing Site: No. 15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China.	Brand name: EDAN Digital Ultrasonic Diagnostic Imaging System Model: DUS60 Shelf Life: N/A Class B LOA validity: 30-06-2027 FSC (China) Validity: 07-01-2026 EC Certificate validity: 17-02-2026 (Mentioned on DOC) ISO 13485 Validity: 30-11-2025	Approved subject to submission of fee as per revised SRO for System.
30.	M/s M/s Bio-Tech Services, 746- Shadman-1, Lahore. ELI-00715 R&I 29-03-2025 Fee: PKR 31000/- Slip: 402349896650 Dated: 19-03-2025	Legal Manufacturer: EDAN Instrument Inc. Manufacturing Site: No. 15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. EC Certificate validity: 17-02-2026 (Mentioned on DOC) ISO 13485 Validity: 30-11-2025	Brand name: EDAN Diagnostic Ultrasound System Model: U50, U60, U20 Shelf Life: N/A Class B LOA validity: 30-06-2027 FSC (China) Validity: 07-01-2026	Approved model U50 subject to submission of fee as per revised SRO for System.
31.	M/s M/s Bio-Tech Services, 746- Shadman-1, Lahore. ELI-00715 R&I 29-03-2025	Legal Manufacturer: EDAN Instrument Inc. Manufacturing Site: No. 15 Jinhui Rd., Jinsha Community, Kengzi	Brand name: EDAN Electrocardiography (ECGs)	Approved model SE- 301. The models SE-601, SE-1200 Express

	Fee: PKR 31000/- Slip: 9761347215 Dated: 19-03-2025	Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. EC Certificate validity: 17-02-2026 (Mentioned on DOC) ISO 13485 Validity: 30-11-2025	Model: SE-301, SE-601, SE-1200 Express Shelf Life: N/A Class B LOA validity: 30-06-2027 FSC (China) Validity: 07-01-2026	approved subject to submission of differential fee as per revised fee SRO.
32.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 29-01-2025 Fee: PKR 6000/- Slip: 8470651550 Dated: 09-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: TRUSTPORE Wound Dressing Shelf Life: 05 years Class A Model: JI-301, JI-302, JI-303, JI- 304, JI-305, JI-306, JI- 307, JI-308, JI-309, LOA validity: 30-10-2034	Approved subject to submission of fee as per revised SRO for Family.
33.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 3867513383 Dated: 02-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: FRESHAIR Hot and Cold Patch Cooling Fever Gel Patch Shelf Life: 03 years Class A Model: JI-201, JI-202, JI-203, JI- 204, JI-205, JI-206, JI- 207, JI-208 LOA validity: 30-10-2034	Approved subject to submission of fee as per revised SRO for Family.
34.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/-	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New	Brand name: FRESHAIR Medical Air Mattress with Pump Shelf Life: 03 years Class A Model:	Approved subject to submission of fee as per revised SRO for Family.

	Slip: 70958472499 Dated: 02-01-2025	District, Zhengzhou, Hanan, China.	JI-100, JI-101, JI-102, JI-103, JI-104, JI-105, JI-106 LOA validity: 30-10-2034	
35.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 7968464584 Dated: 02-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: FRESHAIR Medical Latex Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI-676, JI-677, JI-678, JI-679, LOA validity: 30-10-2034	Approved subject to clarification of type of gloves whether powdered or non- powdered.
36.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 767427828 Dated: 02-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: FRESHAIR Medical Nitrile Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI-676, JI-677, JI-678, JI-679, LOA validity: 30-10-2034 FSC (China) Validity: 24-03-2027	Approved subject to clarification of type of gloves whether powdered or non- powdered.
37.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 844144863 Dated: 02-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: FRESHAIR Medical PE Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI-676, JI-677, JI-678, JI-679, LOA validity: 30-10-2034 FSC (China) Validity: 24-03-2027	Approved subject to clarification of type of gloves whether powdered or non- powdered.
38.	M/s Battla Associates	Legal Manufacturer	Brand name:	Approved subject to

	No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 19004177 Dated: 02-01-2025	M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	FRESHAIR Medical Vinyl Gloves Shelf Life: 05 years Class A Model: JI-674, JI-675, JI-676, JI- 677, JI-678, JI-679, LOA validity: 30-10-2034 FSC (China) Validity: 24-03-2027	clarification of type of gloves whether powdered or non- powdered.
39.	M/s Battla Associates No.04, Allawala Building Kutchi Gali No. 2 Marriot Road Karachi. ELI-00281 R&I 09-01-2025 Fee: PKR 6000/- Slip: 456184441890 Dated: 02-01-2025	Legal Manufacturer M/s Zhengzhou Medcons Import & Export Trading Co. Ltd. C613A, Shangdu Road And Qilihe Road Corssing, Zhendong New District, Zhengzhou, Hanan, China.	Brand name: FRESHAIR Disposable Urine Bag Shelf Life: 05 years Class A Model: JI-1000, JI-2000, JI-601, JI-602, JI-603, JI-604 LOA validity: 30-10-2034 FSC (China) Validity: 24-03-2027	Approved subject to submission of fee as per revised SRO for Family.
40.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 R&I 27-02-2025 Fee: PKR 6000/- Slip: 81112733881 Dated: 24-02-2025	Legal Manufacturer M/s VYGON Address: 5 rue Adeline - 95440 Ecouen – France. FSC (France) Issued: 24/07/2023 ISO 13485: VALID 09-05-27	Brand name: Vystar Ramp of stopcocks Shelf Life: 05 years Class B Model: LOA validity: 31/12/2026	Approved subject to clarification of models / sizes / codes with or without Bionector and shelf life for each model / size / codes.
41.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 02273160 Dated: 08/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022	146009910030 - Magnesium Standard FS (Magnesium Standard) Class: B Codes/Sizes: 146009910030 (6x3Ml) Shelf life: 146009910030 – 12 months	Approved

		ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022		
42.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 902300180830 Dated: 08/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	152109910030 - Phosphate Standard FS (Phosphate Standard) Class: B Codes/Sizes: 152109910030 (6x3mL) Shelf life: 152109910030 – 12 months	Approved
43.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 142444647520 Dated: 08/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	157009910030 - Triglycerides Standard FS (Triglycerides Standard) Class: B Codes/Sizes: 157009910030 (6x3mL) Shelf life: 157009910030 – 12 months	Approved
44.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 6066340705 Dated: 08/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity:	157409910041 - Phospholipids Standard FS (Phospholipids Standard) Class: B Codes/Sizes: 157409910041 (3x1mL) Shelf life: 157409910041 – 24 months	Approved

		21-11-2025 DOC Issue date : 27-07-2022		
45.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 55070610175 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	135709910045 - TruCal Lipid (Lipid Calibrator) Class: B Codes/Sizes: 135709910045 (3x2Ml) Shelf life: 135709910045 – 36 months	Approved
46.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 762075546 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	592009910039 - TruCal Protein (Protein Calibrator) 592009910037 - TruCal Protein high (Protein high Calibrator) Class: B Codes/Sizes: 592009910039 (5x1mL) 592009910037 (3x1mL) Shelf life: 592009910039 – 36 months 592009910037 – 36 months	Approved
47.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 35695152639 Dated: 08/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity:	193109910079 - TruCal E (Calibrator) Class: B Codes/Sizes: 193109910079 (4x3mL) Shelf life: 193109910079 – 24 months	Approved

		21-11-2025 DOC Issue date : 27-07-2022		
48.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 3278825719 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	591009910063 591009910064 - TruCal U (Calibrator) Class: B Codes/Sizes: 591009910063 (20x3mL) 591009910064 (6x3mL) Shelf life: 591009910063 – 24 months 591009910064 – 24 months	Approved
49.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 1829769287 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	122409910037 - TruCal TBA (Total bile acid Calibrator) Class: B Codes/Sizes: 122409910037 (3x1mL) Shelf life: 122409910037 – 36 months	Approved
50.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 94518979715 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025	133209910043 - TruCal HbA1c liquid (Hemoglobin A1c liquid calibrator) 133509910044 – TruCal HbA1c net (Hemoglobin A1c net calibrator) Class: B Codes/Sizes: 133209910043 (4x0.25mL) 133509910044	Approved

		DOC Issue date : 27-07-2022	(2x0.3mL) Shelf life: 133209910043 – 15 months 133509910044 – 18 months	
51.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 89729198021 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	172129910921 172129910930 172129910935 172129910964 - Immunoglobulin G FS (Immunoglobulin G) Class: B Codes/Sizes: 172129910921 (4x80 Test) 172129910930 (4x20mL/2x8mL) 172129910935 (2x20mL/1x8mL) 172129910964 (540 Test) Shelf life: 172129910921 - 24 months 172129910930 - 24 months 172129910935 - 24 months 172129910964 – 24 months	Approved
52.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 73645125430 Dated: 02/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	102009910030 - Albumin Standard FS (Albumin standard) Class: B Codes/Sizes: 102009910030 (6x3mL) Shelf life: 102009910030 – 36 months	Approved
53.	M/s. Nextek Healthcare Plot	Legal Manufacturer	109509910030 -	Approved

	No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 8710631455 Dated: 02/01/2025	DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	Bicarbonate Standard FS (Bicarbonate standard) Class: B Codes/Sizes: 109509910030 (6x3mL) Shelf life: 109509910030 – 15 months	
54.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 05712947 Dated: 02/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	111009910030 - Calcium Standard FS (Calcium Standard) Class: B Codes/Sizes: 111009910030 (6x3mL) Shelf life: 111009910030 – 12 months	Approved
55.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 0741275466 Dated: 02/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	113009910030 - Cholesterol Standard FS (Cholesterol Standard) Class: B Codes/Sizes: 113009910030 (6x3mL) Shelf life: 113009910030 – 12 months	Approved
56.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.	Legal Manufacturer DiaSys Diagnostic Systems GmbH.	117009910030 - Creatinine Standard FS (Creatinine Standard)	Approved

	Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 11150742832 Dated: 02/01/2025	Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	Class: B Codes/Sizes: 117009910030 (6x3ML) Shelf life: 117009910030 – 36 months	
57.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 01204002 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	119009910030 - Iron Standard FS (Iron Standard) Class: B Codes/Sizes: 119009910030 (6x3mL) Shelf life: 119009910030 – 12 months	Approved
58.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 51805789644 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	125009910030 - Glucose Standard FS (Glucose Standard) Class: B Codes/Sizes: 125009910030 (6x3mL) Shelf life: 125009910030 – 12 months	Approved
59.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany	130009910030 - Uric acid Standard FS (Uric acid Standard)	Approved

	R&I detail 19/03/2025 Fee: Slip: 02351836768 Dated: 07/01/2025	LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	Class: B Codes/Sizes: 130009910030 (6x3Ml) Shelf life: 130009910030 – 18 months	
60.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 19/03/2025 Fee: Slip: 6497912100 Dated: 07/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	131009910030 - Urea Standard FS (Urea Standard) Class: B Codes/Sizes: 131009910030 (6x3mL) Shelf life: 131009910030 – 12 months	Approved
61.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 15758046034 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	134009910041 - TruCal Homocysteine (Homocysteine calibrator) Class: B Codes/Sizes: 134009910041 (3x1mL) Shelf life: 134009910041 – 4 weeks	Approved
62.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban- e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee:	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity:	170009910036 - TruCal CRP 150 (C-reactive protein calibrator) 170009910037 - TruCal CRP high	Approved

	Slip: 6803596713 Dated: 09/01/2025	15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	(C-reactive protein calibrator) 170009910039 - TruCal CRP (C-reactive protein calibrator) 170409910059 - TruCal CRP U (C-reactive protein calibrator) 170809910059 - TruCal CRP hs (C-reactive protein calibrator) Class: B Codes/Sizes: 170009910036 (3x2mL) 170009910037 (3x2mL) 170009910039 (5x2mL) 170409910059 (5x1mL) 170809910059 (5x1mL) Shelf life: 170009910036 – 18 months 170009910037 – 18 months 170009910039 – 18 months 170409910059 – 24 months 170809910059 – 24 months	
63.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 0554661449 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025	170109910059 - TruCal ASO (Anti-Streptolysin O calibrator) Class: B Codes/Sizes: 170109910059 (5x1mL) Shelf life: 170109910059 – 03 months	Approved

		DOC Issue date : 27-07-2022		
64.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 50761490 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	170209910059 - TruCal RF (Rheumatoid factor calibrator) Class: B Codes/Sizes: 170209910059 (5x1mL) Shelf life: 170209910059 – 20 months	Approved
65.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 808437808120 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	170509910058 - TruCal Ferritin (Ferritin Calibrator) Class: B Codes/Sizes: 170509910058 (4x1mL) Shelf life: 170509910058 – 19 weeks	Approved
66.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 9642683884 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC	172309910059 - TruCal IgE (Immunoglobulin E calibrator) Class: B Codes/Sizes: 172309910059 (5x1mL) Shelf life: 172309910059 – 6 weeks	Approved

		Issue date : 27-07-2022		
67.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 902374590 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	172409910059 - TruCal Ferritin SR (Ferritin calibrator) Class: B Codes/Sizes: 172409910059 (5x1mL) Shelf life: 172409910059 – 30 days	Approved
68.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 413507767 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	172609910047 - TruCal D-Dimer (D-Dimer calibrator) Class: B Codes/Sizes: 172609910047 (1x1mL/2x2.5mL) Shelf life: 172609910047 – 14 days	Approved
69.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 8776171981 Dated: 09/01/2025	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	173109910082 - TruCal PCT (Procalcitonin calibrator) Class: B Codes/Sizes: 173109910082 (6x1mL) Shelf life: 173109910082 – 12 months	Approved
70.	M/s. Nextek Healthcare Plot	Legal Manufacturer	193009910059 - TruCal	Approved

	No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: Slip: 9712411823 Dated: 09/01/2025	DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 18-08-2022 ISO 13485 Validity: 21-11-2025 DOC Issue date : 27-07-2022	Albumin U/CSF (Albumin U/CSF calibrator) 193009910037 TruCal Albumin U/CSF high (Albumin U/CSF high calibrator) Class: B Codes/Sizes: 193009910059 (5x1mL) 193009910037 (3x1mL) Shelf life: 193009910059 – 3 months 193009910037 3 months	
71.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 03613496919 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-Tissue Transglutaminase ELISA (IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 12 months	Approved subject to submission of Brand name and code/model.
72.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 72717423 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-Tissue Transglutaminase ELISA (IgA) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 12 months	Approved subject to submission of Brand name and code/model.
73.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31,	Anti-SLA/LP ELISA (IgG) Class: B	Approved subject to submission of Brand name and code/model.

	(ELI-00105). Fee: PKR 25000/- Slip: 669356755264 Dated: 19-04-2023	23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 12 months	
74.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 882843492 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-dsDNA-NcX ELISA (IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 18 months	Approved subject to submission of Brand name and code/model.
75.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 284746327964 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-Myeloperoxidase ELISA (IgG) MD Group: Kit Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 12 months	Approved subject to submission of Brand name and code/model.
76.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 17661040 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-Gliadin (GAF-3X) ELISA (IgG) MD Group: Kit Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12-2025 Shelf life: 12 months	Approved subject to submission of Brand name and code/model.
77.	Labserv	Euroimmun	Anti-PLA2R ELISA	Approved subject to

	House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 6889476734 Dated: 19-04-2023	Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	(IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12- 2025 Shelf life: 12 months	submission of Brand name and code/model.
78.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 76458037517 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 ISO 13485 validity: 18-05-2026	Anti-PR3-hn-hr ELISA (IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12- 2025 Shelf life: 12 months DOC dated 25-04-2022	Approved subject to submission of Brand name and code/model.
79.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 16091844752 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 ISO 13485 validity: 18-05-2026	Anti-Acetylcholine Receptor ELISA (IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12- 2025 Shelf life: 12 months DOC dated 25-04-2022	Approved subject to submission of Brand name and code/model.
80.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 05969830622 Dated: 19-04-2023	Euroimmun Medizinische Laboradiagnostika AG, Lubeck Seekamp 31, 23560 Lubeck Germany. EC Certificate validity: 26-05-2025 DOC dated 25-04-2022	Anti-CCP ELISA (IgG) Class: B FSC Germany issuance date: 19-03-2024 LOA validity: 31-12- 2025 Shelf life: 12 months	Approved subject to submission of Brand name and code/model.
81.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi.	The Binding Site Group Limited, 8 Calthroe Road Edgbaston, Birmingham,	Optilite® Rheumatoid Factor Kit Class: B	Approved

	(ELI-00105). Fee: PKR 25000/- Slip: 319552408935 Dated: 31-05-2023	B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 ISO 13485 validity: 10-04-2027	FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months DOC dated 18-05-2022	
82.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 9761601043 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022	Optilite® IgG4 Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months ISO 13485 validity: 10-04-2027	Approved
83.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 71053773 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® C1 Inactivator Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months Storage Conditions: 2 – 8°C	Approved
84.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 3620839498 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity:	VaccZyme™ Anti-PCP IgG Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved

		10-04-2027		
85.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 401392679523 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® IgM Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
86.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 80222884478 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Human IgG4 Subclass Liquid Reagent Kit For Use On The Roche Cobas® 6000 Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
87.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 37894772 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® IgG Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
88.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105).	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom.	Optilite® IgA Kit Class: B FSC UK validity: 19.08.2027	Approved

	Fee: PKR 25000/- Slip: 246090697 Dated: 31-05-2023	EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	LOA validity: 31-12-2025 Shelf life: 18 months	
89.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 46641043778 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® IgG1 Kit MD Group: Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
90.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 79643653 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® IgG2 Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
91.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 7511955840 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® IgG3 Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
92.	Labserv House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme	The Binding Site Group Limited, 8 Calthrope Road	Optilite® C3c Kit Class: B	Approved

	36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 5258200301 Dated: 31-05-2023	Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	
93.	Labserve House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 3351859702 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthorpe Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® C4 Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
94.	Labserve House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 1867596096 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthorpe Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® C-Reactive Protein Reagent Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved
95.	Labserve House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 8337296221 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthorpe Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® Beta-2 Microglobulin Kit Class: B FSC UK issuance date: 19.08.2027 LOA validity: 31-12-2025 Shelf life: 18 months	Approved

96.	Labserve House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. (ELI-00105). Fee: PKR 25000/- Slip: 088646200254 Dated: 31-05-2023	The Binding Site Group Limited, 8 Calthorpe Road Edgbaston, Birmingham, B15 1QT, United Kingdom. EC Certificate validity: 03-05-2028 DOC dated 18-05-2022 ISO 13485 validity: 10-04-2027	Optilite® Anti- Streptolysin O Kit Class: B FSC UK validity: 19.08.2027 LOA validity: 31-12- 2025 Shelf life: 18 months	Approved
97.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 31187535	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: Stent boost Model No: 001007 Class : C Shelf Life: 10 years	Approved
98.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands	Philips Product Name: XperGuide Model No: 001006 Class: C	Approved

	Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 41236346	(Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	
99.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 02130046752	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027.	Philips Product Name: Embo Guide Model No: 001012 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved

		EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025		
100.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 05959162906	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: MR-CT Roadmap Model No: 001004 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved
101.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 45101636591	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC:	Philips Product Name: EP Navigator. Model No: 000071 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved

		Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025		
102.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 0760405962	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: Aneurysm Flow Model No: 001015 Class: C Shelf Life: Do not contain any specific shelf-life items which may decompose/ contaminate/ dysfunction as they are software.	Approved
103.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V,	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V	Philips Product Name: Smart CT	Approved

	Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 83384468811	Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Model No: 001018 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	
104.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 1996301536	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485)	Philips Product Name: XperCT Dual Model No: 001105 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved

		DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025		
105.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 23020295172	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: MR 5300. Model No: 782152 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved
106.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address:	Philips Product Name: Ingenia Ambition X Model No: 782138 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved

	Rs. 62,000/= through slip no. 952853164	622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025		
107.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 952853164	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: Ingenia Ambition X Model No: 782138 Class: C Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	Approved
108.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal	(LEGAL MANUFACTURER)	Philips	Approved

	Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no.80365219	Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025	Product Name: Ingenia Elition X (MASTER FILE) Class : C Model No: 782136 Shelf Life: 10 years	
109.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 1265394896	(LEGAL MANUFACTURER) Philips Healthcare (Suzhou) Co., Ltd. Address: NO.258 Zhong Yuan Road, Suzhou Industrial Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA. (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 27, 2025 LOA Validity: 06-Nov-2029 EUQMS Certificate Validity: 27.5.25 ISO 13485 Validity: 23-11-2025	Philips Product Name: CT 3500 Model No: 728134 Shelf Life: 10 years	Approved
110.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083	(LEGAL MANUFACTURER) Philips Healthcare (Suzhou) Co., Ltd. Address: NO.258 Zhong Yuan Road, Suzhou Industrial	Product Name: 3D Roadmap. (MASTER FILE) Model No: 001003 Shelf Life: N/A	Approved

	Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 022072814350	Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA. (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 27, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025		
111.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 45192177	(LEGAL MANUFACTURER) Philips Healthcare (Suzhou) Co., Ltd. Address: NO.258 Zhong Yuan Road, Suzhou Industrial Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA. (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Chinese FSC valid until 23rd March 2025. FSC: Netherlands FSC valid up to May 27, 2025 LOA	Philips Product Name: Incisive CT Model No: 728144	Approved

		Validity: 06-Aug-2029 (ISO 13485) TUV SUD certification Valid till 3.11.25. EUQMS Certificate TUV SUD certification Valid till 27th May 2025		
112.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 80365219	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Chinese FSC valid until 23rd March 2025. FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 29-Aug-2029 (ISO 13485) Dekra certification Valid till 1.02.27. EUQMS Certificate Dekra certification Valid till 27th May 2025	Philips Product Name: Ingenia Elition X (MASTER FILE) Model No: 782136	Approved
113.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000	Manufacturer: MicroVention, Inc. 1311 Valencia Ave Tustin, CA 92780, USA Manufacturing Sites: 1. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA, USA 92656 2. MicroVention Costa Rica, S.R.L. Zona Franca coyol Alajuela, Costa Rica.	Headway Duo Microcatheter Class D Codes: MC162156S MC162167S Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt)

		3. MicroVention, Inc. 1311 Valencia Ave Tustin, CA 92780, USA (FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France Dqs certification Valid till 13.11.25.USA site CE certificate 26-05-24 LOA valid till 31.3.26		Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000
114.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000	Manufacturer: M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA Manufacturing Sites: 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificio B33, Zona Franca Coyol, Alajuela, Costa Rica. FSC US FDA Valid till 14 December, 2019. FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France Dqs certification Valid till 13.11.25.USA site CE certificate 26-05-24 LOA valid till 31.3.26	Headway 21 Microcatheter Codes: MC212150S MC212156S Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000
115.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.	Legal Manufacturer Microvention Europe: 30 bis rue du Vieli	SOFIA PLUS Percutaneous Catheter (Distal Access + Aspiration)	The board decided to call both the companies to be heard in person. i.e, M/s.

