

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

DECISIONS OF 116th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 07th JANUARY-2026 (MANUAL APPLICATIONS PART-II)

116th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 7th January, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr M Salik Zahid, Chief Drugs Inspector, Nominee of DGHS Baluchistan	Member
3.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
4.	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.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
8.	Prof. Dr Saqib Shafi Sheikh , Interventional Cardiologist, 98, Babar Block, New Garden Town Lahore	Member (attended meeting through videolink)
9.	Prof. Dr Muhammad Nadeem Ahmad, Department of Radiology, Agha Khan University Hospital Multan.	Member (attended meeting through videolink)
10.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Ammar Ashraf Awan	Deputy Director
10.	Mr. Hanif Ullah	Deputy Director

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

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

RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE (ELM) CASES:

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Silver surgical company (pvt) Ltd, Office / godown: Plot No. C-40/41, Scheme-33, SITE, superhighway, Industrial Area, Karachi. ELM-0007	Amir Hussain Siddiqui Pharm D	Anum Zehra Pharm D	<p>The board considered the inspection report and granted renewal of ELM to following sections and also approved below mentioned additional section for manufacture of medical devices.</p> <p>Existing Sections:</p> <ul style="list-style-type: none"> IV Cannula (Peripheral IV Catheters) Auto Disposable syringes Insulin syringes <p>Additional Section:</p> <ul style="list-style-type: none"> IV Set.

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

(FRESH CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Askari Enterprises (Private) Limited Office: Floor No. 6, AWT Plaza the mall road saddr. Godown: Plot No. 14, sanitary market , sector i-11/3, Islamabad.	M Zubair Medical laboratory technology	Approved
2.	M/s Barlas Sale Service, Office/godown: 135, Upper Mall Scheme, Mian Mir, Lahore Lahore	Anum gul Pharm D	Approved
3.	M/s ALTERA HEALTH CARE PVT LTD, Office/godown: No. H-8, Lower ground floor., golden heights, F-11/1, Islamabad.	Ashfaq Munir Pharmacist	Approved
4.	M/s Saqib Traders, Office/godown: Lawyers Club Complex,Near DPO Office,Opp.Ladies Club,Bhimber Road Gujrat	Muaaz Raheel BS computer Science	Deferred for appointment of technical staff in accordance with Medical Devices Rules 2017.

(FRESH RENEWAL CASES-ELI)

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s 3N Lifemed Office/Godown: 18/20 N , Gulberg-II, Lahore. ELI-00392	Muhammad bilal dildar Pharm D	Nazir ahmed CEO	Approved. The firm shall submit an undertaking that the premises shall not be used for residential purposes and office/ godown can be inspected any time without hindrance.
2.	M/s Algene Medical (Pvt Ltd.) Office/Godown: 139-B, Commercial zone 2 nd floor , Second floor, sector c, jasmine block bahria town, Lahore. ELI-00142	Sana Pervaiz Pharm D	M Ramzan waseem Tabish waseem Jacob soren William	Approved
3.	M/s future D Pakistan , Office/Godown: 15-A, Block G johar town ,Lahroe. ELI-00568	Sehrish saeed Pharm D	Umer Hayat CEO	Approved
4.	M/s Intra Health, Office: 56-A, Unit No.1, Justice Inamullah road, block 7/8, KCHS, Karachi. Godown Plot No. 37/1, sector 15, korangi inudstrail area, Karachi. ELI-00049	Raza ali Pharm D	Muhammad Kamran Mudassir CEO	Approved
5.	M/s Medident supplies & services, Office/Godown: 4 th floor plaze 20, orchard rad, near lignum tower, said pur road , DHA, Islamabad. ELI-00542	Ms Farukh nazir Pharmacist	Nabi amin Zia ur Rehman	Approved

6.	M/s M/s Sadqain Healthcare (Pvt.) Limited Office: Safari Villas 11, commercial complex, 3rd Floor, Bahria Town, phase 7, Rawalpindi. godown: Plot No 11-A, Street No.3, RCCI industrial Area, rawat. ELI-00020	Ammara Imtiaz Pharmacist	Zahid Javeed CEO	Approved
7.	M/s Scientific house, Office: 13-c first floor, chaburgi cnetr multan road, Lahore. Godown: upper floor, 51-c, chauburji center Lahore. ELI-00529	Tabish ali Medical laboratory technology	Muhammad Muzammal CEO	Approved
8.	M/s Cor-med, Office/Godown: 2 nd floor, 38/62, rehman plaza, bank road, saddar, Rawalpindi. ELI-00226	Shahana khatoon B. pharmacy Validity; 01-01-2020 to 31-12-2-23	Israr ul haq CEO	Approved
9.	M/s Hospital Appliances, Office/godown: Office No. 1, G-274, Chisti Plaza, Gordon colledge road, Rawalpindi. ELI-00271	Ahmar Iftikhar Pharm D Validity : nil	M Irfan Ali Chishti CEO	Approved
10.	M/s shahbaz scientific corporation, Office/Godown: shahbaz plaza No. 1, street no. 32, mini market , G-15/1, Islamabad. ELI-00234	Maheen shahbaz Bs biomedical engineering	Muhammad shahbaz CEO	Deferred for submission of fee and documents regarding change of technical staff and godown.
11.	M/s Zuis pharmaland, Office/Godown: 3 rd building doctor plaza near ghausia marriage hall , G-13/4, & g-12, Main double road , Islamabad. ELI-00214	Safdar shah Pharmacist	M Ibrahim CEO	Deferred for submission of fee and documents regarding change of godown.