	ELI-00794 62000	Abreuvior, 78100 Saint Germain e Laye, France Production Sites MicroVension, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA MicroVension Inc. 35 Enterprise, Aliso Viejo, CA 92656, USA MicroVension Costa Rica S.R.L Edificio B33 Zona Franca Coyol Alajuela, Costa Rica LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France Dqs certification Valid till 13.11.25.USA site	Size Variants: DA6125ST DA6131ST DA6135ST Class D Shelf life : 03 years	Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000
116.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000	Manufacturer: M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA Manufacturing Sites: 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica. LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France	Headway 27 Microcatheter Codes: MC272150S MC272156S Class D Shelf Life : 05 years Fee submitted: Rs. 62,000/-	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000

		Dqs certification Valid till 13.11.25.USA site		
117.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France Dqs certification Valid till 13.11.25.USA site	Microplex® Coil System MCS-CS (18) Microplex Cosmos (18 System) Class D Shelf Life: 5 Years Codes and Sizes: As per FSC	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000
118.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 Fee: 62000	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France	Microplex® Coil System MCS-CSSR (10) Microplex Cosmos (10 System) Class D Shelf Life: 5 Years Codes and Sizes: As per FSC	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000

		Dqs certification Valid till 13.11.25.USA site		
119.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 Fee: 62000	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France Dqs certification Valid till 13.11.25.USA site	Headway 17 Advanced Soft Microcatheter Code: MC172150S Class D Shelf Life: 5 Years Codes and Sizes: As per FSC	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000
120.	M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 Fee: 62000	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA LOA original valid till 31.3.26 FSC france Date of issue 20-06-2023) (ISO 13485) Dqs certification Valid till 13.11.25. France	Platinum Helical Coils Hypersoft (10 System) (Neuro Vascular Embolization Coils) MCS-HC-HS (10) Platinum Helical Coils-Hypersoft (10 System) 100101HS-V 100102HS-V 100103HS-V 100104HS-V 100105HS-V 100106HS-V 100151HS-V 100152HS-V 100153HS-V 100154HS-V 100155HS-V 100156HS-V 100201HS-V 100202HS-V 100203HS-V 100204HS-V 100206HS-V 100208HS-V	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 62000

		Dqs certification Valid till 13.11.25.USA site	100251HS-V 100252HS-V 100253HS-V 100254HS-V 100256HS-V 100258HS-V 100302HS-V 100303HS-V 100304HS-V 100306HS-V 100308HS-V 100310HS-V 100402HS-V 100403HS-V 100404HS-V 100406HS-V 100408HS-V 100410HS-V 100506HS-V 100508HS-V 100510HS-V 100606HS-V 100608HS-V 100610HS-V 100806HS-V 100808HS-V 100810HS-V Class D Shelf Life : 05 years	
121.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany Date of issue 20-06- 2023) (ISO 13485) Dakks certification Valid till 15.1.26.	Zytolght Spec MDM2/CEN 12 Dual color probe Catalogue no 2013-200 2013-50 Class C	Approved
122.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany	Zytolght Spec ALK dual color break apart probe Catalogue no 2124-200 2124-50 Class C	Approved

		Date of issue 20-06-2023) (ISO 13485) Dakks certification Valid till 15.1.26.		
123.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany Date of issue 20-06-2023) (ISO 13485) Dakks certification Valid till 15.1.26.	Zytolght Spec KMT2A dual color break apart probe Catalogue no 2193-200 2193-50 Class C	Approved
124.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany Date of issue 20-06-2023) (ISO 13485) Dakks certification Valid till 15.1.26.	Zytolght Spec MYC dual color break apart probe Catalogue no 2090-200 2090-50 Class C	Approved
125.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany Date of issue 20-06-2023) (ISO 13485) Dakks certification Valid till 15.1.26.	Zytolght Spec ERBB2/CEN 17 dual color probe Catalogue no 2015-200 2015-50 Class C	Approved

126.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi	Zytovision GMBH fischkai 1 25572 bremerhaeven Germany LOA original valid till 31.12.25 FSC Germany Date of issue 20-06- 2023) (ISO 13485) Dakks certification Valid till 15.1.26.	Zytolght Glioma 1p/19q probe set Catalogue no 2272-20 Class C	Approved
127.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan. ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 1354553818	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address: Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Philips Product Name: Heart Navigator. Model No: 001001 Class : C Shelf Life: 10 years	Approved
128.	Matora Digionics Pvt Ltd Address of Importer 7-A, Aziz Avenue, Canal Bank Road, Gulberg V, Lahore. 54000 Punjab, Pakistan.	(LEGAL MANUFACTURER) Philips Medical Systems Nederland B.V Address:	Philips Product Name: Vessel Navigator Model No: 001013 Class: C	Approved

	ELI-00083 Date of R& I 20/1/2025 Fee Rs. 62,000/= through slip no. 8594672559	Veenpluis 6 5684PC Best, Netherlands (Distributor) Philips Electronics Singapore Pvt Ltd Address: 622 Lorong 1 Toa Payoh, Singapore 319763 FSC: Netherlands FSC valid up to May 29, 2025 LOA Validity: 06-Nov-2029 (ISO 13485) DEKRA certification B.V Netherlands Valid till 1st Feb 2027. EUQMS Certificate DEKRA certification B.V Netherlands Valid till 25th June 2025	Shelf Life: Do not contain any specific shelf- life items which may decompose/ contaminate/ dysfunction as they are software.	
129.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195	Legal Manufacturer: Zybio Inc Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. LOA: 23-11-28 FSC: China. Validity: 03-11-2026. (ISO 13485) BSI certification Valid till 29.11.26	ZYBIO C-Reactive Protein Kit (Immunoturbidimetric Method) Shelf Life: 12 Month Class-C Shelf Life: 3 years Fee 62000/-	Deffered for provision of CE certificate (FQA) or FSC of RRA
130.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. Manufacturing Site: NO.39 South Shengli RD. Jinxian county Jiangxi Province, China Original Legalized Free	Brand Name: AT-Tube (Generic Name :) Potassium Oxalate/Sodium Fluoride Blood Collecting Tube Code: 3 ml Class- A	Approved

		Sale Certificate (FSC) dated: People Republic of China Site Valid till 04.09.2026 ISO 13485 valid up to: ISO 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: CE/ FQA Notifying Body TUV SUD extended	Shelf Life: 3 years Fee: Rs. 5,000/- through slip no. 27666434, dated 06.04.2022	
131.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. Manufacturing Site: NO.39 South Shengli RD. Jinxian county Jiangxi Province, China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 04.09.2026 ISO 13485 valid up to: ISO 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: CE/ FQA Notifying Body TUV SUD extended	Brand Name: AT-Tube (Generic Name :) Potassium Oxalate Vacuum Blood Collecting Tube Code: 3 ml Class- A Shelf Life: 3 years Fee: Rs. 5,000/- through slip no. 513044980637, dated 06.04.2022	Approved
132.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. Manufacturing Site: NO.39 South Shengli RD. Jinxian county Jiangxi Province, China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 04.09.2026	Brand Name: AT-Tube (Generic Name :) Sodium Citrate 9:1 Vacuum Blood Collecting Tube Code: 3 ml Class- A Shelf Life: 3 years Fee: Rs. 5,000/- through slip no. 87019711437,	Approved

		ISO 13485 valid up to: ISO 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: CE/ FQA Notifying Body TUV SUD extended	dated 06.04.2022	
133.	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 19-03-2025 <u>Fee Challan No.</u> 678439356468 dated: 10-03-2025	<u>Legal Manufacture</u> Qingdao Kingon Medical Science and Technology Co., Ltd., Room 301-302, No. 15 Hancheng Road, Qingdao Free Trade Zone, Shandong, China, 266555 Manufacturing Site (s): Qingdao Kingon Medical Science and Technology Co., Ltd., 24th Factory Building, No.252 Yanhe Road, Huangdao, Qingdao, Shandong, China , 266510 LOA: Validity: 02-12-2029 FSC: Country of Origin Validity: 09-12-2026 EC Certificate: Validity: 31-12-2028 ISO 13485: Validity: 09-05-2025	<u>Brand Name:</u> P2 <u>(Generic Name):</u> Portable Oxygen Concentrator Class B <u>Shelf life:</u> 05 Years <u>Codes/Sizes:</u> P2	Approved
134.	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 14-04-2025 <u>Fee Challan No.</u> 690725372246 dated: 10-04-2025	<u>Legal Manufacture</u> SysMed (China) Co., Ltd., No. 299, Baita Third Street, Hunnan District 110169 Shenyang, Liaoning, People's Republic of China Manufacturing Site (s): SysMed (China) Co., Ltd., No. 299, Baita Third Street, Hunnan District 110169 Shenyang, Liaoning, People's Republic of China LOA:	<u>Brand Name:</u> OC-E100 <u>(Generic Name):</u> Oxygen Concentrator Class B <u>Shelf life:</u> 05 Years <u>Codes/Sizes:</u> OC-E100	Approved

		Validity: 10-09-2029 FSC: Country of Origin Validity: 07-05-2025 EC Certificate: Validity: 31-12-2028 ISO 13485: Validity: 29-12-2027		
135.	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 17-03-2025 <u>Fee Challan No.</u> 64004352125 dated: 14-03-2025	<u>Legal Manufacture</u> MEKICS Co., Ltd Address: 21, Sangjiseok-gil, Paju-si, Gyeonggi-do, Republic of Korea <u>Manufacturing Site (s):</u> MEKICS Co., Ltd Address: 21, Sangjiseok-gil, Paju-si, Gyeonggi-do, Republic of Korea <u>LOA:</u> Validity: 03-03-2030 <u>FSC:</u> Country of Origin Validity: 26-02-2027 <u>EC Certificate:</u> Validity: 31-12-2027 <u>ISO 13485:</u> Validity: 11-11-2027	<u>Brand Name:</u> HFT700 <u>(Generic Name):</u> Portable Ventilator <u>Class C</u> <u>Shelf life:</u> 07 Years <u>Codes/Sizes:</u> Product Code: MH0012_00	Approved
136.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore - 54000, Pakistan. ELI-00146 5800-P 50,000/-	<u>Legal Manufacturer:</u> Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany. Original FSC: Germany. Date of Issuance: 27-06-2024. LOA validity 21-11-2029 ISO 13485 validity 14-05-2027 EU QMS certificate (MDR) Validity 29-09-2025	ARTIS Icono (Digital Angiography System) Class-C Service Life: 10 Years Model: Biplane (11327600) Ceiling (11328100) Floor (1132770)	Approved subject to submission of fee for all models as per the revised SRO for Family.
137.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore - 54000, Pakistan.	<u>Legal Manufacturer:</u> Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany.	Cios Flow (Mobile radiographic / fluoroscopic units) Class-C	Approved subject to submission of fee as per the revised SRO.

	ELI-00146 5801-P 50,000/-	Original FSC: Germany. Date of Issuance: 27-06-2024. LOA validity 21-11-2029 ISO 13485 validity 14-05-2027 EU QMS certificate (MDR) Validity 29-09-2025	Service Life: 10 Years Model: 11108110	
138.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore - 54000, Pakistan. ELI-00146 5802-P 62,000/-	<u>Legal Manufacturer:</u> Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany. Original FSC: Germany. Date of Issuance: 27-06-2024. LOA validity 21-11-2029 ISO 13485 validity 14-05-2027 EU QMS certificate (MDR) Validity 29-09-2025	LUMINOS Lotus Max (Stationary general-purpose fluoroscopic X-ray system, digital) Class-C Service Life: 10 Years Model: 11574100	Approved subject to submission of fee as per the revised SRO for System.
139.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore - 54000, Pakistan. ELI-00146 5803-P 62,000/-	<u>Legal Manufacturer:</u> Siemens Medical Solutions USA, Inc. 2501 North Barrington Road Hoffman estates, IL 60192 USA. Original FSC: USA Validity: 07-05-2026. LOA validity 11-05-2029 ISO 13485 validity 05-06-2027	Biograph Trinion EP CT64 EP CT128 EP2 CT64 EP2 CT128 (PET/CT Diagnostic Imaging System) Class-C Service Life: 10 Years Model: EP CT64 EP CT128 EP2 CT64 EP2 CT128	Approved subject to submission of fee for all models as per the revised SRO for System.
140.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore - 54000, Pakistan. ELI-00146 5802-P 62,000/-	<u>Legal Manufacturer:</u> Siemens Medical Solutions USA, Inc. 2501 North Barrington Road Hoffman estates, IL 60192 USA. Original FSC: USA Validity: 07-05-2026. LOA validity 11-05-2029	Biograph Vision.X Biograph Vision.X Edge (PET/CT Diagnostic Imaging System) Class-C Service Life: 10 Years Model: Vision.X	Approved Vision.X subject to submission of fee for System and other model as per the revised SRO for System.

			Vision.X Edge	
141.	Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E, PIA Housing Society, Johar Town, Lahore. ELI-01265 5980-P 62,000/-	<u>Legal Manufacturer:</u> Dongguan TT Medical, Inc. Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, PR China. <u>FSC:</u> Netherlands. <u>Validity:</u> 31-12-2027.	EverFlow (Paclitaxel Coated PTCA Balloon Catheter) Class-D Shelf life: 2 years Codes as per FSC	Deferred for clarification since the subject device is already applied by The Cure, Lahore and addressed in M-69 and decided as “Deferred for the provision of original and attested FSC mentioning the applied device, since the applied device is not mentioned in the submitted FSC of Netherland The board decide to call both the parties in person
142.	Lab Diagnostic Systems (SMC) Pvt Ltd, Rawalpindi. 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00496 5697-P 62,000/-	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa-403722, India. FSC: India. Date of Issuance: 06-05- 2022. LOA validity 26-03-2027 FSC of Belgium issued for Argentina and Colombia ISO 13485 validity 26- 04-2026	Truenat® MTB-RIF Dx (Chip-based Real Time PCR Test for Rifampicin Resistant Mycobacterium tuberculosis) Class-C Shelf Life: 2 Years Codes as per FSC	Referred to Authority for its directions being imported from India.
143.	Lab Diagnostic Systems (SMC) Pvt Ltd, Rawalpindi. 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00496 5703-P 62,000/-	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa-403722, India. FSC: India. Date of Issuance: 06-05- 2022. LOA validity 26-03-2027 FSC of Belgium issued for Argentina and Colombia	Truenat® HAV (Chip-based Real Time PCR Test for Hepatitis A Virus) Class-C Shelf Life: 2 Years Codes as per FSC	Referred to Authority for its directions being imported from India.

		ISO 13485 validity 26-04-2026		
144.	Lab Diagnostic Systems (SMC) Pvt Ltd, Rawalpindi. 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00496 5698-P 62,000/-	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa-403722, India. FSC: India. Date of Issuance: 06-05-2022. LOA validity 26-03-2027 FSC of Belgium issued for Argentina and Colombia ISO 13485 validity 26-04-2026	Truenat® MTB Plus (Chip-based Real Time PCR Test for Mycobacterium tuberculosis) Class-C Shelf Life: 2 Years Codes as per FSC	Referred to Authority for its directions being imported from India.
145.	Lab Diagnostic Systems (SMC) Pvt Ltd, Rawalpindi. 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00496 5702-P 62,000/-	<u>Legal Manufacturer:</u> Molbio Diagnostics Private Limited Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa-403722, India. FSC: India. Date of Issuance: 06-05-2022. LOA validity 26-03-2027 FSC of Belgium issued for Argentina and Colombia ISO 13485 validity 26-04-2026	Truenat® HEV (Chip-based Real Time PCR Test for Hepatitis E Virus) Class-C Shelf Life: 2 Years Codes as per FSC	Referred to Authority for its directions being imported from India.
146.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5976-P 62,000/-	<u>Legal Manufacturer and Manufacturing facilities:</u> Abbott Medical, Address: 15900 Valley View Ct. Sylmar. CA USA 91342 Abbott Medical, Address: LOT A INTERIOR-No. 2ST KM 67.5 Santana Industrial Park Arecibo. PR USA 00612. Abbott Medical, Address:	Neutrino NxT DR (Implantable Cardiovert Defibrillator) Class-D Shelf life: 2 years Codes as per FSC: CDDRA600Q CDDRA600T	Approved subject to submission of fee as per revised SRO for Family.

		SDN BHD Plot 102 Lebuhraya Kamounj Jawa Bayan Lepas Industrial Zone Penang. Pulau Pinang Malaysia 11900 Original FSC: USA. Validity: 05-09-2026. LOA validity 31-12-2026 ISO 13485 validity 31-03-2025 EU QMS certificate MDR validity 14-08-2027 EU Tech Doc Assessment Certificate MDR validity 14-08-2027		
147.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5975-P 62,000/-	<u>Legal Manufacturer and Manufacturing facilities:</u> Abbott Medical, Address: 15900 Valley View Ct. Sylmar. CA USA 91342 Abbott Medical, Address: LOT A INTERIOR-No. 2ST KM 67.5 Santana Industrial Park Arecibo. PR USA 00612. Abbott Medical, Address: SDN BHD Plot 102 Lebuhraya Kamounj Jawa Bayan Lepas Industrial Zone Penang. Pulau Pinang Malaysia 11900 Original FSC: USA. Validity: 05-09-2026. LOA validity 31-12-2026 ISO 13485 validity 31-03-2025 EU QMS certificate MDR validity 14-08-2027 EU Tech Doc Assessment Certificate	Neutrino NxT VR (Implantable Cardiovert Defibrillator) Class-D Shelf life: 2 years Codes as per FSC: CDVRA600Q CDVRA600T	Approved subject to submission of fee as per revised SRO for Family.

		MDR validity 14-08-2027		
148.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5974-P 62,000/-	<u>Legal Manufacturer and Manufacturing facilities:</u> Abbott Medical, Address: 15900 Valley View Ct. Sylmar. CA USA 91342 Abbott Medical, Address: LOT A INTERIOR-No. 2ST KM 67.5 Santana Industrial Park Arecibo. PR USA 00612. Abbott Medical, Address: SDN BHD Plot 102 Lebuhraya Kamounj Jawa Bayan Lepas Industrial Zone Penang. Pulau Pinang Malaysia 11900 Original FSC: USA. Validity: 05-09-2026. LOA validity 31-12-2026 ISO 13485 validity 31-03-2025 EU QMS certificate MDR validity 14-08-2027 EU Tech Doc Assessment Certificate MDR validity 14-08-2027	Neutrino NxT HF (Cardiac Resynchronization Therapy Defibrillator) Class-D Shelf life: 2 years Codes as per FSC: CDHFA600Q CDHfA600T	Approved subject to submission of fee as per revised SRO for Family.
149.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5880-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10-06-2024 LOA validity 31-03-2025 ISO 13485 validity 07-11-2027	VIDAS® β2 Microglobulin kit Class-C Shelf Life: 12 Months Code: 30420	Deferred for the submission of updated and notarized LOA
150.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan.	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France.	VIDAS® Anti-HBs Total II kit Class-D	Deferred for the submission of updated and notarized LOA

	ELI-00109 5881-P 62,000/-	FSC: France. Date of Issuance: 10-06-2024 LOA validity 31-03-2025 ISO 13485 validity 07-11-2027 DEC: N/A	Shelf Life: 23 Month Code: 30318	
151.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5882-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10-06-2024 LOA validity 31-03-2025 ISO 13485 validity 07-11-2027 DEC: N/A (Anex-II-A)	VIDAS® HBe/Anti-Hbe kit Class-D Shelf Life: 12 Months Code: 30305	Deferred for the submission of updated and notarized LOA
152.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 5974-P 62,000/-	<u>Legal Manufacturer:</u> BioMeieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. FSC: France. Date of Issuance: 10-06-2024 LOA validity 31-03-2025 ISO 13485 validity 07-11-2027	VIDAS® Varicella-Zoster IgG kit Class-C Shelf Life: 10 Months Code: 30217	Deferred for the submission of updated and notarized LOA
153.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5918-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028 ISO 13485 validity 15-10-2027	RA (RF) Latex Test Kit 100T with Accessories) Class-C Shelf Life: 30 Months Code: RL-RA100	Approved subject to submission of Brand name of the product.
154.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5919-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028	ASO Latex Test Kit 100T with accessories Class-C Shelf Life: 30 Months Code: RL-ASO100	Approved subject to submission of Brand name of the product.

		ISO 13485 validity 15-10-2027		
155.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5919-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028 ISO 13485 validity 15-10-2027	CRP Latex Test Kit 100T with accessories Class-C Shelf Life: 30 Months Code: RL-CRP100	Approved subject to submission of Brand name of the product.
156.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5923-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028 ISO 13485 validity 15-10-2027 CE validity 27-05-2025 DEC validity 27-05-2025	Anti-A Monoclonal 10ml Monoclonal Anti-A Antibodies Class-D Shelf Life: 30 Months Code: BG-A10	Approved subject to submission of Brand name of the product.
157.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5923-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028 ISO 13485 validity 15-10-2027 CE validity 27-05-2025 DEC validity 27-05-2025	Anti-B Monoclonal 10ml Monoclonal Anti-B Antibodies Class-D Shelf Life: 30 Months Code: BG-B10	Approved subject to submission of Brand name of the product.
158.	Diagnostic Centre, Fatima Mansion, 1st Floor Edward Road, Lahore, Pakistan. ELI-00581 5921-P 62,000/-	<u>Legal Manufacturer:</u> Rapid Labs Ltd. Unit 2 & 2a Hall Farm Church Road Little Bentley, Colchester Essex. C07 8SD. UK. FSC: UK Validity: 27-05-2026. LOA validity 31-01-2028 ISO 13485 validity 15-	Anti-D Monoclonal 10ml Monoclonal Anti-D Antibodies Class-D Shelf Life: 30 Months Code: BG-D10	Approved subject to submission of Brand name of the product.

		10-2027 CE validity 27-05-2025 DEC validity 27-05-2025		
159.	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5816-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03-2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26-05-2024 issued by SZUTEST (2195-MED-2004501)	Biorad Liquid PA 5L (High Level Medical instruments-devices and endoscopes disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5557	Deferred for submission of following. Valid CE certificate (FQA) or FSC of RRA Manufacturing details and Stability studies. Valid ISO 13485.
160.	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5817-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03-2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26-05-2024 issued by SZUTEST (2195-MED-2004501)	Biorad Clean Ak Spray (Surface disinfectant for medical devices) Class-C Shelf Life: 2 Years Codes/sizes: 5001 (1L) 5003 (5L)	Deferred for submission of following. Valid CE certificate (FQA) or FSC of RRA Manufacturing details and Stability studies. Valid ISO 13485.
161.	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5818-P	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti.	Biorad Thermo Clean 50% (Hemodialysis machines disinfectant) Class-C	Deferred for submission of following. Valid CE certificate (FQA) or FSC of RRA

	62,000/-	Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Shelf Life: 2 Years Codes/sizes: 5314 (5L)	Manufacturing details and Stability studies. Valid ISO 13485.
162.	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5819-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Biorad Thermo Clean 21% (Hemodialysis machines disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5442 (5L)	Deferred for submission of following. Valid CE certificate (FQA) or FSC of RRA Manufacturing details and Stability studies. Valid ISO 13485.
163.	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5820-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024.	Biorad GDA 2% (High Level Medical instruments-devices and endoscopes disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5401 (5L)	Deferred for submission of following. Valid CE certificate (FQA) or FSC of RRA Manufacturing details and Stability studies. Valid ISO 13485.

		LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)		
164.	Vertex Medical Pvt Ltd, 401- 402, Block-F, Johar Town, Lahore - Pakistan. ELI-00150 5692-P 62,000/-	<u>Legal Manufacturer:</u> Draeger Medical System, Inc. <u>Address:</u> 3135 Quarry Road, Telford, PA 18969-1042, USA. <u>Head / Operating</u> <u>Office:</u> Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck, Germany. Original FSC: Germany. Validity: 13-09-2024. LOA validity 31-12-2025 ISO 13485 validity 19- 03-2025 EU QMS certificate (MDR) validity 01-08- 2027	Infinity M300 Confi (General-Purpose Multi- parameter Patient Monitoring System) Class-C Shelf Life: N/A Models: MS18501	Approved
165.	Vertex Medical Pvt Ltd, 401- 402, Block-F, Johar Town, Lahore - Pakistan. ELI-00150 5692-P 62,000/-	<u>Legal Manufacturer:</u> Draeger Medical System, Inc. <u>Address:</u> 3135 Quarry Road, Telford, PA 18969-1042, USA. <u>Head / Operating</u> <u>Office:</u> Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck, Germany. Original FSC: Germany. Validity: 13-09-2024. LOA validity 31-12-2025 ISO 13485 validity 19- 03-2025 EU QMS certificate (MDR) validity 01-08- 2027	Infinity Central Station Wide Class-C Shelf Life: N/A Models: MS26800	Approved

166.	Vertex Medical Pvt Ltd, 401-402, Block-F, Johar Town, Lahore - Pakistan. ELI-00150 5693-P 62,000/-	<u>Legal Manufacturer:</u> Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck, Germany. Original FSC: Germany. Validity: 02-10-2024. LOA validity 31-12-2025 ISO 13485 validity 13-01-2027 EU QMS certificate (MDR) validity 17-03-2025	Drager MPW SW 02.x (Mobile Patient Watch) Class-C Shelf Life: N/A Models: MS90154	Approved
167.	Basic Pharmaceuticals (Pvt) Ltd, 14-A, Babar Block, New Garden Town Lahore. ELI-00408 5771-P 62,000/-	<u>Legal Manufacturer:</u> Fresenius Kabi AG 61346 Bad Homburg Germany <u>Manufacturing Site:</u> Fresenius HemoCare GmbH Gruner Weg 10 61169 Friedberg Germany. Original FSC: Germany. Date of Issuance: 21-09-2023. LOA validity 31-12-2025 ISO 13485 validity 31-03-2025 CE validity 26-05-2024 with Extension notification letter.	COM.TEC Apheresis System Class-C Service Life: 7 Years Code: 9008021	Approved subject to submission of fee as per revised SRO for System.
168.	OPTIMUS ENTREPOT, 84, H/3 Block Wapda Town Lahore. ELI-00125 5764-P 62,000/-	<u>Legal Manufacturer:</u> Atakan dede- Miray Medikal Cali mah. 14.(410)sk. 14/B Nilufer/Bursa, Turkiye. FSC: Turkiye Date of Issuance: 29-04-2024. LOA validity 31-12-2026 ISO 13485 validity 10-03-2027 CE validity 26-05-2024 with extension notification letter	CROWNVIS (Sodium Hyaluronate, Viscoelastic solution) Class-C Shelf Life: 3 Years Models: MRY-C34S (1.4%) MRY-C37S (3.0%)	Approved subject to submission of fee as per revised SRO for Family.
169.	OPTIMUS ENTREPOT, 84, H/3 Block Wapda Town Lahore.	<u>Legal Manufacturer:</u> Atakan dede- Miray Medikal Cali mah. 14.(410)sk.	CROWNGEL (2.0% 2ML) (Hydroxypropyl Methylcellulose (HPMC),	Approved

	ELI-00125 5765-P 62,000/-	14/B Nilufer/Bursa, Turkiye. FSC: Turkiye Date of Issuance: 29-04-2024. LOA validity 31-12-2026 ISO 13485 validity 10-03-2027 CE validity 26-05-2024 with extension notification letter	Viscoelastic Solution Class-C Shelf Life: 3 Years Model: MRY-C38S	
170.	OPTIMUS ENTREPOT, 84, H/3 Block Wapda Town Lahore. ELI-00125 5767-P 62,000/-	<u>Legal Manufacturer:</u> Atakan dede- Miray Medikal Cali mah. 14.(410)sk. 14/B Nilufer/Bursa, Turkiye. FSC: Turkiye Date of Issuance: 29-04-2024. LOA validity 31-12-2026 ISO 13485 validity 10-03-2027 CE validity 26-05-2024 with extension notification letter	Ocusil (Silicone Oil) Class-C Shelf Life: 3 Years Models: MRY-R14 (Silicone Oil 1000Cst 10ml vial) MRY-R17 (Silicone Oil 5000Cst 10ml vial)	Approved subject to submission of fee as per revised SRO for Family.
171.	Intek Corporation Pvt Ltd, Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000. ELI-00794 5691-P 62,000/-	<u>Legal Manufacturer:</u> MicroVention, Inc. 35 Enterprise, Aliso Viejo CA 92656 USA. (FSC USFDA Valid Till 21-06-2025) LOA validity 31-03-2026 CE and DEC validity 26-05-2024 with extension notification letter.	Traxcess 14 Guidewire Class-D Shelf Life: 3 Year Codes: GW1420040	The board decided to call both the firms regarding the transfer of registration and updated agreement from the legal manufacturer.
172.	Pharma Consultant Pakistan Pvt Ltd, Suite No. 207, 207-A, Khan Tower DHA Square Walton Road, Lahore Cantt ELI-00176 5978-P 62,000/-	<u>Legal Manufacturer:</u> Shenzhen SiSensing Co., Ltd Room 901, Building 1, Gaoshi Jiulongshan Technology Park, No. 26 Shijing Road, Fumin Community, Fucheng Street, Longhua District, 518110 Shenzhen, Guangdong, People's Republic of China. Original FSC: China.	SIBIONICS Continuous Glucose Monitoring System Class-C Service Life of Sensor kit of Continuous Glucose Monitoring System: 18 Months Model: GS1	Approved

		Validity: 28-03-2026. LOA issuance 03-12-2024 valid for 5 years ISO 13485 validity 24-09-2026 EU QMS certificate (MDR) validity 29-10-2028		
173.	Perfect Medical System, D-442, D Block Satellite Town, Rawalpindi. ELI-00964 5705-P 62,000/-	<u>Legal Manufacturer:</u> Spinreact S.A.U CR Santa Coloma No. 7 SantEsteve, Spain. FSC: Spain. Date of Issuance: 29-04-2022. LOA validity 02-03-2026 ISO 13485 validity 29-05-2025 CE certificate validity 27-05-2025	Spinreact IVD (Coagulation Cluster) Class-C Shelf Life: 2 Years Codes as per FSC	Deferred for the provision of following: Original documents signed and stamped form. Clarification/justification is required since the firm applied as cluster with multiple kits in Class-C. Only d-Dimer and PT are mentioned in FSC
174.	Perfect Medical System, D-442, D Block Satellite Town, Rawalpindi. ELI-00964 5704-P 62,000/-	<u>Legal Manufacturer:</u> Spinreact S.A.U CR Santa Coloma No. 7 SantEsteve, Spain. FSC: Spain. Date of Issuance: 29-04-2022. LOA validity 02-03-2026 ISO 13485 validity 29-05-2025 CE certificate validity 27-05-2025	Spinreact IVD (Syphilis Serodiagnostic Cluster) Class-C Shelf Life: 1.5 Years Codes as per FSC	Deferred for the provision of following: Original documents signed and stamped form. Clarification/justification is required since the firm applied as cluster with multiple kits in Class-C. Only d-Dimer and PT are mentioned in FSC
175.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026	Agfa Digital Radiography X-Ray System Class-C Shelf life: N/A Model: Valory	Approved subject to submission of fee as per revised SRO for System

		EU QMS certificate validity 31-05-2027		
176.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate validity 31-05-2027	Agfa Mobile Diagnostic X-ray System Class-C Shelf life: N/A Model: DR 100s	Approved subject to submission of fee as per revised SRO for System
177.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate validity 31-05-2027	Agfa Mobile Diagnostic X-ray System Class-C Shelf life: N/A Model: DR 100e	Approved subject to submission of fee as per revised SRO for System
178.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate validity 31-05-2027	Agfa Digital Radiographic X-ray System Class-C Shelf life: N/A Model: DR 400	Approved subject to submission of fee as per revised SRO for System
179.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate	Agfa Digital Radiographic X-ray System Class-C Shelf life: N/A Model: DR 600	Approved subject to submission of fee as per revised SRO for System

		validity 31-05-2027		
180.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate validity 31-05-2027	Agfa Stationary Fluoroscopic X-ray System, digital Class-C Shelf life: N/A Model: DR 800	Approved subject to submission of fee as per revised SRO for System
181.	Shahco Medical Pvt Ltd, Office No. 934, Shadman Colony 01, Lahore Pakistan. ELI-00230	<u>Legal Manufacturer:</u> Agfa NV, Septestraat 27, 2640 Mortsel, Belgium. Original FSC: Belgium. Date of Issuance: 22-10-2024. LOA validity 31-03-2026 ISO 13485 validity 31-05-2026 EU QMS certificate validity 31-05-2027	Agfa Diagnostic X-ray System Digital Imaging Conversion System Class-C Shelf life: N/A Model: DR Retrofit	Approved subject to submission of fee as per revised SRO for System
182.	Health Tec, Pakistan H.No 10-B, Valley road, Westridge 1, Rawalpindi Pakistan. (ELI- 00046) R& I Date: (28/10/2024) Fee details: Amount paid: PKR 31,030/ Paid Slip/ challan No:68664655 Dated: (03/10/2024)	<u>Legal Manufacturer:</u> SCW Medicath, LTD, No:4, Baolong 6 road baolong Industrial town, Longang District Shenzhen, Guangdong China. TEL: +86 755- 89312160, Email:sales- 3@scw-medicath.com https://www.scwmed.com/ Free Sale Certificate Validity: 22-10-2026 ISO 13485 certificate validity:(08/07/2027) EC certificate Validity: (26/05/2024) Confirmation validity:31/12/2028 Letter of authorization: Validity: 26/08/2029	Manifold Manifold Class-B Shelf life: 3 years Models / Sizes: YY 0585.2, YY 0585.2-3- SM-P-I, YY 0585.2-3SM- P-II	Approved subject to submission of Brand name.

183.	Health Tec, Pakistan H.No 10-B, Valley road, Westridge 1, RawalPindi Pakistan. (ELI- 00046) R& I Date: (28/10/2024) Fee details: Amount paid: PKR 31,030/ Paid Slip/ challan No:25383020720 Dated: (25/10/2024)	<u>Legal Manufacturer:</u> SCW Medicath, LTD, No:4, Baolong 6 road baolong Industrial town, Longang District Shenzhen, Guangdong China. TEL: +86 755- 89312160, Email:sales- 3@scw-medicath.com https://www.scwmed.co m/ Free Sale Certificate Validity: 22-10-2026 ISO 13485 certificate validity:(08/07/2027) EC certificate Validity: (26/05/2024) Confirmation validity:31/12/2028 Letter of authorization: Validity: 26/08/2029	Pressure Bandage Pressure Bandage Class-B Shelf life: 3 years Models / Sizes: SCW-ZXD-1, SCW- ZXD-2, SCW-ZXD-3, SCW-ZXD-4	Approved subject to submission of Brand name.
184.	Health Tec, Pakistan H.No 10-B, Valley road, Westridge 1, RawalPindi Pakistan. (ELI- 00046) R& I Date: (29/05/2024) Fee details: Amount paid: PKR 62030/ Paid Slip/ challan No.: 5589633581 Dated: (03/10/2024)	<u>Legal Manufacturer:</u> Cardiohealth, Aşık Veysel Mah. 5821/1 Sokak. No:6/B, Karabağlar İzmir, Turkey. Email:info@cardiohealth .com.tr Web: www.cardiohealth.com.tr Tel/Fax: +90 232 43599 00 Free Sale Certificate Validity 13-06-2024 ISO 13485 certificate validity:(10/09/2026) EC certificate Validity: (26/05/2024) Confirmation attached Letter of authorization: Validity: not mentioned.	Cardiohealth Angiography Catheter Class-D Shelf life: 3 years Models / Sizes: AC5AL1, AC5AL2, AC5AR1, AC5AR2, AC5IMA, AC5JL35, AC5JL40, AC5JL45 AC5JR35, AC5JR40, AC5JR45, AC5MPA1, AC5PIG110, AC5TIG, AC6AL1, AC6AL2, AC6AR1, AC6AR2, AC6IMA, AC6JL35, AC6JL40, AC6JL45, AC6JR35, AC6JR40, AC6JR45, AC6MPA1, AC6PIG110, AC6TIG.	Approved subject to submission of fee as per revised SRO for Family.
185.	Health Tec, Pakistan H.No 10-B, Valley road, Westridge 1, RawalPindi	<u>Legal Manufacturer:</u> Translumina GmbH Neue Rottenburger	Yukon Chrome PC Sirolimus Eluting Coronary Stent System.	Deferred for clarification of submission of

	Pakistan. (ELI- 00046) R& I Date: (16/01/2025) Fee details: Amount paid: PKR 62,030/- Paid Slip/ challan No:459137472 Dated: (16/01/2025)	Strasse 50, 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-	application since the subject device is already registered for M/s Trans Angio System, Suit No.507, Progressive Square, Block-6, PECHS, Shahrah-e-Faisal, Karachi in 12th meeting of MDB (MDIR- 0000544)
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			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	
186.	Universal Medicine & Surgical Suppliers Office#A-50, First Floor Liberty Mall Plaza Main University Road Tambwanu Mur Peshawer [ELI No 006633] 31,000/- 01682145496 31,000/- 14280569500	<u>Legal Manufacturer:</u> Super Health Medical (Qingdao) Co., Ltd No 236, Heyauan Road, High-Tech Zone Qingdao 266510, Shandong P.R. China. FSC China validity FSC MHRA scanned copy validity 31-12-2029 LOA validity 25-02-2030 ISO 13485 validity 29-03-2026 CE certificate validity 26-05-2024 with extension notification letter.	SKY CATH (IV Cannula with wings and injection port) Class-B Shelf life: 5 years Sizes: 14G, 16G, 18G, 20G, 22G, 24G & 26G	Approved
187.	Universal Medicine & Surgical Suppliers Office#A-50, First Floor Liberty Mall Plaza Main University Road Tambwanu Mur Peshawer [ELI No 006633] 31,000/- 01682145496 31,000/- 14280569500	<u>Legal Manufacturer:</u> Super Health Medical (Qingdao) Co., Ltd No 236, Heyauan Road, High-Tech Zone Qingdao 266510, Shandong P.R. China. FSC China validity FSC MHRA scanned copy validity 31-12-2029 LOA validity 25-02-2030 ISO 13485 validity 29-03-2026 CE certificate validity 26-05-2024 with extension notification letter.	UNICATH (IV Cannula with small wings and Heparin Cap) Class-B Shelf life: 5 years Sizes: 18G, 20G, 22G, 24G & 26G	Approved
188.	Mediland Pakistan (Pvt) Ltd, Office No. B-09 2nd Floor, masood Arcade IJP Road near Saidpur Road Rawalpindi. ELI-00202	<u>Legal Manufacturer:</u> Wuxi Hisky Medical Technologies Co., Ltd Room B401, 530 Plaza, University Science Park, Taihu International Science & Technology	iLivTouch FT9000 Shear Wave Quantificational Ultrasound Diagnostic System Class-C	Deferred for the provision of following: The applied brand name is not mentioned in LOA and FSC.

	5930-P 62,000/-	Park, 214135 Wuxi, Jiangsu Province, People's Republic of China. FSC: China. Validity: 28-02-2026. LOA validity 24-11-2026 ISO 13485 validity 22- 03-2026 CE certificate validity 26- 05-2024 with extension letter.	Shelf Life: N/A Model: FT9000	Labels Manufacturing details and description of the device. In DoC, the Class of device is IIa (B), clarification is required.
189.	Mediland Pakistan (Pvt) Ltd, Office No. B-09 2nd Floor, masood Arcade IJP Road near Saidpur Road Rawalpindi. ELI-00202 5931-P 62,000/-	<u>Legal Manufacturer:</u> Wuxi Hisky Medical Technologies Co., Ltd Room B401, 530 Plaza, University Science Park, Taihu International Science & Technology Park, 214135 Wuxi, Jiangsu Province, People's Republic of China. FSC: China. Validity: 28-02-2026. LOA validity 24-11-2026 ISO 13485 validity 22- 03-2026 CE certificate validity 26- 05-2024 with extension letter.	iLivTouch FT100 Shear Wave Quantificational Ultrasound Diagnostic System Class-C Shelf Life: N/A Model: FT100	Deferred for the provision of following: The applied brand name is not mentioned in LOA and FSC. Labels Manufacturing details and description of the device. In DoC, the Class of device is IIa (B), clarification is required.
190.	Sigma International, 894 B Block Faisal Town Lahore. ELI-00989 5865-P 62,000/-	<u>Legal Manufacturer:</u> Celitron Medical Technologies Kft Szent Laszlo ut 36., 2600 Vac, Hungary. Original FSC: Hungary. Date of Issuance: 16-10- 2024. LOA validity 31-12-2026 ISO 13485 validity 08- 04-2024 CE certificate 26-05- 2024 with extension letter	Sting 11 B Bench Top Steam Sterilizers Class-C Service life: 10 Years Code: Sting 11 B	Approved
191.	Sigma International, 894 B Block Faisal Town Lahore. ELI-00989 5866-P	<u>Legal Manufacturer:</u> Celitron Medical Technologies Kft Szent Laszlo ut 36., 2600 Vac, Hungary.	Azteca-A Large Steam Sterilizers Class-C	Approved subject to submission of fee as per revised SRO for Family.

	62,000/-	Original FSC: Hungary. Date of Issuance: 16-10-2024. LOA validity 31-12-2026 ISO 13485 validity 08-04-2024 CE certificate 26-05-2024 with extension letter	Service life: 10 Years Code: Azteca-A Series	
192.	Sigma International, 894 B Block Faisal Town Lahore. ELI-00989 5867-P 62,000/-	<u>Legal Manufacturer:</u> Celitron Medical Technologies Kft Szent Laszlo ut 36., 2600 Vac, Hungary. Original FSC: Hungary. Date of Issuance: 16-10-2024. LOA validity 31-12-2026 ISO 13485 validity 08-04-2024 CE certificate 26-05-2024 with extension letter	Azteca-AC Series Large Steam Sterilizers Class-C Service life: 10 Years Code: Azteca AC Series.	Approved subject to submission of fee as per revised SRO for Family.
193.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5912-P 62,000/-	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy. FSC Italy issuance 25-02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	INN61V INNEA AQUA Pre-filled syringe of 2ml, with 2.5% Sodium Hyaluronate (50mg/2ml) Class-D Shelf Life: 36 Months Code/size as per FSC	Deferred for the provision of valid LoA and design examination certificate or FSC of RRA or WHO PQ
194.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5913-P 62,000/-	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy. FSC Italy issuance 25-02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	INN03V INNEA (2% Hyaluronic acid sodium salt) 40mg Class-D Shelf Life: 36 Months Code/size as per FSC	Deferred for the provision of valid LoA and design examination certificate or FSC of RRA or WHO PQ
195.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy.	INN62V INNEA EVIDENCE PRAECLA 2ml, 40mg/2ml (2ml, 2% of High molecular weight Sodium Hyaluronate)	Deferred for the provision of valid LoA and design examination certificate or FSC of RRA or WHO PQ

	5914-P 62,000/-	FSC Italy issuance 25-02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	Class-D Shelf Life: 36 Months Code/size as per FSC	
196.	Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. ELI-00267 5915-P 62,000/-	<u>Legal Manufacturer:</u> INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure - Italy. FSC Italy issuance 25-02-2025 LOA: missing ISO 1348507-05-2026 CE and CED certificates validity 27-05-2024 with extension notification.	PROMVIA HYDRO BALANCE 100mg 2,5% of Sodium Hyaluronate salt and trehalose) Class-D Shelf Life: 36 Months Code/size as per FSC	Deferred for the provision of valid LoA and design examination certificate or FSC of RRA or WHO PQ
197.	Endoaid Biomedica, 85-D, DHA EME Sector, Phase XII, Multan Road, Lahore. ELI-00169 5875-P 62,000/-	<u>Legal Manufacturer:</u> Sejoy Biomedical Co. Ltd Area-C, Building 2, No. 3645, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China. FSC: China. Validity: 03-05-2025. LOA validity 31-12-2025 ISO 13485 validity 18-03-2026 CE certificate validity 26-05-2024 with extension notification letter.	SEJOY Blood Glucose Test Strips Class-C Shelf life: 24 Months Model: BS-102	Approved subject to submission of DoC and EPSP checklist
198.	Endoaid Biomedica, 85-D, DHA EME Sector, Phase XII, Multan Road, Lahore. ELI-00169 5876-P 62,000/-	<u>Legal Manufacturer:</u> Sejoy Biomedical Co. Ltd Area-C, Building 2, No. 3645, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China. FSC: China. Validity: 03-05-2025. LOA validity 31-12-2025 ISO 13485 validity 18-03-2026 CE certificate validity 26-05-2024 with extension notification letter.	SEJOY Blood Glucose Meter Class-C Shelf life: 3 years Model: BG-202	Approved subject to submission of DoC and EPSP checklist and clarification of Class of medical device.
199.	Medical Equipment &	<u>Legal Manufacturer:</u>	AGILIA SP TIVA IN	Approved

	Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan. ELI-00554 5711-P 62,000/-	Fresenius Kabi AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. FSC: France. Date of Issuance: 26-10-2022. LOA validity 31-12-2025 ISO 13485 validity 31-03-2025 EU QMS certificate(MDR) validity 09-03-2026	Syringe Infusion Pump Class-C Service life: 10 Years Code: Z018597	
200.	Medequips SMC Pvt. Ltd, 30-Shahrah E Quaid E Azam, Lahore, 54000, Pakistan. ELI-00362 5821-P 100,030/-	<u>Legal Manufacturer:</u> Canon Medical Systems Corporation 1385 Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan Original FSC: Japan. Date of Issuance: 25-04-2023. LOA validity 31-12-2024 ISO 13485 validity 30-09-2025 CE certificate validity 06-11-2024	Aquillion System (Computed Tomography System) Class-C Shelf Life: N/A Models: TSX-307A, TSX-307B, TSX-202A, TSX-308A, TSX-306A	Approved Aquillion System (Computed Tomography System) model TSX-307A.
201.	Cor-Med, 2nd Floor, 38/62, Bank Road, Saddar, Rawalpindi. ELI-00226 5835-P 62,000/-	<u>Legal Manufacturer:</u> Ezisurg Medical Co Ltd, No. 399, Miaoqiao Rd, Pudong New District, 201315 Shanghai, P.R China. Original FSC: China Validity: 03-02-2025. LOA validity 17-09-2027 ISO 13485 validity 27-11-2025 EU certificate validity 29-10-2028	EasyUS Ultrasonic Surgical Systems Class-C Shelf Life: 3 Years Model: ES01	Approved subject to submission of stability studies and fee as per revised SRO for System.
202.	Safeway Systems Pakistan, 1st Floor Ayub Plaza, Misrial Road, near Bhata Chowk, Rawalpindi. ELI-00308 5961-P 50,000/-	<u>Legal Manufacturer:</u> Disposet Tibbi Urunler San. Ve Tic. A.S. Alci Osb Mah. 2000 Cad. No: 20 Sincan / Ankara, Turkey. Original FSC: Turkey. Date of Issuance: 13-11-2024. LOA validity 31-12-2026	DISPOSET Hemofiltration Set Class-C Shelf Life: 3 Years Models: 935-1100 (Adult) 935-1200 (Pediatric) 935-1300 ((Infant)	Approved subject to clarification of class either in class B or class C.