12.	M/s M/s SBK International Office/Godown: 23, Valley Road, Street 3, Westridge I, Rawalpindi. ELI-00100	Saad bin Qamil BS Computer Scinece	Saad bin kamil Muhammad kamil	Deferred to appointment of technical staff in accordance with Medical Devices Rules 2017.
13.	M/s Care and cure international, Office/Godown: Toyota royal motors opposite road , 1-KM same Nala, Rahim yar khan ELI-00192	Arbab ali shal Pharm D	Raja abdal ur Rahman CEO	Deferred for submission of fee and documents regarding change of godown and for approval of change of management as post licensing variation application.

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

(DEFERRED RENEWAL CASES-ELI):

M/s Excel Corporation, 435, BYJ Society Bahadurabad, Karachi (ELI-00110)	Amna Aftab Pharm-D	Ather Feroze (CEO)	Decision
			Approved

Item No. I(F): ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES - INVALID

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	M/s FABNOS INTERNATIONAL Office/Godown: Building # 26 - C, 3rd Floor, Touheed Commercial Area, Street # 26, Phase – V, D.H.A Karachi ELI No. 00149	22-10-2023	08-12-2025	The board observed that the firm has applied for renewal of license even after expiry of one year grace period given in the medical devices rules 2017 (Rule 7(5) of Medical Devices Rules 2017) therefore it was decided to declare the license invalid. Accordingly, the Board decided to initiate the proceedings for cancellation or suspension of the licence and enlistments and registrations of medical devices of the firm under rule 10(6) & 20 of Medical Devices Rules, 2017 and to issue showcause notice/personal hearing notice for next meeting of MDB.
2.	M/s Analytical Measuring system (Pvt) Ltd, Office/Godown: AMH	26-05-2024	03-07-2025	The board observed that the firm has applied for renewal of license even after expiry of one year grace period given in the medical devices rules 2017 (Rule 7(5) of Medical Devices Rules 2017) therefore it

	<p>House 14-C, main sehar , commercial avenue , lane no. 4, Khayaban e sehar, DHA, Phase VII , Karachi</p> <p>ELI No. 00413</p>			<p>was decided to declare the license invalid. Accordingly, the Board decided to initiate the proceedings for cancellation or suspension of the licence and enlistments and registrations of medical devices of the firm under rule 10(6) & 20 of Medical Devices Rules, 2017 and to issue showcause notice/personal hearing notice for next meeting of MDB.</p>
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Item No. II (A): REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT/ LOCAL PRODUCTS.

Evaluator: Saadat Ali Kha (Deputy Director)

CASES RECEIVED ON CASE MANAGEMEMTN SYSTEM:

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p>M/S Medi Health Services Address: 1st Floor, 16/E, Mehta Street, Temple Road, Lahore ELI-00180</p> <p>R&I Details: 26th July, 2022</p> <p>Fee Challan No.: 384671997616 Dated: 15th July, 2022</p>	<p>Bioland Technology Ltd. Address: No. A6B7, Block G, Shang Rong Industrial Park, Boalong 5th Road, Long Gang, 518116, Shenzhen, China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 21-07-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 02-09-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-01-2027</p>	<p>Fast Lab Blood Pressure Monitor. Applied as: Set Class: B Shelf Life: 24 months Models/Code/sizes: 2008 A221-2</p>	<p>Approved as per the data available for 510(k) Premarket Notification by USFDA.</p>