		ISO 13485 validity 28-02-2025 EC certificate validity 27-05-2024 with Extension notification.		
203.	Z&Z Traders, 15-Km Feroz Pur Road, Lahore. ELI-01310 5937-P 62,000/-	<u>Legal Manufacturer:</u> YASEE BioMedical Inc. No. 9 Xiuyuan Road, High-tech Industrial Development Zone, Qingdao City, 266000 Shandong Province China. FSC: China. Validity: 21-04-2025.	Blood Glucose Meter (GLM-71, GLM-72, GLM-73, GLM-74, GLM- 75, GLM-76, GLM-77, GLM-78, GLM-79, GLM- 73P, GLM-76L, GLM- 77L, GLM-78L, GLM- 79L). Class-C Shelf Life: 1000 Tests	Deferred for the provision of following: Original documents including LOA, FSC, ISO 13485, FSC of Ref country or CE marked document. EP checklist. Specify the model required in this application.
204.	Imtiaz Brothers, Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore - 54600, Pakistan. ELI-00133 5969-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan District, Tianjin, People's Republic of China, 300350 FSC: China. Date of Issuance: 13-05- 2024 valid for 2 years LOA validity 31-12-2025 ISO 13485 validity 30- 09-2026 CE certificate validity 26- 05-2024 with extension notification.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Infant) Class-D Shelf Life: 3 Years Model: Extra Corporeal Circuit Tube with Membrane Oxygenator for Infant	Deferred for the clarification of Class
205.	Imtiaz Brothers, Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore - 54600, Pakistan. ELI-00133 5970-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan District, Tianjin, People's Republic of China, 300350 FSC: China. Date of Issuance: 13-05- 2024 valid for 2 years	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Pediatric) Class-D Shelf Life: 3 Years Model: Extra Corporeal Circuit Tube with Membrane	Deferred for the clarification of Class

		LOA validity 31-12-2025 ISO 13485 validity 30-09-2026 CE certificate validity 26-05-2024 with extension notification.	Oxygenator for Pediatric	
206.	Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road, Saddar, Rawalpindi. ELI-00919 5718-P 62,000/-	<u>Legal Manufacturer:</u> Eyekon Medical Inc. 2451 Enterprises Road, Clearwater, Florida. Exportability certificate: USA. Validity: 16-03-2025.	ACU GEL 2% (HPMC) Prefilled 2ml Glass Syringe Class-C Shelf Life: 2 years	Deferred for the provision of following: Original, updated and notarized LOA. FSC having the subject device. Updated ISO 13485 and FQA certificate.
207.	Name: Fresenius Medical Care Pakistan Pvt. Ltd Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore Warehouse Address: 1. Al-Madina Warehouse, 28-Km, Multan Road, Lahore 2. Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi R&I Details: 07/12/2022	<u>Legal Manufacturer:</u> Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany <u>Manufacturing Site:</u> Name: Nova Med GmbH Address: Antalya Serbest Bölgesi Merkez Subesi No:16, Liman Serbest Bölgesi Mahallesi 07070 Antalya, Turkey. <u>LOA:</u> Validity:18-12-2025 <u>FSC:</u> Country of Origin: Germany <u>FSC:</u> FSC of Reference Country: Germany OR <u>EC Certificate</u> Validity: 18-06-2025 ISO 13485 Validity: 04-04-2028	AV-Set ONLINEplus BVM Paed 5008-R Class B Shelf Life: 02 Years Codes/Sizes: F00001068	Approved
208.	Fresenius Medical Care Pakistan Pvt. Ltd TAMC, First Floor, 27-C III,	<u>Legal Manufacturer:</u> Ningbo Tianyi Medical Appliance Co., Ltd	FRESLINE (Extra-corporeal Blood Circuit for	Approved

	M.M. Alam Road Gulberg III, Lahore Warehouse Address: 3. Al-Madina Warehouse, 28-Km, Multan Road, Lahore 4. Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi R&1 30 JAN 2024	No.788, Mozhi North Road, Tourism Resort, Dongqian Lake 315121 Ningbo, People's Republic of China <u>Manufacturing Site:</u> Ningbo Tianyi Medical Appliance Co., Ltd Address: No.788, Mozhi North Road, Tourism Resort, Dongqian Lake 315121 Ningbo, People's Republic of China & No.1 Xinye Road, Tourism Resort, Dongqian Lake 310021 Ningbo, China. <u>LOA:</u> Validity:21-04-2026 <u>FSC:</u> Country of Origin: China Validity:13-06-2025 <u>FSC:</u> FSC of Reference Country: Germany Validity:27-06-2028 ISO 13485 Validity: 14-03-2027	Haemodialysers, Haemodiafilters and Haemofilters) Class-B Shelf Life: 03 Years Codes/Sizes: TX-JB-10 TX-KA-13 TX-KA-14 TX-KB-15 TX-KB-16 TX-HA-17	
209.	Fresenius Medical Care Pakistan Pvt. Ltd Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore Warehouse Address: 5. Al-Madina Warehouse, 28-Km, Multan Road, Lahore 6. Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi	Legal Manufacturer: Fresenius Medical Care AG Address: Else-Kröner-Str. 1 61352 Bad Homburg, Germany <u>Manufacturing Site:</u> Name: Nova Med GmbH Antalya Address: Serbest Bölgesi Merkez Subesi No.16, Liman Serbest Bölgesi Mahallesi 07070 Antalya Turkey	SN-Set ONLINE plus 5008-R Class: B Shelf Life: 02 Years Codes/Sizes: F00000386	Approved

	R n I 16-01-2025	LOA: Validity:24-09-2029 FSC: Country of Origin: Germany Validity:11-01-2029 FSC: FSC of Reference Country: Germany Validity:11-01-2029 OR EC Certificate Validity:18-06-2025 ISO 13485 Validity:04-04-2028		
210.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi. Date of R& I 15.01.2024 Fee Rs. 25,000/ through slip no. 8175926341	Legal Manufacturer: M/s Microcure (Suzhou) Medical Technology Co. Ltd. China. FSC (Netherlands): Issuance Date: 28/04/2022 - Validity Date: 26.04.2024 (extended up to 31.12.2028) Marketing Authorization Letter: LOA: 5 years Issuance Date: 09.10.2023 ISO - Validity Date: 19.12.2025 EC-FQAS: Issuance Date: 15.01.2020 - Validity Date: 26/05/2024	Microcure Disposable Incision Protection Sleeve (Type A) Class B Shelf life: 3 years Model: WZIPS-A Codes: 60/40-60/100 60/70-60/100 50/50-50/220 60/70 80/90-80/100 90/90-90/100 110/110-110/100 120/130-120/100 150/160-150/100 170-180-170/100 180/190-180/100 210/220-200/100 250/260-250/100 280/290-280/100 60/70-60/150 80/90-80/150 120/130-120/220 150/160-150/220	Approved.

			120/130-120/250 150/160-150/250 180/190-180/250 220/230-220/250 290/280-270/250 320/330-320/250	
211.	M/s ACP Systems 13&23 Navel Fleet Club, Iqbal SJ (Shaheed) Road, Karachi Date of R& I 15.01.2024 Fee Rs.25000 Slip No.084703108754	<u>Legal Manufacturer:</u> M/s Microcure (Suzhou) Medical Technology Co. Ltd. China. FSC (Netherlands): Issuance Date: 28/04/2022 - Validity Date: 26.04.2024 (extended up to 31.12.2028) Marketing Authorization Letter: LOA: 5 years Issuance Date: 09.10.2023 ISO - Validity Date: 19.12.2025 EC-FQAS: Issuance Date: 15.01.2020 - Validity Date: 26/05/2024	Microcure Disposable Incision Protection Sleeve (Type B) Class B Shelf life: 3 years Model: WZIPS-A Codes: 60/50-25/5 70/60-35/5 100/50-35/5 150/70-60/5 40/30-15/10 40/30-15/20 50/40-15/20 40/30-15/25 50/40-25/25 60/50-25/25 70/60-35/25 70/70-35/25 70/60-45/25 70/70-45/25 100/80-60/25 100/100-60/25 110/100-60/25 120/100-60/25 120/120-60/25 50/40-25/35 70/60-45/35 70/70-45/35 70/60-35/40 70/70-35/40 120/100-60/40 120/120-60/40 60/50-25/50 70/60-35/50 100/50-35/50 150/70-60/50 1220/100-60/70	Approved.
212.	LifeSpan Healthcare Address of Importer: Office #11, 7 th Floor Gold Mine Plaza,105-Ferozpur Road, Lahore, Pakistan.	<u>Legal Manufacturer:</u> Name: Ultra for Medical Products Co. (Ultramed) Address: 64 Nakhla El Motaiy St., Triumph	Zenflon I.V Cannula with Leur Lock & Injection Port (Sterile)	Approved

	ELI-00736 Date of R& I Submission date: 08-July-2024 Fee Rs 25,000	Square, Cairo, Egypt (Manufacturing site) Name: Ultra for Medical Products Co. (Ultramed) Address: Arab Al Awamer, Industrial Zone, Abnoub, Assiut, Egypt. FSC Egypt Validity: 13-May-2026 LOA- Validity- 31-May-2029 ISO 13485- Validity: 20-May-2026 CE- Validity: 31-Dec-2028 (CE)	Class-B Shelf life: 5 years Sizes/codes: 1001-14 1001-16 1001-18 1001-20 1001-22 1001-24 1001-26	
213.	Applicant: M/s Rison Trading Est, House No. 25/56, Street No. 3, Mohallah Islamabad, Sialkot (ELI-00986) R& I Date: (15 Nov 2023) Fee details: Amount paid: PKR 5000 /- Paid Slip/ challan No1442587862: Dated: (30/05/2023)	(Legal Manufacturer) Name: M/S PERGO MEDIKAL VE ILAC SANAYI A.S. located at Buca OSB Mah. 2/20 Sok. BEGO Sit. No:9 / BUCA / Izmir 35400, Turkey Free Sale Certificate Validity:(13/03/2023) ISO 13485 certificate validity:(24/05/2023) EC certificate Validity: (26/05/2024) Letter of authorization: Validity: (14/02/2025)	Brand Name: PERGO Suction Linear HF 3000ML (Sample Port) Class-B Shelf life: 5 Years	Approved subject to submission of valid documents.
214.	M/s Rison Trading Est, House No. 25/56, Street No. 3, Mohallah Islamabad, Sialkot (ELI-00986) R& I Date: (15 Nov 2023) Fee details: Amount paid: PKR 25000 /- Paid Slip/ challan No 1442587862 Dated: (30/05/2023)	(Legal Manufacturer) M/S PERGO MEDIKAL VE ILAC SANAYI A.S. located at Buca OSB Mah. 2/20 Sok. BEGO Sit. No:9 / BUCA / Izmir 35400, Turkey Free Sale Certificate Validity:(13/03/2023) ISO 13485 certificate validity:(24/05/2023)	Brand Name: PERGO Suction Linear HF 3000ML (Sample Port) Class-B Shelf life: 5 Years	Deferred for the submission of updated documents, brief description and stability studies.

		EC certificate Validity: (26/05/2024) Letter of authorization: Validity: (14/02/2025)		
215.	M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 122004778478 Dated: 29-01-2025	M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Brand Name: Life Care Plus Generic: Absorbable Polyglactin (PGLA) Surgical Suture with Needle for Single Use Sizes: 7-0#, 6-0#, 5-0#, 4- 0#, 3-0#, 2-0#, 0#, 1#, 2# Length: 2cm~550cm Needle: Round Needle, Cutting Needle, Reverse Cutting Needle, Spatula Needle Needle Arc: ½ arc, 3/8 arc, 5/8 arc, Straight Class-D Shelf Life: 5years Storage Conditions: Room Temperature	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.
216.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 93329000676 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM)	Brand Name: Life Care Plus Generic: Non-Absorbable Nylon Suture with Needle for Single Use Sizes: #11-0, #10-0, #9-0, #8-0, #7-0, #6-0, # 5-0, #4-0, #3-0, #2-0, #0, 1#, 2#, 3# Length: 45cm-5.5M Needle: Round Needle, Cutting Needle, Spatula Needle Needle Arc: Straight, ½ arc, 3/8 arc Class-C	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.

		Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Shelf Life: 5years Storage Conditions: Room Temperature	
217.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 20737662584 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Brand Name: Life Care Plus Generic: Non-Absorbable Polypropylene Suture with Needle for Single Use Sizes: 7-0#, 6-0#, 5-0#, 4- 0#, 3-0#, 2-0#, 0#, 1#, 2# Length: 45cm-5.5M Needle: Round Needle, Cutting Needle, Spatula Needle Needle Arc: Straight, ½ arc, 3/8 arc, 5/8 arc Class-C Shelf Life: 5years Storage Conditions: Room Temperature	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.
218.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 00274292807 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate:	Brand Name: Life Care Plus Generic: Non-Absorbable Silk Braided Suture with Needle for Single Use Sizes: #8-0, #7-0, #6-0, #5-0, #4-0, #3-0, #2-0, 0#, 1# ,2# , 3# 4# Length: 45cm-5.5M Needle: Round Needle, Cutting Needle, Spatula Needle Needle Arc: ½ arc, 3/8 arc Class-C LOA: 01-04-2027 Shelf Life: 5years Storage Conditions:	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.

		Validity: 19-04-2026	Room Temperature	
219.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 011226256539 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Brand Name: Life Care Plus Generic: Absorbable Polyglycolic Acid (PGA) Surgical Suture with Needle for Single Use Sizes: 6-0#, 5-0#, 4-0#, 3- 0#, 2-0#, 0#, 1#, 2# Length: 10~550cm Needle: Round Needle, Cutting Needle, Reverse Cutting Needle, Spatula Needle Needle Arc: ½ arc, 3/8 arc, 5/8 arc, Straight Class-D LOA: 01-04-2027 Shelf Life: 5years	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.
220.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 6778015635 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Brand Name: Life Care Plus Generic: Non-Absorbable Polyester Suture with Needle for Single Use Sizes: 0#, 1#, 2#, 3#, 4#, 5#, 2-0#, 3-0#, 4-0#, 5-0#, 6-0# Length: 45cm-5.5M Needle: Round Needle, Cutting Needle, Spatula Needle Needle Arc: Straight, ½ arc, 3/8 arc, 5/8 arc. Class-C LOA: 01-04-2027 Shelf Life: 5years Storage Conditions: Room Temperature	Approved, Subject to submission of valid & Notarized EC Design examination certificate and CE Certificate.

221.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) Date of R&I 04-02-25 Fee Details: Paid Fee: 62,000/- Fee challan Number: 76874895686 Dated: 29-01-2025	Name of Manufacturer: M/s. Shandong Haidike Medical Products Co., Ltd. Address: located at Tianfu Road, Dongcheng District, Shan Country, 274300 Heze City, Shangdong Province, China FSC China Validity: 09-12-2026 LOA Validity: 01-04-2027 EC Design Examination Certificate (UDEM) Validity: 09-04-2024 ISO Certificate: Validity: 19-04-2026	Brand Name: Life Care Plus Generic: Absorbable Surgical Suture Chromic Catgut with Needle for Single Use Sizes: 7-0#, 6-0#, 5-0#, 4- 0#, 3-0#, 2-0#, 0#, 1#, 2# 3#,4# Length: 2cm~550cm Needle: Round Needle, Cutting Needle, Reverse Cutting Needle, Spatula Needle Needle Arc: ½ arc, 3/8 arc, 5/8 arc, Straight Class-D Shelf Life: 5years Storage Conditions: Room Temperature	Deferred for the provision of valid & Notarized EC Design examination certificate and CE Certificate. (Certificates should also contain the said Catgut suture) or FSC of RRA or WHO PQ certificate
222.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) <u>Date of R&I</u> 21-12-2022 Fee: 50,000 Slip Number 76626585507	Name of Manufacturer: Taidoc Technology Corporation Address: B1-7F No.127, Wugong 2 nd Road, Wugu Dist, 24888 New Taipei City, Taiwan FSC Validity (Germany) Issued on 10-05-23 ISO-13485 valid till 01-03-2026 LOA Valid till 04-11-2027 CE Certificate valid from 29.04.22 Valid until 26.05.25	Brand Name: Atom Medical Generic: Blood Glucose Test Strips Model: AT-600 Sizes:10s, 50s, 100s Class-C Shelf Life: 25 months Storage Conditions: Room Temperature	Approved
223.	Applicant Name: M/s. Maqsood Brothers	Name of Manufacturer: Taidoc Technology	Brand Name: LifeCheck	Approved

	Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) <u>Date of R&I</u> 21-12-2022 Fee: 50,000/- Slip Number: 1016324001	Corporation Address: B!-7F No.127, Wugong 2nd Road, Wugu Dist, 24888 New Taipei City, Taiwan FSC Validity (Germany) Issued on 10-05-23 ISO-13485 valid till 01-03-2026 LOA Valid till 04-11-2027 CE Certificate valid from 29.04.22 Valid until 26.05.25	Generic: Blood Glucose Test Strips Model: TD4141 Sizes: Sizes: 10s, 50s, 100s Class-C Shelf Life: 25 months Storage Conditions: Room Temperature	
224.	Applicant Name: M/s. Maqsood Brothers Address: 50B Saima Trade Tower, I.I Chandrigar Road Karachi. (ELI-00282) <u>Date of R&I</u> 21-12-2022 Fee: 50,000/- Slip Number 017765910	Name of Manufacturer: Taidoc Technology Corporation Address: B!-7F No.127, Wugong 2nd Road, Wugu Dist, 24888 New Taipei City, Taiwan FSC Validity (Germany) Issued on 10-05-23 ISO-13485 valid till 01-03-2026 LOA Valid till 04-11-2027 CE Certificate valid from 29.04.22 Valid until 26.05.25	Brand Name: U-Check Generic: Blood Glucose Test Strips Model UC-1001 Sizes:10s, 50s, 100s Class-C Shelf Life: 25 months Storage Conditions: Room Temperature	Approved
225.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400	Name of Manufacturer: Gene Proof a.s Manufacturing Site: Videnska 101/119, Dolni Herspace 619 00 Brno. Czech Republic	Brand Name: GeneProof™ HIV type 1 (HIV-1) Diagnostic PCR Kit (Generic name): HIV type 1 (HIV-1) Diagnostic PCR Kit	Approved

	(ELI-00015) Date of R&I 24-01-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 987884156 Dated: 15-01-2025	FSC: UK Validity- 31-12-2028 LOA Validity: 31-Dec -2025 EC Certificate Validity: 17-01-2024 extension letter provided ISO 13485 Validity: 26-11-2026	Class-D Shelf Life: 9 months Codes/Sizes: A58119	
226.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400 (ELI-00015) Date of R&I 07-01-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 0603703590 Dated: 08-01-2025	Name of Manufacturer: Gene Proof a.s Manufacturing Site: Videnska 101/119, Dolni Herspace 619 00 Brno. Czech Republic FSC: UK Validity- 31-12-2028 FSC: NA LOA Validity: 31-Dec -2025 EC Certificate Validity: 17-01-2024 extension letter provided ISO 13485 Validity: 26-11-2026	Brand Name: GeneProof™ Hepatitis C Virus (HCV) Diagnostic PCR Kit (Generic name): Hepatitis C Virus (HCV) Diagnostic PCR Kit Class: D Shelf Life: 23 months Codes/Sizes: A58427	Deferred since the same product is already addressed in M-46 meeting of MDB for M/s Med Lab Services, Rawalpindi.
227.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400 (ELI-00015) Date of R&I 24-01-2025 Fee Details: Paid Fee: 62,000/-	Name of Manufacturer: Legal Manufacturer: Gene Proof a.s Manufacturing Site: Videnska 101/119, Dolni Herspace 619 00 Brno. Czech Republic FSC: UK Validity- 31-12-2028 LOA Validity: 31-Dec -2025	Brand Name: GeneProof™ Hepatitis B Virus (HBV) PCR Kit (Generic name): Hepatitis B Virus (HBV) PCR Kit Class: D Shelf Life: 23 months Codes/Sizes: A58426	Deferred since the same product is already addressed in M-46 meeting of MDB for M/s Med Lab Services, Rawalpindi.

	Fee challan Number: 45051683 Dated: 15-01-2025	EC Certificate Validity: 17-01-2024 extension letter provided ISO 13485 Validity: 26-11-2026		
228.	Applicant Name: M/s. Briogene Pvt. Ltd Address: 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400 (ELI-00015) Date of R&I 24-01-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 10071932 Dated: 02-01-2025	Name of Manufacturer: Thermo Fisher Scientific Manufacturing Site: Thermo Fisher Scientific OY, Ratastie 2, FI-01620 Vantaa, Finland FSC: Country of Origin: Finland Validity- NA Issue Date: 24-feb-2021. MHRA Letter also attached. LOA Validity: 6-Nov-2025 ISO 13485 Validity: 31-03-2027	Brand Name: Thermo Fisher CK-MB (Generic name): CK-MB Class: C Shelf Life: 15 months Codes/Sizes: 981834-CK-MB 4 x 25 ml 981837-CK-MB 2 x 20 ml	Approved.
229.	Applicant Name: M/s. Med Art, Pakistan. Address: A-175 Block 13-C KDA Scheme 24, Gulshan-e-Iqbal Karachi, Pakistan-75300. (ELI-00024) Date of R&I 10-02-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 050171899 Dated: 01-02-2025	Name of Manufacturer: Regen Lab SA, Address: En Budron B2, 1052 Le- Mont-Sur-Lausanne, Switzerland (CH) FSC Valid till: Swiss Agency for therapeutic products, certificate number 00021682 valid till 14.05.2027 ISO Certificate valid till: 13485:2016 & ISO 13485:2016 certificate number MD 642990 valid till 12-12-2025 legalized in Switzerland.	Brand Name: RegenKit®-ATS-T RK-ATS-T 07640138980916 Class – C Shelf life 2 Years Storage temperature and conditions Well packaged products should be kept in a place where is in normal temperature (02~30) centigrade.	Approved

		CE certificate extension letter from BSI and manufacturer DoC valid till: 31-12-2028 for class IIb medical devices classified as class C medical devices in Pakistan LOA valid till: Regan Lab Switzerland for M/S Med Art Pakistan valid till June 4, 2029 apostille legalized in Switzerland.		
230.	Applicant Name: M/s. Med Art, Pakistan. Address: A-175 Block 13-C KDA Scheme 24, Gulshan-e-Iqbal Karachi, Pakistan-75300. (ELI-00024) Date of R&I 10-02-2025 Fee Details: Paid Fee: 62,000/- Fee challan Number: 11428078229 Dated: 01-02-2025	Name of Manufacturer: Regen Lab SA, Address: En Budron B2, 1052 Le-Mont-Sur-Lausanne, Switzerland (CH) FSC Valid till: Swiss Agency for therapeutic products, certificate number 00021682 valid till 14.05.2027 ISO Certificate valid till: 13485:2016 & ISO 13485:2016 certificate number MD 642990 valid till 12-12-2025 legalized in Switzerland. CE certificate extension letter from BSI and manufacturer DoC valid till: 31-12-2028 for class IIb medical devices classified as class C medical devices in Pakistan LOA valid till:	Brand Name: RegenKit®-THT RegenKit®-THT-3 RK-THT-3 07640138981258 Class – C Shelf life 24 Months Storage temperature and conditions Well packaged products should be kept in a place where is in normal temperature (02~30) centigrade.	Approved

		Regan Lab Switzerland for M/S Med Art Pakistan valid till June 4, 2029 apostille legalized in Switzerland.		
231.	Applicant Name: M/s. K.S. Agencies Address: Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) R&I Dated: 02/26/2025 Fee Challan No.: 0979222172 PKR: 62,000/-	Name of Manufacturer: Haolang Medical USA Corporation. Address: 1100 Bellevue Way NE 8A-533, Bellevue, WA 98004, USA (Manufacturing Site) Haolang Technology (Foshan) Limited Corporation. Address: Xinyuan 2nd RD, Jili Industry Park, Nanzhuang, ChanCheng District, Foshan, Guangdong, China LOA Validity: 04/11/2027 FSC USA Validity: 02/27/2026 ISO 13485 Validity: 07/23/2026	Brand Name: NEXUS MEDILINE CT CATHETER Class: D MD group: Single Codes/Sizes: Single, Double, Triple, Quadruple Lumen Catheter with Kit. P120-03108 - P120-05220 A120-03108-N - A120- 05220-N Shelf Life: 3 Years	Approved having FSC of USA
232.	Applicant Name: M/s. K.S. Agencies Address: Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi. (ELI-00382) R&I Dated: 02/26/2025 Fee Challan No.: 00024468915 PKR: 62,000/-	Name of Manufacturer: Haolang Medical USA Corporation. Address: 1100 Bellevue Way NE 8A-533, Bellevue, WA 98004, USA (Manufacturing Site) Haolang Technology (Foshan) Limited Corporation Address: Xinyuan 2nd RD, Jili Industry Park, Nanzhuang, ChanCheng District, Foshan,	Brand Name: ORION™ II CT CVC Class: D MD group: Single Codes/Sizes: Single, Double, Triple, Quadruple Lumen Catheter with Kit. A33-05113 - A33-07325 A3303347 A33-05113-B - A33- 07325-B A3303347-B	Approved Single kit having FSC of USA. The firm shall apply separately for Double, triple and Quadruple along with form and fee.