	<ul style="list-style-type: none"> • CE certificate (Production QA): <p>Type: Scan copy of non-notarized copy. Validity: 26-5-2024. With extension letter.</p> <p>The firm has submitted online link of USFDA for 510(k) Premarket Notification dated 26-01-2022. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202934</p>			
2.	<p>M/S Royal Medical Address: Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi ELI-00691 R&I Details: 22nd April, 2025 Fee Challan No.: 4758574886 Dated: 15th April, 2025</p>	<p>M/S QualiMed Innovative Medizinprodukte GmbH Address of Manufacturer: Boschstraße 16, 21423 Winsen, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy Issued By: Germany</p> <p>Validity: 31-12-2028</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy Validity: 01-08-2025</p> <ul style="list-style-type: none"> • CE certificate: <p>Type: Scan copy of non-notarized copy. Validity: 26-5-2024. With extension letter.</p>	<p>TsunaMed- EMAX Aspiration Catheter</p> <p>Class: D Shelf life: 3 years</p> <p>Codes/sizes: VX6HO5, VX6H15, VX6H13, VX7H13, VX7H15, VX6H13B, VX6H15B, VX6HO5B, VX7H13B, VX7H15B</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied products & if justified family fee as per current SRO will also be required. 2. Valid notarized ISO 13485
3.	<p>M/S Royal Medical Address: Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi</p>	<p>M/S Shenzhen Antmed Co., Ltd.</p> <p>Address of Manufacturer: 18 Jinhui Ave., Pingshan New District, Shenzhen 518122, China.</p>	<p>ANTMED-Disposable Pressure Transducer</p> <p>Class: C Shelf life: 5 years</p> <p>Codes/sizes:</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified

	<p>ELI-00691</p> <p>R&I Details: 22nd April, 2025 Fee Challan No.: 4758574886 Dated: 15th April, 2025</p>	<p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 17-02-2030</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of Apostille & notarized copy.</p> <p>Issued By: Drug Supervision (as translated by Google through online) China</p> <p>Validity: 26-10-2025</p> <p>• ISO 13485:</p> <p>Type: Scan copy of notarized copy</p> <p>Validity: 30-10-2026</p> <p>EU QMS certificate (MDR) :</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity: 05-02-2029.</p>	<p>PT-01, PT-012, PT-013, PT-02, PT-022, PT-023, PT-03, PT-032, PT-033.</p>	<p>family fee as per current SRO will also be required.</p> <p>2. Valid notarized & Embassay Attested FSC from country of origin issued by the concerned regulatory authority or FSC from any reference country.</p>
4.	<p>M/S Royal Medical</p> <p>Address: Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi</p> <p>ELI-00691</p> <p>R&I Details: 22nd April, 2025 Fee Challan No.: 501445524411 Dated: 15th April, 2025</p>	<p>M/S Shenzhen Antmed Co., Ltd.</p> <p>Address of Manufacturer: 18 Jinhui Ave., Pingshan New District, Shenzhen 518122, China.</p> <p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 17-02-2030</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of Apostille & notarized copy.</p> <p>Issued By: Drug Supervision (as translated by Google through online) China</p> <p>Validity: 26-10-2025</p> <p>• ISO 13485:</p> <p>Type: Scan copy of notarized copy</p> <p>Validity: 30-10-2026</p>	<p>ANTMED- Manifold</p> <p>Class: B</p> <p>Shelf life: 3 years</p> <p>Codes/sizes:</p> <p>MD-M-1, MD-M-2, MD-M-3, MD-M-4, MD-L-1, MD-L-2, MD-L-3, MD-L-4</p>	<p>Deferred for submission of the followings:</p> <p>1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized & Embassay Attested FSC from country of origin issued by the concerned regulatory authority or FSC from any reference country.</p>

		EU QMS certificate (MDR) : Type: Scan copy of notarized copy. Validity: 05-02-2029.		
5.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)	Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404	Chiba Biopsy Needle Biopsy Needle Class: B Applied as: Family Shelf life: 5 years Codes: DCHN-18-10.0 DCHN-18-10.0-U DCHN-18-15.0 DCHN-18-15.0-SUGAI-050987 DCHN-18-15.0-U DCHN-18-20.0 DCHN-18-20.0-U DCHN-19UT-10.0 DCHN-19UT-15.0 DCHN-19UT-5.0 DCHN-20-10.0 DCHN-20-15.0 DCHN-20-15.0-U DCHN-20-20.0 DCHN-20-20.0-U DCHN-21-15.0 DCHN-21-15.0-SUGAI-050987 DCHN-21-15.0-U DCHN-21-20.0 DCHN-21-65.5-U DCHN-22-10.0 DCHN-22-10.0-U DCHN-22-15.0 DCHN-22-15.0-U DCHN-22-20.0 DCHN-22-20.0-U DCHN-22-25.0 DCHN-22-5.0 DCHN-22-5.0-U DCHN-23-15.0 DCHN-23-5.0-U DCHN-25-15.0 DCHN-25-5.0-U	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA.
6.	M/s Verizon	Cook Incorporated	Advance 14LP Low Profile	Deferred for submission of