		Guangdong, China LOA Validity: 04/11/2027 FSC USA Validity: 02/27/2026 ISO 13485 Validity: 07/23/2026	Shelf Life: 3 Years	
233.	Applicant Name: M/s. K.S. Agencies Address: Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi. (ELI-00382) R&I Dated: 02/26/2025 Fee Challan No.: 6151790319 PKR: 62,000/-	Name of Manufacturer: Haolang Medical USA Corporation. Address: 1100 Bellevue Way NE 8A-533, Bellevue, WA 98004, USA (Manufacturing Site) Haolang Technology (Foshan) Limited Corporation Address: Xinyuan 2nd RD, Jili Industry Park, Nanzhuang, ChanCheng District, Foshan, Guangdong, China LOA Validity: 04/11/2027 FSC USA Validity: 02/26/2026 ISO 13485 Validity: 07/23/2026	Brand Name: UNI-PICCTM Class: D MD group: Single Codes/Sizes: Single, Double, Triple, Quadruple Lumen Catheter with Kit. A20032101-A20343203 Shelf Life: 3 Years	Approved Single kit having FSC of USA. The firm shall apply separately for Double, triple and Quadruple along with form and fee.
234.	Applicant Name: M/s. Hoor Pharma (pvt) Ltd. Address: WH-01-20-A7-A8, Korangi- Creek Industrial Park, Near Pakistan Refinery, Karachi. (ELI-00037) R&I Dated: 18/02/2025	Name of Manufacturer: M/s. M.A Med Alliance SA, Rue de Rive 5, 1260 Nyon, Switzerland. Manufacturing Site: M/s Med Alliance LLC, 4 Jenner, Suite 190, 92618, Irvine, California, USA.	Brand Name: SELUTION SLRTM 018 PTA Balloon Catheter Class: D	Deferred for the clarification regarding the application

	Fee Paid: PKR: 62,000/-			
235.	Applicant Name: M/s. Hoora Pharma (pvt) Ltd. Address: WH-01-20-A7-A8, Korangi-Creek Industrial Park, Near Pakistan Refinery, Karachi. (ELI-00037) R&I Dated: 18/02/2025 Fee Paid: PKR: 62,000/-	Name of Manufacturer: M/s. M.A Med Alliance SA, Rue de Rive 5, 1260 Nyon, Switzerland. Manufacturing Site: M/s Med Alliance LLC, 4 Jenner, Suite 190, 92618, Irvine, California, USA.	Brand Name: SELUTION SLR™ 014 PTA Balloon Catheter Class: D	Deferred for the clarification regarding the application
236.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany	Angio Band Air TR Closure Band Codes and sizes as per FSC Class: A Shelf Life: not Mentioned Fee: 5000	Deferred for the submission of FSC of country of origion
237.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany	VAS Power Balloon Inflation Devices Kit Codes and Sizes as per FSC Class: A Shelf Life: not Mentioned Fee: 5000	Deferred for the submission of FSC of country of origion and CE
238.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH, Havelstr. 16 64295 Darmstadt, Germany	Guard Hemostasis Valve Set Codes and Sizes as per FSC Class: B Shelf Life: 3 Years Fee: 25000	Deferred for the submission of FSC of country of origion and CE
239.	Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi.. (ELI- 00290) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.:	(Legal Manufacturer) Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Manifolds Generic: Models / Sizes: (15587) 500PSI Right “ON” handle 500PSI Right “ON” handle with line 500PSI Right “OFF”	Deferred for the submission of FSC of country of origion and CE

	0973946316		handle 500PSI Right “OFF” handle with line Class-B Shelf life: As per stability studies	
240.	Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi.. (ELI- 00290) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 213944321136	(Legal Manufacturer) Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Hemostatic Valve Sets Generic: Models / Sizes: (17578) HV-02 7Fr Puss/pull HV02 7Fr Push/pull with line HV-01 8Fr Screw HV-01 8Fr Screw with line HV-03 8Fr Push/pull click HV-03 8Fr Push/pull click with line Class-B Shelf life: As per stability studies	Deferred for the submission of FSC of country of origion and CE
241.	Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi.. (ELI- 00290) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 5696653243	(Legal Manufacturer) Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Balloon Inflation Devices Generic: Models / Sizes: (17541) BID-20 20ml, 30bar BID- 25 25ml, 30bar BID-30 30ml, 30ba Class-B Shelf life: 03 Years	Deferred for the submission of FSC of country of origion and CE
242.	Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi.. (ELI- 00290) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 9442858643	(Legal Manufacturer) Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Introducer Sets Generic: Models / Sizes: (10678) IS-04 4FX9CM IS-05 5FX11CM IS-06 65X11CM IS-07 7FX11CM IS-08 8FX11CM IS-09 9FX11CM IS-10 10FX11CM IS-11 11FX11CM IS-14 14FX14CM IS-18 18FX14CM	Deferred for the submission of FSC of country of origion and CE

			Class-B Shelf life: As per stability studies	
243.	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024 Fee 62000/-	Legal Manufacturer: Medcaptain Medical Technology co., ltd. Legal address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA Manufacturing address: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. Building C. Jiale Science and Technology Industrial Park, Matian Street, Guangming, 518106 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA FSC: China Validity: 15-03-2025 LOA Validity: 14-08-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted	SYS-70 (Infusion Pump) FSC Valid till:15-03-2025 Class: C Claimed Shelf Life:10-years	Approved
244.	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024 Fee 62000/-	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building No. 5158 Shahe West Road, Xiii, Nanshan, 51 8055 Shenzhen, Guangdong, PEOPLE's REPUBLIC OF CHINA Medcaptain Medical Technology Co., Ltd.,	Patient Monitor PMS 8310/ Vitavue 12 Patient Monitor 9018.1900 33586 Class: C Claimed Shelf Life:10-years	Deferred for submission of the apostile FSC of country of origion or FSC of RRA or WHO PQ evidence

		Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted		
245.	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024 Fee 62000/-	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building No. 5158 Shahe West Road, Xiii, Nanshan, 51 8055 Shenzhen, Guangdong, PEOPLE's REPUBLIC OF CHINA Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu	Patient Monitor PMS 8300/ Vitavue 10 Patient Monitor 9018.1900 33586 Class: C Claimed Shelf Life:10-years	Deferred for submission of the apostile FSC of country of origion or FSC of RRA or WHO PQ evidence

		Province, PEOPLE'S REPUBLIC OF CHINA FSC not submitted LOA Validity: 16-11s- 2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted		
246.	NI Healthcare Proudcts (Pvt) Ltd., Office No. A, Unit 10, Survey No. 263 Damlotte Road malir, Karachi (ELI-01117 Fee 62000/-	Shenzhen Narig Bio- Medical Technology Co., Ltd., Room 516, Podium Building 12, shenzhen Bay Science and Technology Ecological Park, High-tech community, No.18, Technology South road, Yuehai streest, Nanshan District, Shenzhen City, Guangdong Province, People's Republic of China FSC Valid till: 01-09- 2026 EU Quality management system 3.07.2027 LOA valid till 6 th August 2027 ISO 13485 valid till 3.07.2025	FRO-100 Pulse Oximeter Class: C Claimed Shelf Life:3years	Approved
247.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan- E-Iqbal, Karachi (ELI-00285	<u>Changzhou Kenno</u> <u>Medical Instruments</u> <u>CO.,LTd., No. 2188</u> <u>Longcheng Road, Xinza</u> <u>Street, Zhonglou District,</u> <u>Changzhou 213012,</u> <u>Jiangsu, China</u> LOA valid till 8.01.2030 FSC valid till 09.02.2027	KN I.V Catheter With wings HK10041 (Disposable IV catheter) Class B Shelf life 05 years Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G FSC Valid till: 09-02- 2027	Approved subject to confirmation of brand name

		FSC Spain Issuance date 17.02.2025 (online checked from website given on the copy of FSC on 23.04.2025) ISO 13485 valid till 2027		
248.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-E-Iqbal, Karachi (ELI-00285)	<u>Changzhou Kenno Medical Instruments CO.,LTd., No. 2188 Longcheng Road, Xinza Street, Zhonglou District, Changzhou 213012, Jiangsu, China</u> LOA valid till 8.01.2030 FSC valid till 09.02.2027 FSC Spain Issuance date 17.02.2025 (online checked from website given on the copy of FSC on 23.04.2025) ISO 13485 valid till 2027	KN I.V Catheter Pen Like Disposable IV catheter HK10031 Class B Shelf life 05 years Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G FSC Valid till: 09-02-2027	Approved
249.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-E-Iqbal, Karachi (ELI-00285)	<u>Changzhou Kenno Medical Instruments CO.,LTd., No. 2188 Longcheng Road, Xinza Street, Zhonglou District, Changzhou 213012, Jiangsu, China</u> LOA valid till 8.01.2030 FSC valid till 09.02.2027 FSC Spain Issuance date 17.02.2025 (online checked from website given on the copy of FSC on 23.04.2025) ISO 13485 valid till 2027	KN I.V Catheter Saftey with wings HK10083 Class B Shelf life 05 years Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G FSC Valid till: 09-02-2027	Approved
250.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-E-Iqbal, Karachi (ELI-00285)	<u>Changzhou Kenno Medical Instruments CO.,LTd., No. 2188 Longcheng Road, Xinza Street, Zhonglou District,</u>	KN I.V Catheter with wings & Heparin Cap HK10043 Disposable IV Catheter Class B	Approved

		<u>Changzhou 213012,</u> <u>Jiangsu, China</u>	Shelf life 05 years Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G FSC Valid till: 09-02- 2027	
251.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan- E-Iqbal, Karachi (ELI-00285	<u>Changzhou Kenno</u> <u>Medical Instruments</u> <u>CO.,LTd., No. 2188</u> <u>Longcheng Road, Xinza</u> <u>Street, Zhonglou District,</u> <u>Changzhou 213012,</u> <u>Jiangsu, China</u> FSC Valid till: 09-02- 2027	KN I.V Catheter with wings & Injection Port HK10022 Disposable IV Catheter Class B Shelf life 05 years Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G	Approved
252.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan- E-Iqbal, Karachi (ELI-00285	<u>Changzhou Kenno</u> <u>Medical Instruments</u> <u>CO.,LTd., No. 2188</u> <u>Longcheng Road, Xinza</u> <u>Street, Zhonglou District,</u> <u>Changzhou 213012,</u> <u>Jiangsu, China</u> LOA valid till 8.01.2030 FSC valid till 09.02.2027 FSC Spain Issuance date 17.02.2025 (online checked from website given on the copy of FSC on 23.04.2025 ISO 13485 valid till 2027	KN 3-Way Stopcock Size: Plain, with 15cm Tube Class B Shelf life 05 years FSC valid till: 09-02-2027	Approved
253.	Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan- E-Iqbal, Karachi (ELI-00285	<u>Changzhou Kenno</u> <u>Medical Instruments</u> <u>CO.,LTd., No. 2188</u> <u>Longcheng Road, Xinza</u> <u>Street, Zhonglou District,</u> <u>Changzhou 213012,</u> <u>Jiangsu, China</u> LOA valid till 8.01.2030 FSC valid till 09.02.2027 FSC Spain Issuance date 17.02.2025 (online checked from website given on the copy of FSC on 23.04.2025 ISO 13485 valid till 2027	KN I.V Catheter Safety with wings & Injection Port HK10084 Size: 14G, 16G, 18G, 20G, 22G, 24G, 26G FSC Valid till: 09-02- 2027	Approved

254.	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory LOA valid till 31.12.2027 FSC Japan Issue date 01.01.2025	TOP-5530 Syringe Pump 9018.1900 Class C Shelf life 6 years	Deferred for submission FSC confirming the availability of the product in the market. Notarized and valid LOA & ISO 13485
255.	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju- Nakai-Cho, Adachi-Ku Tokyo 120- 0035, Japan Inside Country of Origin: Top Corporation Koshigaya Factory, 40- 34 Noborito-cho, Koshigaya-shi Saitama, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory FSC issue date: 22-01- 2025	Infusio Pump MJ-210 Class C Shelf life 6 years	Deferred for submission FSC confirming the availability of the product in the market. Notarized and valid LOA & ISO 13485
256.	National Enterprises, office No. 409, 4th Floor, AL-Sehat Center, Shahra-E- Faisal/Rafiquee shaheed Road, Karachi, Pakistan (ELI-0043)	Misonix, Inc, 1938 New Hwy Farmingdale, NY USA 27596 Manufacturing Site: Bioventus LLC 7101 Goodlett Farms Pkwy, Cordova TN, USA 38016 Sterilization Site:	Misonix® Inc Nexus Ultrasonic Surgical Aspirator System Class C Shelf life not claimed	Deferred for submission of the following Evidence of Fee of Rs 100000/- Notarized and valid LOA Apostille valid FSC

		Bioventus LLC 7101 Goodlett Farms Pkwy, Cordova TN USA 38016 LOA valid till 31.12.2025 FSC USFDA Valid Till: 05-05-2026 ISO 13485 09.07.2024 CE certificate 09.07.2023		
257.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e- Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 28831605276 PKR: 62,000/-	Authorized Representative: Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Manufacturer: Covidien Iic. 15 Hampshire Street 02048 Mansfield, Massachusetts USA Manufacturing facilities 1. Covidien Iic. 15 Hampshire Street 02048 Mansfield, Massachusetts USA 2. Plexus Corp. 2400 Millbrook Dr. Buffalo Grove, IL 60089 USA 3. Viant AS&O Holdings, LLC a.t.a. (formerly Lake Region Medical) 45 Lexington Dr Laconia, NH 03246 USA 4. DAS Medical International, SRL Industrial Free Zone II 22000 La Romana Dominican Republic 5. Covidien (Davis & Geck Caribe, Ltd.) Zona Franca de San Isidro Carretera San Isidro Km 17 Santa Domingo, Dominican Republic. 6. Covidien 60 Middletown Ave	Hugo™ Robotically Assisted Surgery (RAS) System Generic Name: Robotic Surgery system Class: C Shelf Life: N/A Codes/ Sizes: Hugo™ RAS Surgeon Console MRASC0001, Hugo™ RAS Tower (120VAC) MRASC0003, Hugo™ RAS Tower (240VAC) MRASC0005, Hugo™ RAS Arm Cart Assembly MRASC0002.	Approved subject to submission of the differential fee of RS 38000/- as system is applied

		North Haven, CT 06473 USA LOA: Issuance Date: 15-01-2025 Validity Date: N/A (Original, notarized attached) FSC: Netherlands Validity: 11-12-2025 EC Certificate: Validity: 06-10-2026 (Original, Valid and Notarized attached) ISO13485 (Original, Valid and Notarized attached) ISO for Covidien Inc. & Covidien LLC 60 Middletown Ave., USA Effective date: 12-12-2022 Expiry date: 11-12-2025 Effective date: 06-03-2024 Expiry date: 11-12-2025 ISO for Plexus Corp, USA Effective date: 01-09-2022 Expiry date: 31-08-2025 ISO for Viant AS&O Holdings, USA Effective date: 30-09-2024 Expiry date: 29-09-2027 ISO for DAS Medical International Effective date: 07-09-2023 Expiry date: 04-04-2026		
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		ISO for Covidien (Davis & Geck Carible, Ltd.) Effective date: 05-12-2024 Expiry date: 04-12-2027		
258.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 687631807164 PKR: 62,000/-	Authorized Representative: Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Manufacturer: Covidien IIC. 15 Hampshire Street 02048 Mansfield, Massachusetts USA Manufacturing facilities 1. Covidien IIC. 15 Hampshire Street 02048 Mansfield, Massachusetts USA 2. Plexus Corp. 2400 Millbrook Dr. Buffalo Grove, IL 60089 USA 3. Viant AS&O Holdings, LLC a.t.a. (formerly Lake Region Medical) 45 Lexington Dr Laconia, NH 03246 USA 4. DAS Medical International, SRL Industrial Free Zone II 22000 La Romana Dominican Republic 5. Covidien (Davis & Geck Caribe, Ltd.) Zona Franca de San	Hugo™ RAS Wristed Instruments (Electrosurgical) Generic Name: Robotic Surgery system Class: C Shelf Life: No Shelf Life for Wristed Active Instruments. Shelf life 3 Years for monopolar Tip cover Codes/ Sizes: Monopolar Curved Shears MRASI0001, Bipolar Fenestrated Grasper MRASI0004, Bipolar Maryland Forceps MRASI0005, Monopolar Tip Cover MRASA0009.	Approved subject to submission of the differential fee of RS 38000/- as system is applied

		Isidro Carretera San Isidro Km 17 Santa Domingo, Dominican Republic. 6. Covidien 60 Middletown Ave North Haven, CT 06473 USA LOA: Issuance Date: 15-01- 2025 Validity Date: N/A Original, notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025 FSC: Netherlands Validity: 11-12-2025 EC Certificate: Validity: 06-10-2026 (Original, Valid and Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01- 2025) ISO13485 (Original, Valid and Notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01- 2025) ISO for Covidien Ilc. & Covidien LLC 60 Middletown Ave., USA Effective date: 12-12- 2022		
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		Expiry date: 11-12-2025 Effective date: 06-03-2024 Expiry date: 11-12-2025 ISO for Plexus Corp, USA Effective date: 01-09-2022 Expiry date: 31-08-2025 ISO for Viant AS&O Holdings, USA Effective date: 30-09-2024 Expiry date: 29-09-2027 ISO for DAS Medical International Effective date: 07-09-2023 Expiry date: 04-04-2026 ISO for Covidien (Davis & Geck Carible, Ltd.) Effective date: 05-12-2024 Expiry date: 04-12-2027		
259.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 24-05-2024 Fee Challan No.: 585397464 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites i. Medtronic Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-	CSF VALVES AND BUTTONS Generic Name: Pressure Control Valves Class: C Shelf Life: 5 Years Codes/ Sizes: 24003 L Button Valve, Low Pressure With Integral Inlet Silicone Tubing, 2.5cm, 24003 LL Button Valve, Low-Low Pressure With Integral Inlet Silicone Tubing, 2.5cm, 24003 M Button Valve,	Approved subject to submission of the differential fee of RS 38000/- For the following 24003 L Button Valve, Low Pressure With Integral Inlet Silicone Tubing, 2.5cm, 24003 LL Button Valve, Low-Low Pressure With Integral Inlet Silicone Tubing, 2.5cm, 24003 M Button Valve, Medium Pressure With Integral Inlet Silicone Tubing, 2.5cm,

		2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	Medium Pressure With Integral Inlet Silicone Tubing, 2.5cm, 92326 CSF-Flow Control Valve With Bioglide, Contoured Regular, High Pressure, 92322 CSF-Flow Control Valve With Bioglide, Contoured Regular, Low Pressure, 92324 CSF-Flow Control Valve With Bioglide, contoured Regular, Medium Pressure, 92316 CSF-Flow Control Valve With Bioglide, Contoured Small, High Pressure, 92312 CSF-Flow Control Valve With Bioglide, Contoured Small, Low Pressure, 92314 CSF- Flow Control valve With Bioglide, Contoured Small, Medium Pressure, 42536 CSF-Flow Control Valve, Burr Hole, 12 mm, High Pressure, 42532 CSF-Flow Control Valve, Burr Hole, 12 mm, Low Pressure, 42534 CSF-Flow Control Valve, Burr Hole, 12 mm Medium Pressure, 42546 CSF-Flow Control Valve, Burr Hole, 16 mm, High Pressure, 42542 CSF-Flow Control Valve, Burr Hole, 16mm, Low Pressure,	The firm may apply separately for the other codes or justify as per MDR 2017
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			42544 CSF-Flow Control Valve, Burr Hole, 16 mm, Medium Pressure, 42326 CSF-Flow Control Valve, Contoured Regular, High Pressure, 42322 CSF-Flow Control Valve, Contoured Regular, Low Pressure, 23093 CSF-Flow Control Valve, Contoured Regular, Low-Low Pressure, 42324 CSF-Flow Control Valve, Contoured Regular, Medium Pressure, 27102 CSF-Flow Control Valve, Contoured Small 42312 CSF-Flow Control Valve, Contoured Small, Low Pressure, 42314 CSF-Flow Control Valve, Contoured Small, Medium Pressure, 42316 CSF-Flow Control Valve, Contoured Small, High Pressure, 42414 CSF-Ultra Small Valve Medium Pressure, 42410 CSF-Ultra Small Valve, Low-Low Pressure, 42412 CSF-Ultra Small Valve, Low Pressure.	
260.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton,	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432	PERITONEAL CATHETERS Generic Name: Catheters	Approved subject to submission of the differential fee of RS 38000/- all codes except the given below for which

Karachi. (ELI-00273) R&I Dated: 24-05-2024 Fee Challan No.: 1752721008 PKR: 62000/-	Manufacturing sites i. Medtronic Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	Class: C Shelf Life: 5 years with exception of CFN mentioned below: 4 years 10 months – (93522 PERITONEAL CATHETER WITH BIOGLIDE® STANDARD, BARIUM STRIPE, OPEN ENDED WITH WALL SLITS, 90 CM) Annexure Attached in form 7A. Codes/ Sizes: 23047 CARDIAC/PERITONEAL STANDARD, OPEN END, BARIUM IMPREGNATED, 120 CM 93522 PERITONEAL CATHETER WITH BIOGLIDE® STANDARD, BARIUM STRIPE, OPEN ENDED WITH WALL SLITS, 90 CM 43551 PERITONEAL CATHETER, OPEN ENDED WITH WALL SLITS, STANDARD, PLIANT, BARIUM IMPREGNATED, 90 CM 25024 PERITONEAL CATHETER, OPEN ENDED WITH WALL SLITS, 90CM 21004 PERITONEAL CATHETER, OPEN ENDED WITH WALL SLITS, SMALL, BARIUM IMPREGNATED 90CM	The firm may apply separately for the 23047 CARDIAC/PERITONEAL STANDARD, OPEN END, BARIUM IMPREGNATED, 120 CM or justify as per MDR 2017
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			43555 PERITONEAL CATHETER, SMALL LUMEN, 120 CM 22013 PERITONEAL CATHETER, SMALL, OPEN ENDED, BARIUM IMPREGNATED, 90 CM 22014 PERITONEAL CATHETER, STANDARD, BARIUM IMPREGNATED, 96 CM 43522 PERITONEAL CATHETER, STANDARD, OPEN END WITH WALL SLITS, BARIUM IMPREGNATED 90 CM 23092 PERITONEAL CATHETER, STANDARD, OPEN END, BARIUM IMPREGNATED, 120CM	
261.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 24-05-2024 Fee Challan No.: 869343617 PKR: 62000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites i. Medtronic Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137	DELTA SHUNT ASSEMBLY & VALVES Generic Name: Shunt Assemblies and Valves Class: C Shelf Life: Attached as Annexure IV in Form 7A Codes/ Sizes: 27499-5 DELTA SNAP SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5 46833 DELTA® SNAP SHUNT ASSEMBLY, NEONATAL,	Approved subject to submission of the differential fee of RS 38000/- Codes/ Sizes: 27499-5 DELTA SNAP SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5 46833 DELTA® SNAP SHUNT ASSEMBLY, NEONATAL, PERFORMANCE LEVEL 1.5 46834 DELTA® SNAP SHUNT ASSEMBLY, NEONATAL,

		LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	PERFORMANCE LEVEL 1.5 46834 DELTA® SNAP SHUNT ASSEMBLY, NEONATAL, PERFORMANCE LEVEL 2.0 42830 DELTA® BURR HOLE VALVE, 12 MM, PERFORMANCE LEVEL 0.5 42832 DELTA® BURR HOLE VALVE, 12 MM, PERFORMANCE LEVEL 1.0 42833 DELTA® BURR HOLE VALVE, 12 MM, PERFORMANCE LEVEL 1.5 42843 DELTA® BURR HOLE VALVE, 16 MM, PERFORMANCE LEVEL 1.5 42840 DELTA® BURR HOLE VALVE, 16 MM, PERFORMANCE LEVEL 0.5 42842 DELTA® BURR HOLE VALVE, 16 MM, PERFORMANCE LEVEL 1.0 24053 DELTA® CHAMBER WITH INTEGRAL STANDARD INLET TUBING 96824 DELTA® SHUNT ASSEMBLY WITH BIOGLIDE®, REGULAR, PERFORMANCE LEVEL 2.0	PERFORMANCE LEVEL 2.0 And stability studies . The firm may apply separately for the other code or justify as per MDR 2017
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			96822 DELTA® SHUNT ASSEMBLY WITH BIOGLIDE®, REGULAR, PERFORMANCE LEVEL 1.0 96812 DELTA® SHUNT ASSEMBLY WITH BIOGLIDE®, SMALL, PERFORMANCE LEVEL 1.0 96813 DELTA® SHUNT ASSEMBLY WITH BIOGLIDE®, SMALL, PERFORMANCE LEVEL 1.5 96814 DELTA® SHUNT ASSEMBLY WITH BIOGLIDE®, SMALL, PERFORMANCE LEVEL 2 26026-5 DELTA® SHUNT ASSEMBLY, NEONATAL, PERFORMANCE LEVEL 1.5 WITH INTEGRAL VENTRICULOSTOMY RESERVOIR 46822 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.0 46823 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.5 46824 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 2.0	
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			24039-1 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.0 24039-5 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.5 24039-2 DELTA® SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 2.0 46812 DELTA® SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.0 46813 DELTA® SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5 96823 DELTA® SHUNT ASSEMBLY, WITH BIOGLIDE, REGULAR, PERFORMANCE LEVEL 1.5 46814 DELTA® SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 2.0 46832 DELTA® SNAP SHUNT ASSEMBLY, NEONATAL, PERFORMANCE LEVEL 1.0 25121-1 DELTA® SNAP SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.0 27499-1 DELTA® SNAP SHUNT ASSEMBLY, SMALL,	
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			PERFORMANCE LEVEL 1.0 25121-5 DELTA® SNAP SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5 25121-2 DELTA® SNAP SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 2.0 24027-1 DELTA® UNITIZED SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.0 24027-5 DELTA® UNITIZED SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5 24027-2 DELTA® UNITIZED SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 2.0 SNAP ASSEMBLY SMALL 27219-1 DELTA® VALVE NEONATAL, PERFORMANCE LEVEL 1.0 27219-2 DELTA® VALVE NEONATAL, PERFORMANCE LEVEL 2.0 27219-5 DELTA® VALVE NEONATAL, PERFORMANCE LEVEL 1.5 92814 DELTA® VALVE WITH BIOGLIDE® SMALL, PERFORMANCE	
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			LEVEL 2.0 92813 DELTA® VALVE WITH BIOGLIDE®, SMALL, PERFORMANCE LEVEL 1.5 92822 DELTA® VALVE WITH BIOGLIDE®, REGULAR, PERFORMANCE LEVEL 1.0 92812 DELTA® VALVE WITH BIOGLIDE®, SMALL, PERFORMANCE LEVEL 1.0 92823 DELTA® VALVE WITH BIOGLIDE®, REGULAR, PERFORMANCE LEVEL 1.5 92824 DELTA® VALVE WITH BIOGLIDE®, REGULAR, PERFORMANCE LEVEL 2.0 42822 DELTA® VALVE, REGULAR PERFORMANCE LEVEL 1.0 24048 DELTA® VALVE, REGULAR, PERFORMANCE LEVEL 0.5 42823 DELTA® VALVE, REGULAR, PERFORMANCE LEVEL 1.5 42824 DELTA® VALVE, REGULAR, PERFORMANCE LEVEL 2.0 24147 DELTA®	
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			VALVE, SMALL, PERFORMANCE LEVEL 0.5 42812 DELTA® VALVE, SMALL, PERFORMANCE LEVEL 1.0 42813 DELTA® VALVE, SMALL, PERFORMANCE LEVEL 1.5 42814 DELTA® VALVE, SMALL, PERFORMANCE LEVEL 2.0 24028-5 DELTA®, SNAP SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.5 24028-2 DELTA®, SNAP SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 2.0 24028-1 DELTA®, SNAP SHUNT ASSEMBLY, REGULAR. PERFORMANCE LEVEL 1.0	
262.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e- Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 24-05-2024 Fee Challan No.:	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites i. Medtronic Covidien Zona Franca De San Isidro Carretera San Isidro Km 17-Santo	STRATA SHUNT ASSEMBLY & VALVES Generic Name: Shunt Assemblies and Valves Class: C Shelf Life: Attached as Annexure IV inform 7A	Approved subject to submission of the differential fee of RS 38000/- Codes/ Sizes: 27815 STRATA® II SHUNT ASSEMBLY, REGULAR 27814 STRATA® II SHUNT ASSEMBLY, SMALL

40664983508 PKR: 62,000/-		Domingo Dominican Republic, ii. Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	Codes/ Sizes: 46837 STRATA® BURR HOLE SHUNT ASSEMBLY 46636 STRATA® NSC BURR HOLE SHUNT ASSEMBLY 42836 STRATA® BURR HOLE VALVE 27815 STRATA® II SHUNT ASSEMBLY, REGULAR 27819 STRATA® II SHUNT ASSEMBLY, REGULAR, WITH BIOGLIDE® 27814 STRATA® II SHUNT ASSEMBLY, SMALL 46856 STRATA® II SHUNT ASSEMBLY, SMALL WITH PERITONEAL CATHETER, OPEN END WITH WALL SLITS, 120 CM 27818 STRATA® II SHUNT ASSEMBLY, SMALL, WITH BIOGLIDE® 27817 STRATA® II SNAP SHUNT ASSEMBLY, REGULAR 27823 STRATA® II SNAP SHUNT ASSEMBLY, REGULAR, WITH BIOGLIDE 27816 STRATA® II SNAP SHUNT ASSEMBLY, SMALL	And stability studies . The firm may apply separately for the other code or justify as per MDR 2017
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			27822 STRATA® II SNAP SHUNT ASSEMBLY, SMALL, WITH BIOGLIDE® 42866 STRATA® II VALVE, REGULAR 46866 STRATA® II VALVE, REGULAR 27827 STRATA® II VALVE, REGULAR EXTRACTED 92866 STRATA® II VALVE, REGULAR, WITH BIOGLIDE® 42856 STRATA® II VALVE, SMALL 27812 STRATA® II VALVE, SMALL, EXTRACTED 92856 STRATA® II VALVE, SMALL, WITH BIOGLIDE® 42335 STRATA® NSC BURR HOLE VALVE 44465 STRATA® NSC LUMBOPERITONEAL VALVE 27740 STRATA® NSC SHUNT ASSEMBLY, REGULAR 96665 STRATA® NSC SHUNT ASSEMBLY, REGULAR WITH BIOGLIDE® 46665 STRATA® NSC SHUNT ASSEMBLY, REGULAR WITH PERITONEAL CATHETER, 120 CM 46655 STRATA® NSC SHUNT ASSEMBLY,	
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			SMALL WITH PERITONEAL CATHETER, 120 CM 96655 STRATA® NSC SHUNT ASSEMBLY, SMALL, WITH BIOGLIDE® 27739 STRATA® NSC SNAP SHUNT ASSEMBLY, SMALL 42365 STRATA® NSC VALVE, REGULAR 92365 STRATA® NSC VALVE, REGULAR WITH BIOGLIDE® 42355 STRATA® NSC VALVE, SMALL 92355 STRATA® NSC VALVE, SMALL WITH BIOGLIDE®	
263.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 19-02-2025 Fee Challan No.: 9237739834 PKR: 62,000/-	Legal Manufacturer M/s Covidien llc 15 Hampshire Street Mansfield, MA, USA 02048 Manufacturing sites i. M/s Plexus Corp. 2400 Millbrook Dr Buffalo Grove, IL USA 60089 ii. M/s Covidien Ilc 15 Hampshire Street Mansfield, MA USA 02048 iii. M/s Freudenberg Medical, LLC 2301 Centennial Blvd Jeffersonville, IN USA 47130 LOA: Effective Date: 15-01-2025 Validity: N/A	Beacon™ Fine Needle Fiducial System Generic Name: Endoscopic Ultrasound System Class: C Shelf Life: 25 Months Codes/ Sizes: DSF-19-01 - Beacon™ Fine Needle Fiducial System, DSF-22-01 - Beacon™ Fine Needle Fiducial System.	Approved subject to submission of the differential fee of RS 38000/- DSF-19-01 - Beacon™ Fine Needle Fiducial System, The firm may apply separately for the other code or justify as per MDR 2017 or submit additional fee of RS 100000/-

		Original, notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025 FSC: US FDA Issuance date: 21-06-2024 Validity: 20-06-2026 (Original, Valid & Legalized attached) EC Certificate: Validity: 25-05-2024 (Original attached with FQA Certificate validity extension letter attached) ISO13485 Site I: Validity: 31-08-2025 Site II: Validity: 10-11-2027 Site III: Validity: 19-09-2025 (Original, Valid & Notarized ISO Certificate attached)		
264.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 19-02-2025 Fee Challan No.: 07662927 PKR: 62,000/-	Legal Manufacturer M/s Covidien llc 15 Hampshire Street Mansfield, MA, USA 02048 Manufacturing sites i. M/s Plexus Corp. 2400 Millbrook Dr Buffalo Grove, IL USA 60089 ii. M/s Covidien Ilc 15 Hampshire Street Mansfield, MA USA 02048 iii. M/s Freudenberg Medical, LLC 2301 Centennial Blvd	Beacon™ Fine Needle Fiducial Needle Generic Namdeltae: Endotherapy needle Class: C Shelf Life: 25 Months Codes/ Sizes: F-19-05 - Beacon™ Fine Needle Fiducial Needle, F-22-05 - Beacon™ Fine Needle Fiducial Needle.	Approved subject to submission of the differential fee of RS 38000/- Codes/ Sizes: F-19-05 - Beacon™ Fine Needle Fiducial Needle, The form may be advised to apply separately for the other code or submit additional fee of RS 100000/-

		Jeffersonville, IN USA 47130 LOA: Effective Date: 15-01-2025 Validity: N/A Original, notarized attached with registration application of Hugo™ Robotically Assisted Surgery (RAS) System dated 22-01-2025 FSC: US FDA Issuance date: 21-06-2024 Validity: 20-06-2026 (Original, Valid & Legalized attached with registration application of Beacon Fine Needle Fiducial System Dated 06-02-2025) EC Certificate: Validity: 25-05-2024 (Original attached with FQA Certificate validity extension letter attached with Registration Application of Beacon Fine Needle Fiducial System dated 06-02-2025) ISO13485 Site I: Validity: 31-08-2025 Site II: Validity: 10-11-2027 Site III: Validity: 19-09-2025 (Original, Valid & Notarized ISO Certificate attached with Registration Application of Beacon Fine Needle		
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		Fiducial System dated 06-02-2025)		
265.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 36667026114 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro, Carretera San Isidro, Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery, 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized	STRATA NSC LP SHUNT Generic Name: Shunt Class: D Shelf Life: 5 Years Codes/ Sizes: 44420 STRATA® NSC LUMBOPERITONEAL SHUNT KIT, CLOSED TIP 44421 STRATA® NSC LUMBOPERITONEAL SHUNT KIT, OPEN TIP 44430 STRATA® NSC LUMBOPERITONEAL SHUNT KIT, WITH INTEGRAL PERITONEAL CATHETER	Approved subject to submission of the differential fee of RS 38000/- Codes/ Sizes: 44420 STRATA® NSC LUMBOPERITONEAL SHUNT KIT, CLOSED TIP 44421 STRATA® NSC LUMBOPERITONEAL SHUNT KIT, OPEN TIP The firm may apply separately for the other code or justify as per MDR 2017 or submit additional fee of RS 62000/-

		with validity extension letter attached with registration application of Ventriculostomy Kit dated 31 st January 2025) ISO13485 Validity: 19-08-2024		
266.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 196736124 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and	EXTERNAL DRAINAGE AND MONITORING CATHETERS Generic Name: Catheters Class: D Shelf Life: 5 years except the CFNs mentioned below: 4 years 10 months (96115 EDM, VENTRICULAR CATHETER, BIOGLIDE®, 20 CM. 96118 EDM, VENTRICULAR CATHETER, BIOGLIDE®, 35 CM, WITH TROCAR. 27705 EDM, VENTRICULAR CATHETER, BIOGLIDE®, NUMBERED LENGTH MARKERS, 35 CM, WITH TROCAR.) Attached as Annexure IV in Form 7A Codes/ Sizes: 27156 BECKER, EDMS, FIXATION COLLAR, VENTRICULAR CATHETER, 20 CM 26057 EDM	Approved subject to submission of the differential fee of RS 38000/- and stability studies 26057 EDM VENTRICULAR CATHETER 23 CM, WITH TROCAR 27384 EDM, VENTRICULAR CATHETER, 20 CM, WITH TROCAR The firm may apply separately for the other code or justify as per MDR 2017

		Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	VENTRICULAR CATHETER 23 CM, WITH TROCAR 27384 EDM, VENTRICULAR CATHETER, 20 CM, WITH TROCAR 27695 EDM, VENTRICULAR CATHETER, BARLUM STRIPE, 35 CM, WITH TROCAR 96115 EDM, VENTRICULAR CATHETER, BIOGLIDE®, 20 CM 96118 EDM, VENTRICULAR CATHETER, BIOGLIDE®, 35 CM, WITH TROCAR 27705 EDM, VENTRICULAR CATHETER, BIOGLIDE®, NUMBERED LENGTH MARKERS, 35 CM, WITH TROCAR 27637 EDM, VENTRICULAR CATHETER, LARGE, TRANSLUCENT, WITH TROCAR 27842 EDMS VENTRICULAR CATHETER, 28CM 46115 BECKER® EDMS VENTRICULAR CATHETER, 20 CM, BARIUM IMPREGNATED 46118 EDM VENTRICULAR	
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			CATHETER, BARIUM IMPREGNATED, 35CM 46418 EDM LUMBAR CATHETER, BARIUM IMPREGNATED 46419 EDM LUMBAR CATHETER, 80 CM, CLOSED TIP, BARIUM IMPREGNATED 46420 EDM LUMBAR CATHETER, 80CM, OPEN TIP, BARIUM IMPREGNATED	
267.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 1796455752 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA	VENTRICULAR CATHETERS Generic Name: Catheters Class: D Shelf Life: 5 Years with the exception of CFN mentioned below: 4 years 10 months - (91503 VENTRICULAR CATHETER WITH BIOGLIDE®, STANDARD, BARIUM STRIPLE, 23 CM) Attached as Annexure IV in Form 7A Codes/ Sizes: 41407 CSF SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 7 CM. 41408 CSF SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 8 CM. 41409 CSF SNAP	Approved subject to submission of the differential fee of RS 38000/- and stability studies 9025 VENTRICULAR CATHETER WITH EXTRA LENGTH MARKS, 23 CM. 24154 VENTRICULAR CATHETER, 23 CM. 27211 VENTRICULAR CATHETER, LARGE, SLOTTED, 15 CM. 5005 H VENTRICULAR CATHETER, RIGHT ANGLE, 10 CM. 5005 C VENTRICULAR CATHETER, RIGHT ANGLE, 11 CM. 5005 F VENTRICULAR

		Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 9 CM. 24004 B SNAP SHUNT VENTRICULAR CATHETER, BARIUM IMPREGNATED, STANDARD, 3 CM. 41404 SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED 4CM. 22082 F SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 10 CM. 22082 G SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 11 CM. 41405 SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 5 CM. 22082 I SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 5.5 CM. 41406 SNAP SHUNT VENTRICULAR CATHETER, STANDARD, BARIUM IMPREGNATED, 6 CM. 22082 H SNAP SHUNT VENTRICULAR CATHETER,	CATHETER, RIGHT ANGLE, 4 CM. 5005 E VENTRICULAR CATHETER, RIGHT ANGLE, 5 CM. 5005 G VENTRICULAR CATHETER, RIGHT ANGLE, 6 CM. 5005 A VENTRICULAR CATHETER, RIGHT ANGLE, 7 CM. 5005 I VENTRICULAR CATHETER, RIGHT ANGLE, 8 CM. 5005 B VENTRICULAR CATHETER, RIGHT ANGLE, 9 CM. The firm may apply separately for the other code or justify as per MDR 2017
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			STANDARD, BARIUM IMPREGNATED, 6.5 CM. 91503 VENTRICULAR CATHETER WITH BIOGLIDE®, STANDARD, BARIUM STRIPLE, 23 CM. 9025 VENTRICULAR CATHETER WITH EXTRA LENGTH MARKS, 23 CM. 24094 VENTRICULAR CATHETER WITH SNAP ASSEMBLY VENTRICULOSTOMY RESERVOIR BASE. 24154 VENTRICULAR CATHETER, 23 CM. 27211 VENTRICULAR CATHETER, LARGE, SLOTTED, 15 CM. 5005 H VENTRICULAR CATHETER, RIGHT ANGLE, 10 CM. 5005 C VENTRICULAR CATHETER, RIGHT ANGLE, 11 CM. 5005 F VENTRICULAR CATHETER, RIGHT ANGLE, 4 CM. 5005 E VENTRICULAR CATHETER, RIGHT ANGLE, 5 CM. 5005 G VENTRICULAR CATHETER, RIGHT ANGLE, 6 CM. 5005 A VENTRICULAR CATHETER, RIGHT ANGLE, 7 CM. 5005 I VENTRICULAR	
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			CATHETER, RIGHT ANGLE, 8 CM. 5005 B VENTRICULAR CATHETER, RIGHT ANGLE, 9 CM. 27607 A VENTRICULAR CATHETER, RIGHT ANGLE, INTRACRANIAL LENGTH: 4 CM. 27607 B VENTRICULAR CATHETER, RIGHT ANGLE, INTRACRANIAL LENGTH: 5 CM. 27607 C VENTRICULAR CATHETER, RIGHT ANGLE, INTRACRANIAL LENGTH: 6 CM. 27607 D VENTRICULAR CATHETER, RIGHT ANGLE, INTRACRANIAL LENGTH: 7 CM. 27251 VENTRICULAR CATHETER, SMALL, 23 CM WITH 8 MM OF FLOW HOLES. 41207 VENTRICULAR CATHETER, SMALL, BARIUM IMPREGNATED 41308 VENTRICULAR CATHETER, SMALL, FLANGED, BARIUM IMPREGNATED, 23 CM. 41101 VENTRICULAR CATHETER,	
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			STANDARD, BARIUM IMPREGNATED, 23 CM 41103 VENTRICULAR CATHETER, STANDARD, PLIANT, BARIUM IMPREGNATED, 15 CM 41115 VENTRICULAR CATHETER, STANDARD, TRANSLUCENT, 23 CM.	
268.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 5954217764 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024	INNERVISION CATHETER Generic Name: Catheters Class: D Shelf Life: 5 Years with exception of below mentioned CFNs: 4 years 10 months – (99102 INNERVISION VENTRICULAR CATHETER WITH BIOGLIDE®, 15 CM) 2 years – (27600 INNERVISION VENTRICULAR CATHETER, SLOTTED, 15 CM) Attached as Annexure IV in Form 7A Codes/ Sizes: 27065 G INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 10 CM 27065 H INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 11 CM 27065 A INNERVISION SNAP SHUNT	Approved subject to submission of the differential fee of RS 38000/- and stability studies 27065 G INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 10 CM 27065 H INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 11 CM 27065 A INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 4 CM 27065 B INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 5 CM 27065 C INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 6 CM 27065 D

		Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	VENTRICULAR CATHETER, 4 CM 27065 B INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 5 CM 27065 C INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 6 CM 27065 D INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 7 CM 27065 E INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 8 CM 27065 F INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 9 CM 99102 INNERVISION VENTRICULAR CATHETER WITH BIOGLIDE®, 15 CM 27298 INNERVISION VENTRICULAR CATHETER WITH SNAP RESERVOIR BASE, 15 CM 27240 INNERVISION VENTRICULAR CATHETER, BARIUM IMPREGNATED, 15 CM 27165 INNERVISION VENTRICULAR CATHETER, LARGE DIAMETER, 15 CM 27600 INNERVISION VENTRICULAR CATHETER, SLOTTED, 15 CM	INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 7 CM 27065 E INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 8 CM 27065 F INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 9 CM 27165 INNERVISION VENTRICULAR CATHETER, LARGE DIAMETER, 15 CM 27600 INNERVISION VENTRICULAR CATHETER, SLOTTED, 15 CM 27065 K INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 5.5CM 27065 L INNERVISION SNAP SHUNT VENTRICULAR CATHETER, 6.5CM The firm may apply separately for the other code or justify as per MDR 2017
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			27588 INNVERVISION ENDOSCOPIC SHUNT PLACEMENT KIT WITH SLOTTED VENTRICULAR CATHETER, LARGE 27065 K INNVERVISION SNAP SHUNT VENTRICULAR CATHETER, 5.5CM 27065 L INNVERVISION SNAP SHUNT VENTRICULAR CATHETER, 6.5CM	
269.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e- Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 866365356463 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10- 2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA	OPUS VENTRICULAR CATHETERS Generic Name: Catheters Class: D Shelf Life: 5 Years Codes/ Sizes: 41501 OPUS® VENTRICULAR CATHETER, SMALL 41503 OPUS® VENTRICULAR CATHETER, STANDARD	Approved subject to submission of the differential fee of RS 38000/-

		Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024		
270.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 37242675068 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A	RIVULET VENTRICULAR CATHETERS Generic Name: Catheters Class: D Shelf Life: 2 Years Codes/ Sizes: 41701 RIVULET™ VENTRICULAR CATHETER, 15 CM	Approved

		(Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024		
271.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 994832517052 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North	CARDIAC/PERITONEAL CATHETERS Generic Name: Catheters Class: D Shelf Life: 5 Years Codes/ Sizes: 43418 CARDIAC CATHETER, REDUCED TIP, BARIUM IMPREGNATED, 58 CM 24148 CARDIAC/PERITONEAL CATHETER	Approved subject to submission of the differential fee of RS 38000/- and stability studies 9007 H CARDIAC/PERITONEAL CATHETER, 90 CM, CLOSING PRESSURE: HIGH 9007 L CARDIAC/PERITONEAL CATHETER, 90 CM, CLOSING PRESSURE: LOW

		Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	9007 H CARDIAC/PERITONEA L CATHETER, 90 CM, CLOSING PRESSURE: HIGH 9007 L CARDIAC/PERITONEA L CATHETER, 90 CM, CLOSING PRESSURE: LOW 9007 M CARDIAC/PERITONEA L CATHETER, 90 CM, CLOSING PRESSURE: MEDIUM 25104 CARDIAC/PERITONEA L CATHETER, CLOSED ENDED, 90CM 22002 H CARDIAC/PERITONEA L CATHETER, SMALL PLIANT, BARIUM IMPREGNATED, 75 CM, CLOSING PRESSURE: HIGH 22002 M CARDIAC/PERITONEA L CATHETER, SMALL PLIANT, BARIUM IMPREGNATED, 75 CM, CLOSING PRESSURE: MEDIUM 22002 L CARDIAC/PERITONEA L CATHETER, SMALL PLIANT, BARIUM IMPRENATED, 75 CM, CLOSING PRESSURE: LOW 43209 CARDIAC/PERITONEA L CATHETER, SMALL,	9007 M CARDIAC/PERITONEAL CATHETER, 90 CM, CLOSING PRESSURE: MEDIUM The firm may apply separately for the other code or justify under the MDR 2017
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			BARIUM IMPREGNATED, 90 CM 24010 CARDIAC/PERITONEAL CATHETER, STANDARD, BARIUM IMPREGNATED, 120 CM WITH BARIUM STRIP 43103 CARDIAC/PERITONEAL CATHETER, STANDARD, BARIUM IMPREGNATED, 90 CM 43111 CARDIAC/PERITONEAL CATHETER, STANDARD, TRANSLUCENT, 90 CM	
272.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 11000195 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming	SHUNT KITS Generic Name: Shunts Class: D Shelf Life: 5 years Codes/ Sizes: 22011 L CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, LOW PRESSURE 22011 LL CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, LOW-LOW PRESSURE 22011 M CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, MEDIUM PRESSURE 46220 CSF-SHUNT KIT, ULTRA SMALL, LOW-LOW PRESSURE 46222 CSF--SHUNT KIT, ULTRA SMALL,	Approved subject to submission of the differential fee of RS 38000/- and stability studies Codes/ Sizes: 22011 L CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, LOW PRESSURE 22011 LL CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, LOW-LOW PRESSURE 22011 M CSF-FLOW CONTROL SHUNT KIT, ULTRA SMALL, MEDIUM PRESSURE The firm may apply separately for the other code or justify under the MDR 2017

		submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	LOW PRESSURE 46224 CSF-SHUNT KIT, ULTRA SMALL, MEDIUM PRESSURE 46242 CSF-SHUNT KIT, UNITIZED, ULTRA SMALL, LOW PRESSURE 46244 CSF-SHUNT KIT, ULTRA SMALL, MEDIUM PRESSURE 9003 A CSF-FLOW CONTROL SHUNT KIT, CONTOURED SMALL, LOW PRESSURE 9003 B CSF-FLOW CONTROL SHUNT KIT, CONTOURED SMALL, MEDIUM PRESSURE 9003 C CSF-FLOW CONTROL SHUNT KIT, CONTOURED SMALL, HIGH PRESSURE 9003 D CSF-FLOW CONTROL SHUNT KIT, CONTOURED REGULAR, LOW PRESSURE 9003 E CSF-FLOW CONTROL SHUNT KIT, CONTOURED REGULAR, MEDIUM PRESSURE 9003 F CSF-FLOW CONTROL SHUNT KIT, CONTOURED REG, HIGH PRESSURE 9040 A CSF-FLOW CONTROL SHUNT KIT BURR HOLE, 12MM, LOW PRESSURE 9040 B CSF-FLOW	
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			CONTROL SHUNT KIT BURR HOLE, 12MM, MEDIUM PRESSURE 9040 C CSF-FLOW CONTROL SHUNT KIT BURR HOLE, 12MM, HIGH PRESSURE 9040 D CSF-FLOW CONTROL SHUNT KIT BURR HOLE, 16MM, LOW PRESSURE 9040 E CSF-FLOW CONTROL SHUNT KIT BURR HOLE, 16MM, MEDIUM PRESSURE 9040 F CSF-FLOW CONTROL SHUNT KIT BURR HOLE, 16MM, HIGH PRESSURE	
273.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 59720289622 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming	DELTA SHUNT KITS Generic Name: Shunts Class: D Shelf Life: 5 Years Codes/ Sizes: 25132-1 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 1.0 25132-5 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 1.5 25132-2 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 1.5 25132-2 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 2.0 25131-1 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 2.0 25131-1 DELTA® SHUNT KIT, SMALL, PERFORMANCE	Approved subject to submission of the differential fee of RS 38000/- an stability studies Codes/ Sizes: 25132-1 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 1.0 25132-5 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 1.5 25132-2 DELTA® SHUNT KIT, REGULAR, PERFORMANCE LEVEL 2.0 25131-1 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 1.0

		submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	LEVEL 1.0 25131-5 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 1.5 25131-2 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 2.0 24013-1 DELTA® UNITIZED SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.0 WITH INTEGRAL VENTRICULAR CATHETER, 13 CM, AND PERITONEAL CATHETER, OPEN ENDED, 90 CM 24013-5 DELTA® UNITIZED SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 1.5 WITH INTEGRAL VENTRICULAR CATHETER, 13CM, & PERITONEAL CATHETER, OPEN ENDED, 90CM UNITIZED SHUNT REG 24013-2 DELTA® UNITIZED SHUNT ASSEMBLY, REGULAR, PERFORMANCE LEVEL 2.0 WITH INTEGRAL VENTRICULAR CATHETER, 13CM, & PERITONEAL CATHETER, OPEN ENDED, 90CM UNITIZED SHUNT	25131-5 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 1.5 25131-2 DELTA® SHUNT KIT, SMALL, PERFORMANCE LEVEL 2.0 The firm may apply separately for the other code or justify under the MDR 2017
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			REG 24012-5 DELTA® UNITIZED SHUNT ASSEMBLY, SMALL, PERFORMANCE LEVEL 1.5, WITH INTEGRAL VENTRICULAR CATHETER, SMALL, 11CM, & PERITONEAL CATHETER, SMALL, OPEN ENDED, 65CM 25014-1 DELTA® UNITIZED SHUNT, SMALL PERFORMANCE LEVEL 1.0 25014-5 DELTA® UNITIZED SHUNT, SMALL PERFORMANCE LEVEL 1.5 25014-2 DELTA® UNITIZED SHUNT, SMALL PERFORMANCE LEVEL 2.0	
274.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 09409751890 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery 4620 North Beach Street Fort Worth, TX USA 76137	STRATA SHUNT KITS Generic Name: Shunts Class: D Shelf Life: 3 Years Codes/ Sizes: 27821 STRATA® II UNITIZED SHUNT KIT, REGULAR 46886 STRATA® II UNITIZED SHUNT KIT, REGULAR VENTRICULAR CATHETER, 13 CM AND PERITONEAL CATHETER, 120 CM	Approved subject to submission of the differential fee of RS 38000/- Codes/ Sizes: 27821 STRATA® II UNITIZED SHUNT KIT, REGULAR Codes/ Sizes: 27821 STRATA® II UNITIZED SHUNT KIT, REGULAR The firm may apply separately for the other code or justify under the MDR 2017

		LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	46881 STRATA® II UNITIZED SHUNT KIT, REGULAR WITH VENTRICULAR CATHETER, 11 CM AND PERITONEAL CATHETER, 120 CM 27820 STRATA® II UNITIZED SHUNT KIT, SMALL 46876 STRATA® II UNITIZED SHUNT KIT, SMALL WITH VENTRICULAR CATHETER, 11 CM AND PERITONEAL CATHETER, 120 CM 46871 STRATA® II UNITIZED SHUNT KIT, SMALL WITH VENTRICULAR CATHETER, 8 CM AND PERITONEAL CATHETER, 120 CM	
275.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 14-02-2025 Fee Challan No.: 296352822 PKR: 62,000/-	Legal Manufacturer M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. M/s Covidien Zona Franca De San Isidro Carretera San Isidro Km 17- Santo Domingo Dominican Republic, 2. M/s Medtronic Neurosurgery	UNITIZED SHUNTS Generic Name: Shunts Class: D Shelf Life: 5 years Codes/ Sizes: 46022 CSF-UNITIZED SHUNT, CONTOURED REGULAR, LOW PRESSURE 46012 CSF-UNITIZED SHUNT, CONTOURED SMALL, LOW	Approved subject to submission of the differential fee of RS 38000/- And stability studies

		4620 North Beach Street Fort Worth, TX USA 76137 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 11-06-2024 Validity: 10-06-2026 Original, Valid and Legalized attached with registration application of Ventricular Catheters dated 31-01-2025 EC Certificate: Validity: 01-05-2024 (Original and Notarized with validity extension letter attached with registration application of Ventriculostomy Kit dated 31st January 2025) ISO13485 Validity: 19-08-2024	PRESSURE 46014 CSF-UNITIZED SHUNT, CONTOURED SMALL, MEDIUM PRESSURE 46016 CSF-UNITIZED SHUNT, CONTOURED SMALL, HIGH PRESSURE 46024 CSF-UNITIZED SHUNT, CONTOURED REGULAR, MEDIUM PRESSURE 46026 CSF-UNITIZED SHUNT KIT, REGULAR HIGH PRESSURE	
276.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) R&I Dated: 30-01-2025	Legal Manufacturer: M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. Medtronic Ireland Parkmore Business Park West Galway, Galway Ireland,	Micra AV2 Transcatheter Pacing System Generic Name: Pacemaker Class: D Shelf Life: 18 months Codes/ Sizes:	Approved subject to submission of the differential fee of RS 38000/- And stability studies

	Fee Challan No.: 667423943474 PKR: 62,000/-	2. Medtronic Inc 8200 Coral Sea Street NE Mounds View MN USA 55112 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 8-Oct-2024 Validity: 7-Oct-2026 (Original, Valid and Legalized attached) EC Certificate: Validity: 10-04-2027 (Original, Valid and Notarized Attached) ISO13485 Original, Valid and Notarized Attached ISO for IRELAND Effective date: 17-07-2024 Expiry date: 16-07-2027 ISO for USA Effective date: 13-06-2023 Expiry date: 31-03-2025	MC2AVR1	
277.	M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273)	Legal Manufacturer: M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN USA 55432 Manufacturing sites 1. Medtronic Ireland Parkmore	Micra VR2 Transcatheter Pacing System Generic Name: Pacemaker Class: D	Approved subject to submission of the differential fee of RS 38000/- And stability studies

	R&I Dated: 30-01-2025 Fee Challan No.: 7228527629 PKR: 62,000/-	Business Park West Galway, Galway Ireland, 2. Medtronic Inc 8200 Coral Sea Street NE Mounds View MN USA 55112 LOA: Issuance Date: 11-10-2022 Validity Date: N/A (Original Letter of Authorization attached with shortcoming submission of Affinity Temperature probe dated 16th November 2022) FSC: US FDA Issuance date: 8-Oct-2024 Validity: 7-Oct-2026 (Original, Valid, and Legalized Attached with registration application of Micra AV2 Transcatheter Pacing System dated 03-12-2024) EC Certificate: Validity: 10-04-2027 (Original, Valid and Notarized Attached with registration application of Micra AV2 Transcatheter Pacing System dated 03-12-2024) ISO13485 (Original, Valid and Notarized Attached with registration application of Micra AV2 Transcatheter Pacing System dated 03-12-2024)	Shelf Life: 18 months Codes/ Sizes: MC2VR01	
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		ISO for IRELAND Effective date: 17-07-2024 Expiry date: 16-07-2027 ISO for USA Effective date: 13-06-2023 Expiry date: 31-03-2025																													
278.	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI-00043)	<u>Legal Manufacturer:</u> <u>Disa Medinotec (Pty) Ltd</u> Manufacturing Site: Northlands Business Park Stand 171,Bush Telegraph Street Northriding, Johannesburg,2169 South africa Date of R&I 18-10-2024 <u>FSC:</u> Country of Origin Original & Apostille Validity: 06-02-2025 <u>FSC:</u> FSC of Reference Country Original & Apostille Validity: 07-01-2025 <u>LOA</u> Issue date 01.01.2027 <u>EC Certificate</u> Original & Apostille Validity: 07-01-2024 Notifying body confirmation letter is attached <u>ISO 13485</u> Original & Apostille Validity: 26-04-2025 DOC: Original and apostille	Brand Name: Cape Cross Rx PTCA Balloon Catheter (Generic name) PTCA Balloon Dilatation Catheter Class D Shelf Life: 03 years <table><tr><td>CCD1-1508</td></tr><tr><td>CCD1-2008</td></tr><tr><td>CCD1-2508</td></tr><tr><td>CCD1-3008</td></tr><tr><td>CCD1-3508</td></tr><tr><td>CCD1-4008</td></tr><tr><td>CCD1-4508</td></tr><tr><td>CCD1-5008</td></tr><tr><td>CCD1-1510</td></tr><tr><td>CCD1-2010</td></tr><tr><td>CCD1-2510</td></tr><tr><td>CCD1-3010</td></tr><tr><td>CCD1-3510</td></tr><tr><td>CCD1-4010</td></tr><tr><td>CCD1-4510</td></tr><tr><td>CCD1-5010</td></tr><tr><td>CCD1-1512</td></tr><tr><td>CCD1-2012</td></tr><tr><td>CCD1-2512</td></tr><tr><td>CCD1-3012</td></tr><tr><td>CCD1-3512</td></tr><tr><td>CCD1-4012</td></tr><tr><td>CCD1-4512</td></tr><tr><td>CCD1-5012</td></tr><tr><td>CCD1-1515</td></tr><tr><td>CCD1-2015</td></tr><tr><td>CCD1-2515</td></tr></table>	CCD1-1508	CCD1-2008	CCD1-2508	CCD1-3008	CCD1-3508	CCD1-4008	CCD1-4508	CCD1-5008	CCD1-1510	CCD1-2010	CCD1-2510	CCD1-3010	CCD1-3510	CCD1-4010	CCD1-4510	CCD1-5010	CCD1-1512	CCD1-2012	CCD1-2512	CCD1-3012	CCD1-3512	CCD1-4012	CCD1-4512	CCD1-5012	CCD1-1515	CCD1-2015	CCD1-2515	Approved The firm will submit FSC of UK
CCD1-1508																															
CCD1-2008																															
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CCD1-2515																															

		<u>Validity :31-12-2027</u>	CCD1-3015 CCD1-3515 CCD1-4015 CCD1-4515 CCD1-5015 CCD1-1520 CCD1-2020 CCD1-2520 CCD1-3020 CCD1-3520 CCD1-4020 CCD1-4520 CCD1-5020 CCD1-1525 CCD1-2025 CCD1-2525 CCD1-3025 CCD1-3525 CCD1-4025 CCD1-4525 CCD1-5025 CCD1-2030 CCD1-2530 CCD1-3030 CCD1-3530 CCD1-4030 CCD1-4530 CCD1-5030 CCD1-2030 CCD1-2540 CCD1-3040 CCD1-3540 CCD1-4040 CCD1-4540 CCD1-5040 As per DOC	
279.	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI-00043)	<u>Legal Manufacturer:</u> Disa Medinotec (Pty) Ltd Manufacturing Site: Northlands Business Park Stand 171,Bush Telegraph Street Northriding,	Brand Name: Cape Cross NC Rx PTCA Balloon Catheter (Generic name) NC PTCA Balloon Dilatation Catheter Class D	Approved The firm will submit FSC of UK

		Johannesburg,2169 South africa Date of R&I 18-10-2024 <u>FSC:</u> Country of Origin Original & Apostille Validity: 06-02-2025 <u>FSC:</u> FSC of Reference Country UK Original & Apostille by south Africa Validity: 07-01-2025 <u>LOA</u> Original & Apostille Validity: 01-01-2027 <u>EC Certificate</u> Original & Apostille Validity: 10-03-2024 Notifying body confirmation letter is attached <u>ISO 13485</u> Original & Apostille Validity: 26-04-2025 <u>DOC:</u> Original and apostille <u>Validity :31-12-2027</u>	Shelf Life: 03 years Codes/Sizes: NCD1-20006 NCD1-22506 NCD1-25006 NCD1-27506 NCD1-30006 NCD1-32506 NCD1-35006 NCD1-37506 NCD1-40006 NCD1-45006 NCD1-20010 NCD1-22510 NCD1-25010 NCD1-27510 NCD1-30010 NCD1-32510 NCD1-35010 NCD1-37510 NCD1-40010 NCD1-45010 NCD1-20012 NCD1-22512 NCD1-25012 NCD1-27512 NCD1-30012 NCD1-32512 NCD1-35012 NCD1-37512 NCD1-40012 NCD1-45012 NCD1-20015 NCD1-22515 NCD1-25015 NCD1-27515 NCD1-30015 NCD1-32515 NCD1-35015 NCD1-37515 NCD1-40015 NCD1-45015 NCD1-20020 NCD1-22520	
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			NCD1-25020 NCD1-27520 NCD1-30020 NCD1-32520 NCD1-35020 NCD1-37520 NCD1-40020 NCD1-45020 NCD1-20025 NCD1-22525 NCD1-25025 NCD1-27525 NCD1-30025 NCD1-32525 NCD1-35025 NCD1-37525 NCD1-40025 NCD1-45025 NCD1-20030 NCD1-22530 NCD1-25030 NCD1-27530 NCD1-30030 NCD1-32530 NCD1-35030 NCD1-37530 NCD1-40030 NCD1-45030 As per DOC	
280.	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI-00043)	Manufacturer M/s HP BIOPROTESES LTDA, located at Rua Maria José Rangel, 83, Vila São Paulo, SP - Brazil - CEP 04650- <u>Manufacturing site:</u> <u>HP BIOPRÓTESES</u> Address: Rua Maria José Rangel, 83 Vila São Paulo, São Paulo - SP - Brazil CEP: 04650-180 <u>FSC:</u>	HPBIO CSF SPHERA DUO SHUNTS & EVD DRAIANGE SYSTEMS <u>Class D</u> <u>Shelf life 04 years</u> PHERA PRO HYDROCEPHAL US PROGRAMMAB LE SHUNT SYSTEM -SPHERA ANTI- SIPHON	Approved SPHERA DUO HYDROCEPHALUS SHUNT SYSTEM The firm shall apply separtly for the others wirh the names as per FSC or justify under the MDR 2017.

		Country of Origin Scan apostile and embassy attested -Validity: 31-03-2025 FSC: Country of Origin Scan apostile and embassy attested Validity: 08-10-2025 FSC: Country of Origin Scan apostile and embassy attested Validity: Not mentioned FSC: Country of Origin Scan apostile and embassy attested Validity: 21-01-2028 FSC: Country of Origin Scan apostile and embassy attested Validity: 28-02-2026 FSC: Country of Origin Scan apostile and embassy attested Validity: 03-09-2027 <u>LOA issued 26.04.2024</u> <u>Valid 04.2027</u> <u>Scan Full Quality Assurance Certificate</u> Validity: 04-07-2023 Scan Design Examination certificate 24.05.2024 Extension letter	HYDROCEPHAL US SHUNT SYSTEM -SPHERA DUO HYDROCEPHAL US SHUNT SYSTEM -EVD EXTERNAL CSF VENTRICULAR DRAINAGE SYSTEM FREE FLOW -EVD-EC EXTERNAL VENTRICULAR DRAINAGE ECONOMIC -HPPIC INTRACRANIAL PRESSURE MONITORING AND TEMPERATURE MONITORING CATHETER -EXTERNAL LUMBAR DRAINAGE -VENTRICULAR CATHETERS -PERITONEAL CATHETERS -VENTRICULAR RESERVOIRS (OMMAYA) -STRAIGHT CONNECTORS & Y- CONNECTORS	
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		ISO 13485 Validity: 17-01-2025									
281.	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI-00043)	Legal Manufacturer: Medikokim Tıbbi ve Kimyevi Malzeme Sanayi ve Ticaret Limited Şirketi Manufacturing Site: İkitelli O.S.B. Demirciler San. Sit. B-7 Blok No:157 Başakşehir / İSTANBUL / TÜRKİYE Fee 62000/- Date of R&I 28-10-2024 & 15-04- 2025 FSC: Country of Origin Scan Original & Apostille Validity: 15-03-2027 LOA Original & attested Validity: 15-02-2028 EC Certificate Original & Notarizes Validity: 27-02-2023 Notifying body confirmation letter is attached ISO 13485 Original & Apostille Validity: 27-08-2026 DOC: Original and apostille Validity :31-12-2027	Brand Name: Saugermed (neurosurgical pads) (Generic name) (neurosurgical pads) Class C Shelf Life: 03 years <table><tr><td>SAUGERMED SURGICAL PATTIES SMALL (SOFT)12.5X25MM BPSFT1225</td></tr><tr><td>SAUGERMED SURGICAL PATTIES SMALL (PURE COTTON)12.5X25MM BPPCTK1225</td></tr><tr><td>SAUGERMED SURGICAL PATTIES MEDIUM (SOFT)10X40MM BPSFT1040</td></tr><tr><td>SAUGERMED SURGICAL PATTIES LARGE (SOFT)25X75MM BPSFT2575</td></tr><tr><td>SAUGERMED SURGICAL PATTIES MEDIUM LARGE (SOFT)15X45MM BPSFT1545</td></tr><tr><td>SAUGERMED SURGICAL PATTIES TINY SMALL (SOFT)12.5X12.5M M BPSFT1212</td></tr><tr><td>SAUGERMED SURGICAL PATTIES TINY SMALL(PURE COTTON)12.5X12.5MM</td></tr></table>	SAUGERMED SURGICAL PATTIES SMALL (SOFT)12.5X25MM BPSFT1225	SAUGERMED SURGICAL PATTIES SMALL (PURE COTTON)12.5X25MM BPPCTK1225	SAUGERMED SURGICAL PATTIES MEDIUM (SOFT)10X40MM BPSFT1040	SAUGERMED SURGICAL PATTIES LARGE (SOFT)25X75MM BPSFT2575	SAUGERMED SURGICAL PATTIES MEDIUM LARGE (SOFT)15X45MM BPSFT1545	SAUGERMED SURGICAL PATTIES TINY SMALL (SOFT)12.5X12.5M M BPSFT1212	SAUGERMED SURGICAL PATTIES TINY SMALL(PURE COTTON)12.5X12.5MM	Approved subject to submission of the valid CE certificate and stability studies
SAUGERMED SURGICAL PATTIES SMALL (SOFT)12.5X25MM BPSFT1225											
SAUGERMED SURGICAL PATTIES SMALL (PURE COTTON)12.5X25MM BPPCTK1225											
SAUGERMED SURGICAL PATTIES MEDIUM (SOFT)10X40MM BPSFT1040											
SAUGERMED SURGICAL PATTIES LARGE (SOFT)25X75MM BPSFT2575											
SAUGERMED SURGICAL PATTIES MEDIUM LARGE (SOFT)15X45MM BPSFT1545											
SAUGERMED SURGICAL PATTIES TINY SMALL (SOFT)12.5X12.5M M BPSFT1212											
SAUGERMED SURGICAL PATTIES TINY SMALL(PURE COTTON)12.5X12.5MM											

			BPPCTK1212																											
			SAUGERMED SURGICAL PATTIES LARGE CP+(PURE COTTON)25X90MM BPPCTK2590																											
			SAUGERMED SURGICAL PATTIES MEDIUM LARGE CP+(PURE COTTON)25X50MM BPPCTK2550																											
282.	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI-00043)	(LEGAL MANUFACTURER) M/S Nakanishi Inc., (Address of Manufacturer) M/S Nakanishi Inc., 700 Shimohinata,Kanuma, Tochigi,322-8666,Japan Date of R&I 11-04-2025 FSC: Country of Origin Ok not mentioned in defer provisions FSC: FSC of Reference Country Validity: 00-00-2000 LOA Ok not mentioned in defer provisions EC Certificate Ok not mentioned in defer provisions ISO 13485 Ok not mentioned in defer provisions DOC: Ok not mentioned in defer provisions	Brand Name: Primado 2 (Cutting Accessories Sterile Drills, Sterile Burs, Saw, Blades, Rasps & Flies) (Generic name) Primado 2 (Cutting Accessories Sterile Drills, Sterile Burs, Saw, Blades, Rasps & Flies) Class B Shelf Life: 05 years Codes/Sizes: Primado 2 (Cutting Accessories Sterile Drills, Sterile Burs, Blades, Rasps & Flies) 1. NSK sterile burs/drills Components <table><tr><td>Model</td><td></td></tr><tr><td>PDS-1C155-20</td><td></td></tr><tr><td>PDS-1C155-30</td><td></td></tr><tr><td>PDS-1C155-40</td><td></td></tr><tr><td>PDS-1C175-20</td><td></td></tr><tr><td>PDS-1C175-30</td><td></td></tr><tr><td>PDS-1C175-40</td><td></td></tr><tr><td>PDS-2CMS-10</td><td></td></tr><tr><td>PDS-2CMS-20</td><td></td></tr><tr><td>PDS-2CMS-30</td><td></td></tr><tr><td>PDS-2CMS-40</td><td></td></tr><tr><td>PDS-2CMS-50</td><td></td></tr><tr><td>PDS-2CMS-60</td><td></td></tr></table>	Model		PDS-1C155-20		PDS-1C155-30		PDS-1C155-40		PDS-1C175-20		PDS-1C175-30		PDS-1C175-40		PDS-2CMS-10		PDS-2CMS-20		PDS-2CMS-30		PDS-2CMS-40		PDS-2CMS-50		PDS-2CMS-60		Approved NSk sterile Burs and drills The firm shall apply separately for the other sa per MDR 2017
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			PDS-1RD110-20		
			PDS-1RD110-30		
			PDS-1RD110-40		
			PDS-1RD130-20		
			PDS-1RD130-30		
			PDS-1RD130-40		
			PDS-1RD170-35		
			PDS-1RD170-40		
			PDS-1RD170-50		
			PDS-1RD240-30		
			PDS-1RD240-40		
			PDS-1RD240-45		
			PDS-1RD240-50		
			PDS-1RCD110-20		
			PDS-1RCD110-30		
			PDS-1RCD110-40		
			PDS-1RCD110-50		
			PDS-1RCD130-20		
			PDS-1RCD130-30		
			PDS-1RCD130-40		
			PDS-1RCD130-50		
			PDS-1RCD170-35		
			PDS-1RCD170-40		
			PDS-1RCD170-50		
			PDS-1RCD240-30		
			PDS-1RCD240-40		
			PDS-1RCD240-45		

			PDS-1RCD240-50		
			PDS-1MHD110-20		
			PDS-1MHD110-30		
			PDS-1MHD110-40		
			PDS-1MHD130-20		
			PDS-1MHD130-30		
			PDS-1MHD130-40		
			PDS-1MHCD110-30		
			PDS-1MHCD110-40		
			PDS-1MHCD130-30		
			PDS-1MHCD130-40		
			PDS-1RTD110-45		
			PDS-1RTD130-45		
			PDS-1RTCD110-45		
			PDS-1RTCD130-45		
			PDS-2RFUL-10		
			PDS-2RFUL-15		
			PDS-2RFUL-20		
			PDS-2RFUL-25		
			PDS-2RFUL-30		
			PDS-2RFUL-35		
			PDS-2RFUL-40		
			PDS-2RFUL-50		
			PDS-2RFUL-60		
			PDS-2RFUL-70		
			PDS-2RDUL-06		
			PDS-2RDUL-20		
			PDS-2RDUL-25		
			PDS-2RDUL-30		
			PDS-2RDUL-35		
			PDS-2RDUL-40		
			PDS-2RDUL-50		
			PDS-2RCDUL-10		
			PDS-2RCDUL-15		
			PDS-2RCDUL-20		
			PDS-2RCDUL-25		
			PDS-2RCDUL-30		
			PDS-2RCDUL-40		
			PDS-2RCDUL-50		
			PDS-2RCDUL-60		
			PDS-2RCDUL-70		
			PDS-2RECDUL-30		
			PDS-2RECDUL-40		
			PDS-2RECDUL-50		
			PDS-2RECDUL-60		

			PDS-2RECDUL-70		
			PDS-2RSCDUL-30		
			PDS-2RSCDUL-40		
			PDS-2RSCDUL-50		
			PDS-2RSCDUL-60		
			PDS-2MHCDUL-20		
			PDS-2MHCDUL-30		
			PDS-2MHCDUL-40		
			PDS-2AUL-50		
			PDS-2AUL-60		
			PDS-2AUL-75		
			PDS-2RUL-13		
			PDS-2WUL-10		
			PDS-2WUL-12		
			PDS-2WUL-15		
			PDS-2QEUL-30		
			PDS-2QEUL-40		
			PDS-2QEUL-50		
			PDS-2QEUL-60		
			PDS-2MHFUL-18		
			PDS-2MHFUL-22		
			PDS-2MHFUL-30		
			PDS-2CYL-50		
			PDS-2CYL-60		
			PDS-2CYUL-50		
			PDS-2CYUL-60		
			PDS-3NCBS-18		
			PDS-3NCBS-22		
			PDS-3NCBS-30		
			PDS-3NCBM-18		
			PDS-3NCBM-22		
			PDS-3NCBM-30		
			PDS-3NCBL-18		
			PDS-3NCBL-22		
			PDS-3NCBL-30		
			PDS-2BCDL-30		
			PDS-2BCDL-50		
			PDS-2BCDL-30E		
			PDS-2BCDL-50E		
			PDS-2EL-40		
			PDS-2EL-60		
			2-NSK STERILE BLADES		
			MODEL		
			PDS-SO-411		

			PDS-SO-412 PDS-SO-422 PDS-SO-431 PDS-SO-432 PDS-SO-441 PDS-SO-442 PDS-SO-452 PDS-SO-622 PDS-SO-632 PDS-SO-642 PDS-SO-433 PDS-SO-453 PDS-SO-643 PDS-OSC-422 PDS-OSC-432 PDS-RE-4023 PDS-RE-4028 PDS-RE-4023E PDS-RE-4028E PDS-RE-4114 PDS-RE-4127 PDS-RE-6127 PDS-RE-4217 PDS-RE-4223 3-NSK STERILE RASPS/FLIES MODEL PDS-RE-R011 PDS-RE-R012 PDS-RE-R111 PDS-RE-R112	
283.	M/s ElectroMed Corporation ELI-00163 <u>R&I Details</u> 14-04-2025 <u>Fee Challan No.</u> 2742352217 dated: 10-04-2025	<u>Legal Manufacture</u> Kunshan Dynmed Medical Technology Co. , Ltd., No. 66, Shunxing Road, Lujia Town, 215331 Kunshan Suzhou City, Jiangsu Province, People's Republic of China Manufacturing Site (s): Kunshan Dynmed Medical Technology Co. , Ltd., No. 66, Shunxing Road,	<u>Brand Name:</u> DO2-5E <u>(Generic Name):</u> Oxygen Concentrator Class B <u>Shelf life:</u> 05 Years - <u>Codes/Sizes:</u> DO2-5E	Approved

		Lujia Town, 215331 Kunshan Suzhou City, Jiangsu Province, People's Republic of China LOA: Validity: 16-11-2028 FSC: Country of Origin Validity: 11-10-2026 EC Certificate: Validity: 31-12-2028 ISO 13485: Validity: 05-09-2025		
284.	U.M. Enterprises 3 Boulevard Raymond poincare, 92430 Marnes-la- Coquette, France	BIO-RAD Laboratories 3 Boulevard Raymond Poincare, 92430 Marnes- la-Conquette, France FSC Original France Copy of LOA expiry 31.12.2020	Platelia Rabbies II Class A Shel life 12 months 2-8°C Fee 5000	Deferred for submission of the valid and notarized LOA and valid FSC Valid ISO 13485 Clarify the classification under the MDR 2017 and submit required fee.

DEFERRED CASES

285.	Ali sons room no 37, 2nd floor Luxmi Building M.A Jinnah Road, Karachi (ELI- 00711) Godown: KPT plot no 30, West Wharf, Karachi. Dossier# 4368 Submission date: 22/04/2022 Fee submitted: 50,000/- Challan No. 02645472630	Legal Manufacturer: NRS Global Partners Sdn Bhd no.30, Jalan Tasik selatan, 57000, Kuala Lumpur, Malaysia. FSC: Malaysia. (Original) Valid till: 16-11-2023	Ectasy Latex Condoms (Male Prophylactic Condoms) Codes& sizes: Length: min. 180mm Packing: 3s, 6s,12s Design: Reservoir ended Type: contoured super dotted Class-C Shelf Life: 5 Years	Approved
286.	M/s Treu-Dynamic International(Pvt) Ltd ELI-00175 R&I Details:20.11.2023 Fee Challan No70602753 Dated: 17.11.2023.	EUROFARM S.p.A Zona Industriale di Piano Tavola, 95032 Belpasso (CT) ITALY. Manufacturing Site (s): (Same as above mentioned) LOA: Validity 05-Year (Jan-2024 to Dec-2027).	Eurofarm (Surgical Dressing) Class D Shelf life: 05 Years 892063 892066 501510 501515 501520	Approved

		FSC: FSC: Country of origin Italy. Validity: 31-12-2029 FSC: FSC of Reference Country (as mentioned in rule, 67) Validity: 00-00-20— OR EC Certificate (Production Quality Assurance certificate/ Full quality assurance certificate): Validity: 31-12-2026 OR WHO PQ (verifiable from the official WHO site) ISO 13485: Validity July 2023 –April 2027.	893320 892013 892015 892017 501705 717803 717806 717807 717808 717809 720006 720007 720008 501008 501009	
287.	M/s ElectroMed Corporation ELI-00163 R&I details: 06-Mar-2023	Legal Manufacturer: M/s MIR-Medical International Research S.p.A Manufacturing Site: Viale Luigi Schiavonetti 270 00173, Roma, Italy LOA: 01-Mar-2027 FSC: 01-Mar-2027 Country of Origin: Italy EC Certificate: 15-Feb- 2028 ISO 13485: 15-Feb-2027	Brand Name: Spirobank II Generic Name: Spirometer Class B Shelf Life: 10 years Codes/Sizes: 911028 Spirobank II Without Turbine Flowmeter	Approved

REGISTRATION OF MEDICAL DEVICES LOCAL.

S#	Name of Manufacturer	Name of Medical Device	
1.	Faisal Pharmaceuticals 602-B, Punjab Small industrial Estate Sargodha Road Faisalabad (ELM-0019) [756-6L]	Steripax Eyepads BPC Absorbent Cotton Wool & Absorbent Muslin Cloth Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 5506779900	Approved with 2 years of Shelf Life

2.	Faisal Pharmaceuticals 602-B, Punjab Small industrial Estate Sargodha Road Faisalabad (ELM-0019) [756-6L]	Steripax Eyepads BPC Absorbent Cotton Wool & Absorbent Muslin Cloth Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 5506779900	Approved with 2 years of Shelf Life
3.	Faisal Pharmaceuticals 602-B, Punjab Small industrial Estate Sargodha Road Faisalabad (ELM-0019) [757-6L]	Bandax Cotton Confirming Bandage BPC Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 92720525	Approved with 2 years of Shelf Life
4.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Triangular Bandage Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 735096520 Sizes: Not mentioned.	Approved with 2 years of Shelf Life
5.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Gauze Swab Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 53067423 Sizes (in cm): 5x5, 7.5x7.5, 10x10	Approved with 2 years of Shelf Life
6.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed X-Ray Detectable Gauze Swab Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 175317878 Sizes (in cm): 5x5, 7.5x7.5, 10x10	Approved with 2 years of Shelf Life
7.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Non-Woven Gauze Swab Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 233080514 Sizes (in cm): not mentioned	Approved with 2 years of Shelf Life
8.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Gauze Swab (Sponges) Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 8261153314 Sizes (in inches): 2x2, 3x3, 4x4	Approved with 2 years of Shelf Life

9.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed X-Ray Detectable Abdominal Packs Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 7670842368 Sizes (in cm): 5x5, 7.5x7.5, 10x10	Approved with 2 years of Shelf Life
10.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Para Tulle Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 715680128 Sizes (in cm): not mentioned	The board decided to constitute the panel comprising of Prof. Dr. Mahmood Ahmad, Member MDB and Mr. Waqar Dy. Dir. MDMC DRAP to evaluate the manufacturing and testing facility of Para-Tulle impregnated with paraffin, petroleum jelly, or another non-occlusive substance, preventing the dressing from sticking to the wound and reducing pain during dressing changes. Some variants may also contain antimicrobial agents such as chlorhexidine or silver to aid in infection prevention. The firm shall submit sizes also.
11.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Undercast Padding Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 74242754984 Sizes: Not mentioned.	Approved with 2 years of Shelf Life
12.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Cotton Bandage Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 359728135836 Sizes: Not mentioned.	Approved with 2 years of Shelf Life
13.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi	Ultimed Absorbent Ribbon Gauze Class: B Shelf Life: 5 Years Fee: 25000	Approved with 2 years of Shelf Life

	(ELM-0078)	Fee Slip No. 23870938 Sizes: Not mentioned.	
14.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Kytograft Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 32586090965 Sizes: Not mentioned.	The board decided to constitute the panel comprising of Prof. Dr. Mahmood Ahmad, Member MDB and Mr. Waqar Dy. Dir. MDMC DRAP to evaluate the manufacturing and testing facility of Kytograft which is an advanced wound care product made from chitosan-based biomaterial , derived from natural sources such as crustacean shells. Kytograft is available in various forms, including sheets, meshes, or sponges, to cater to different wound care needs. The unique properties of Kytograft, including its antimicrobial activity and ability to modulate the wound healing environment, make it suitable for use in a variety of acute and chronic wound care applications..
15.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Pro Max Combined Dressing Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 63998495657 Sizes: Not mentioned.	Approved with 2 years of Shelf Life
16.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Absorbent Lint Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 873984326013 Sizes: Not mentioned.	Approved with 2 years of Shelf Life

17.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed IV Catheter with Injection Port Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 74782365699 Sizes: Not mentioned.	The board decided to constitute the panel comprising of Prof. Dr. Abdul Aleem, Member MDB and Mr. Asfandiyar Dy. Dir. MDMC DRAP to evaluate the assembling and testing facility of Intravenous (IV) catheter.
18.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Surgi Swab Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 78292740274 Sizes: Not mentioned.	Approved with 2 years of Shelf Life
19.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	Unistrip Pregnancy Detection Test Strip Class: A Shelf Life: 5 Years Fee: 25000 Fee Slip No. 803635820	The board decided to constitute the panel comprising of Prof Dr. Brig (r Nuzhat Mushahid, Member MDB and Mr. Arsalan Tariq Dy. Dir. DRAP to evaluate the manufacturing & testing facility of UNiSTRIP Pregnancy Test Strip being a rapid, qualitative immunoassay designed for the detection of human chorionic gonadotropin (hCG) in urine to determine pregnancy. It is a highly sensitive and specific test strip commonly used for early pregnancy detection at home or in clinical settings.
20.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UnibBag Single Blood Bag with CPDA-1 for whole Blood (human) with 16/17G for Single Use Class: D Shelf Life: 2 Years Fee: 25000 Fee Slip No. 060033303283 Sizes: 100mL, 250mL, 350mL, 450mL, 500mL	The board decided to constitute the panel comprising of Prof Dr. Brig (r) Nuzhat Mushahid, Member MDB and Mr. Arsalan Tariq Dy. Dir. DRAP to evaluate the manufacturing & testing facility of UNiBBAG Single Blood Bag which

			is a sterile, single-use system designed for the collection, storage, and transfusion of whole blood. It contains CPDA-1 (Citrate Phosphate Dextrose Adenine-1), an anticoagulant-preservative solution that extends the shelf life of collected blood. The bag is part of a closed system, minimizing contamination risks.
21.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UNiViTEX Nitrile Powder Free Examination Gloves, XS, S, M, L, XL Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1514425744	Deferred for clarification regarding the manufacturing & testing facility of Nitrile Powder Free Examination Gloves,
22.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UNiViTEX Latex Pre-Powdered Examination Gloves, XS, S, M, L, XL Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0585046989	Deferred for clarification regarding the manufacturing & testing facility of Nitrile Powder Free Examination Gloves,
23.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UNiViTEX Disposable Non-Sterile Latex Powder Free Examination Gloves, XS, S, M, L, XL Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0585046989	Deferred for clarification regarding the manufacturing & testing facility of Nitrile Powder Free Examination Gloves,
24.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UNiViTEX Disposable Latex Powder Free Sterile Single Use Only Surgical Gloves, XS, S, M, L, XL Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 884032824469	Deferred for clarification regarding the manufacturing & testing facility of Nitrile Powder Free Examination Gloves,

25.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002) [758-6L]	UNiViTEX Disposable Latex Surgical Gloves (Powdered) , Sizes 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 071765457519	Deferred for clarification regarding the manufacturing & testing facility of Nitrile Powder Free Examination Gloves,
26.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diapulv Dry Hemodialysis Concentrate (35X) Pack Sizes: 1-5 HD Sessions (Part-A, Part-B & Part-C) Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 73971777333	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
27.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diacarb Dry Hemodialysis Concentrate 36.83X Pack Sizes: Part-A Solution: 3.5-10L Part-B Powder: 1-20 HD Sessions Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 925974468393	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
28.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diacit-S Hemodialysis Concentrate Pack Sizes: 4L, 5L, 10L Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 8139492122	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
29.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diapulv-N Hemodialysis Concentrate Pack Sizes: 1-5 HD Sessions Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 37926946347	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
30.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan	Diacarb Dry Hemodialysis Concentrate 35X Pack Sizes: Part-A Solution: 3.5-10L Part-B Powder: 1-20 HD Sessions Composition as per dossier	Approved The firm will submit commitment/ undertaking that they will perform the

	(ELM-0096)	Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 4892375645	Stability study of the product and submit report.
31.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diacarb Dry Hemodialysis concentrate (DBR) 35X Pack Size: 4L, 5L, 10L, 25L Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 2058493852	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
32.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diacart Hemodialysis Concentrate- 35X Sodium Bicarbonate Pack Size: 650, 720, 750, 1200, 1250g Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 9307758860	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
33.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diapulv-D (45X) Dry Hemodialysis Concentrate Pack Sizes: 1-20 HD Sessions Composition as per dossier Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 57211996014	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
34.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diabag Hemodialysis Concentrate Sodium Bicarbonate Pack Size: 500gm, 650gm, 900gm Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 4409475787	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
35.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Diacit (35X) Dry Hemodialysis Concentrate Pack Sizes: 4L, 5L, 10L Composition as per dossier. Shelf Life: 02 Years Class: C Fee: 25,000 Fee Slip No: 888836980717	Approved The firm will submit commitment/ undertaking that they will perform the Stability study of the product and submit report.
36.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Fixer Powder (Fixer, Alkali, Retainer, Preservative) Pack Sizes: To make 10L Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 2627741713	Deferred for clarification of manufacturing & testing facility for the applied product

37.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Film Developer Powder (Fixer, Alkali , Retainer, Preservative) Pack Size: 2 gallons (9 liters), 3 gallons (13.5 liter) Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 25509411781	Deferred for clarification of manufacturing & testing facility for the applied product and pack/size.
38.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Towels Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 195988186 Sizes: Pack of 6 Towels 12" x 17"	Deferred for clarification of manufacturing & testing facility for the applied product and pack/size.
39.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Sterile Surgical Drape-All Purpose Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 68684024735	Deferred for clarification of manufacturing & testing facility for the applied product
40.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Side Adhesive Drape STD/Laminated Sheet Pack Size: 70*90cm, 75*90cm, 100*100cm, 100*130cm, 100*150cm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 58225351205	Deferred for clarification of manufacturing & testing facility for the applied product
41.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Standard/ Reinforced Gown Sterile/ Unsterile Pack Size: L, XL, XXL , XXXL Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 4014501622	Deferred for clarification of manufacturing & testing facility for the applied product
42.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Dignity Sheets Pack Size 10/15/20/30 pieces (60x90 cm) Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 471360306	Deferred for clarification of manufacturing & testing facility for the applied product

43.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Drape Pack Sterilized Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 7842732216	Deferred for clarification of manufacturing & testing facility for the applied product
44.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	TeriClean Cart-C Anhydrous Citric Acid Powder 32gm Pack Size: 32gm Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 63055207438	Approved
45.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	TeriStril 20% Disinfectant Solution (20% Disinfectant Solution Citric Acid, Lactic acid, Malic Acid) Pack Sizes: 1000/3000/ 4000/5000ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 8483350101	Approved
46.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	TeriStril 50% Disinfectant Solution Pack Sizes: 1000/3000 /4000/5000ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 36732673782	Approved
47.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	TeriClean Cart-A 13gm Pack Size: 13gm Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 25532506	Approved
48.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	EquaSafe Solution Pack Sizes: 100/200/400/500 /1000/5000ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 893883399912	Approved

49.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	EquaSafe Powder Pack Sizes: 100/125/ 162/300/500 gm Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 5598622537	Deferred for clarification of manufacturing & testing facility.
50.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Eroxlit Gel Ethanol, Propylene Glycol, Glycerin, Carbomer, Potassium Hydroxide, Aqua Pack Size / Tube: 10g , 15g, 30g Shelf Life: 03 Years Class: A Fee: 6,000 Fee Slip No: 9598582203	Deferred for clarification on the nature of the product & its intended use whether the applied product is medical device or otherwise & for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed prescribed form & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
51.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim ECG Gel Pack Size: Variable Pack Size Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 493914129360	Deferred for clarification of manufacturing & testing facility for the applied product.
52.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Liquid Paraffin Pack Size: 400ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 00389225	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise & for the confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.

53.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Glycerin Pack Size: 30ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 85011132	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise & for the confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
54.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Methylated spirit Pack Size: 300ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 736957207258	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR & for the confirmation of manufacturing & testing facility for the applied product.
55.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Zetol Pack Size: 50/100 /125/200/250 /500/1000/4000/ 5000/30000ml Conetnts: Chloroxylenol Compe Pine oil Isopropanol Castor oil Soap RO water Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 39400137	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR
56.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Ostomy Gel 60gm Pack Size: 60gm Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 0316705669	Approved The firm will submit stability studies and submit report.

57.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 40519293115 PKR: 6000/-	Surgimed Absorbent Cotton Wool (BPC) (Non-Sterile) Class: A Shelf Life: 03 Years Code / Sizes 25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram	Approved
58.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 8093063223 PKR: 6000/-	Surgimed Cotton Bandage (BP Type I) (Non-Sterile) Class: A Shelf Life: 03 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25 x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved
59.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 528589576 PKR: 6000/-	Surgimed Cotton Bandage (BP Type II) (Non-Sterile) Class: A Shelf Life: 03 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25 x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm	Approved

		x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	
60.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 7305348744 PKR: 6000/-	Surgimed Cotton Bandage (BP Type III) (Non-Sterile) Class: A Shelf Life: 03 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25 x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved
61.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 120951598 PKR: 6000/-	Surgimed Cotton Bandage (USP Type-IV) (Non-Sterile) Class: A Shelf Life: 03 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 5cm x 5m, 5cm x 5.5m, 5cm x 6m, 5cm x 6.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 7.5cm x 5m, 7.5cm x 5.5m, 7.5cm x 6m, 7.5cm x 6.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 10cm x 5m, 10cm x 5.5m, 10cm x 6m, 10cm x 6.5m, 6.25cm x 2.5m, 6.25cm x 3m, 6.25cm x 3.5m, 6.25cm x 4m, 6.25 x 4.5m, 6.25cm x 5m, 6.25cm x 5.5m, 6.25cm x 6m, 6.25cm x 6.5m 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m, 15cm x 5m, 15cm x 5.5m, 15cm x 6m, 15cm x 6.5m, 30cm x 2.5m, 30cm x 3m, 30cm x 3.5m, 30cm x 4m, 30cm x 4.5m, 30cm x 5m, 30cm x 5.5m, 30cm x 6m	Approved

62.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 8998887214 PKR: 6000/-	Surgimed Cotton Crepe Bandage (BPC) (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m.	Approved
63.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 817072036122 PKR: 6000/-	Surgimed Elastic Stretch Crepe Bandage (BPC) Class: A Shelf Life: 05 Years Code / Sizes: 5cm x 2.5m, 5cm x 3m, 5cm x 3.5m, 5cm x 4m, 5cm x 4.5m, 7.5cm x 2.5m, 7.5cm x 3m, 7.5cm x 3.5m, 7.5cm x 4m, 7.5cm x 4.5m, 10cm x 2.5m, 10cm x 3m, 10cm x 3.5m, 10cm x 4m, 10cm x 4.5m, 15cm x 2.5m, 15cm x 3m, 15cm x 3.5m, 15cm x 4m, 15cm x 4.5m.	Approved
64.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 5402131675 PKR: 6000/-	Surgimed Gauze Sponges (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 7.5cm x 7.5cm, 10cm x 10cm (single pack), 15cm x 15cm (8ply), 30cm x 30cm, 45cm x 45cm, 1 x 10m, 1 x 20m, 1 x 30m, 1 x 40m, 1 x 50m, 1 x 60m, 1 x 70m, 1 x 80m, 1 x 90m, 1 x 100m	Approved
65.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 184940724079 PKR: 6000/-	Surgimed Gauze Swab (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 7.5cm x 7.5cm, 10cm x 10cm (single pack), 15cm x 15cm (8ply), 30cm x 30cm, 45cm x 45cm, 1 x 10m, 1 x 20m, 1 x 30m, 1 x 40m, 1 x 50m, 1 x 60m, 1 x 70m, 1 x 80m, 1 x 90m, 1 x 100m	Approved
66.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad	Surgimed Gauze (BPC) (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 7.5cm x 7.5cm, 10cm x 10cm (single pack),	Approved

	(ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 940575639 PKR: 6000/-	15cm x 15cm (8ply), 30cm x 30cm, 45cm x 45cm, 1 x 10m (roll), 1 x 20m (roll), 1 x 30m (roll), 1 x 40m (roll), 1 x 50m (roll), 1 x 60m (roll), 1 x 70m (roll), 1 x 80m (roll), 1 x 90m (roll), 1 x 100m(roll)	
67.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 57722410 PKR: 6000/-	Surgimed Arthopedic Absorbent Cotton wool (BPC) (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram, 1000gram	Approved
68.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 33074443646 PKR: 6000/-	Surgimed Paraffin Gauze (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram, 1000gram	Approved
69.	M/s Ali Raza Surgimed (Pvt) Ltd., Factory Address: 3K-0M Chak No. 196 RB Ghona Bhai Wala Road, Faisalabad (ELM-0094) R&I Dated: 19/03/2025 Fee Challan No.: 01630375371 PKR: 6000/-	Surgimed Arthopedic Costoon Cotton wool (BPC) (Non-Sterile) Class: A Shelf Life: 05 Years Code / Sizes: 25gram, 50gram, 100gram, 200gram, 300gram, 400gram, 500gram, 1000gram	Approved

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