	<p>Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 03/09/2024</p> <p>Fee Challan No: 37616543336</p> <p>PKR: 25,030/-</p>	<p>Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG)</p> <p>Type: Scan copy of Apostille & notarized copy.</p> <p>Issued By: USFDA</p> <p>Validity: 23-04-2026</p> <p>• ISO 13485:</p> <p>Type: Scan copy of notarized copy</p> <p>Validity: 14-05-2027</p> <p>EC (FQA) certificate (MDR) :</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity: 28-05-2024.</p> <p>Extension letter attached.</p>	<p>PTA Balloon Dilatation Catheter. Angioplasty Balloon Catheters</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes:</p> <p>PTAX4-14-170-2.5-12 PTAX4-14-170-2.5-16 PTAX4-14-170-2.5-2 PTAX4-14-170-2.5-20 PTAX4-14-170-2.5-4 PTAX4-14-170-2.5-6 PTAX4-14-170-2.5-8 PTAX4-14-170-2-12 PTAX4-14-170-2-16 PTAX4-14-170-2-2 PTAX4-14-170-2-20 PTAX4-14-170-2-4 PTAX4-14-170-2-6 PTAX4-14-170-2-8 PTAX4-14-170-3-12 PTAX4-14-170-3-16 PTAX4-14-170-3-2 PTAX4-14-170-3-20 PTAX4-14-170-3-4 PTAX4-14-170-3-6 PTAX4-14-170-3-8 PTAX4-14-170-4-12 PTAX4-14-170-4-16 PTAX4-14-170-4-2 PTAX4-14-170-4-20 PTAX4-14-170-4-4 PTAX4-14-170-4-6 PTAX4-14-170-4-8.</p>	<p>the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.
7.	<p>M/s Verizon</p> <p>Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 23/08/2024</p> <p>Fee Challan No: 53862296224</p>	<p>Cook Incorporated</p> <p>Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 29-11-2025</p>	<p>Advance 35LP Low Profile PTA Balloon Dilatation Catheter. Angioplasty Balloon Catheters</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA. 3. Justification of Class as

PKR: 25,030/-	<p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026 • ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Codes:</p> <p>PTA5-35-135-10-10.0 PTA5-35-135-10-12.0 PTA5-35-135-10-14.0 PTA5-35-135-10-2.0 PTA5-35-135-10-3.0 PTA5-35-135-10-4.0 PTA5-35-135-10-6.0 PTA5-35-135-10-8.0 PTA5-35-135-12-10.0 PTA5-35-135-12-12.0 PTA5-35-135-12-14.0 PTA5-35-135-12-2.0 PTA5-35-135-12-4.0 PTA5-35-135-12-8.0 PTA5-35-135-3-10.0 PTA5-35-135-3-12.0 PTA5-35-135-3-14.0 PTA5-35-135-3-17.0 PTA5-35-135-3-2.0 PTA5-35-135-3-20.0 PTA5-35-135-3-4.0 PTA5-35-135-3-6.0 PTA5-35-135-3-8.0 PTA5-35-135-4-10.0 PTA5-35-135-4-12.0 PTA5-35-135-4-14.0 PTA5-35-135-4-17.0 PTA5-35-135-4-2.0 PTA5-35-135-4-20.0 PTA5-35-135-4-4.0 PTA5-35-135-4-6.0 PTA5-35-135-4-8.0 PTA5-35-135-5-10.0 PTA5-35-135-5-12.0 PTA5-35-135-5-14.0 PTA5-35-135-5-17.0 PTA5-35-135-5-2.0 PTA5-35-135-5-20.0 PTA5-35-135-5-4.0 PTA5-35-135-5-6.0 PTA5-35-135-5-8.0 PTA5-35-135-6-10.0 PTA5-35-135-6-12.0 PTA5-35-135-6-14.0 PTA5-35-135-6-17.0 PTA5-35-135-6-2.0 PTA5-35-135-6-20.0 PTA5-35-135-6-4.0 PTA5-35-135-6-6.0 PTA5-35-135-6-8.0 PTA5-35-135-7-10.0</p>	per MDR 2017 & accordingly revise its fee.
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		PTA5-35-135-7-12.0 PTA5-35-135-7-14.0 PTA5-35-135-7-17.0 PTA5-35-135-7-2.0 PTA5-35-135-7-20.0 PTA5-35-135-7-4.0 PTA5-35-135-7-6.0 PTA5-35-135-7-8.0 PTA5-35-135-8-10.0 PTA5-35-135-8-12.0 PTA5-35-135-8-14.0 PTA5-35-135-8-17.0 PTA5-35-135-8-2.0 PTA5-35-135-8-20.0 PTA5-35-135-8-4.0 PTA5-35-135-8-6.0 PTA5-35-135-8-8.0 PTA5-35-135-9-10.0 PTA5-35-135-9-12.0 PTA5-35-135-9-14.0 PTA5-35-135-9-2.0 PTA5-35-135-9-3.0 PTA5-35-135-9-4.0 PTA5-35-135-9-6.0 PTA5-35-135-9-8.0 PTA5-35-80-10-10.0 PTA5-35-80-10-12.0 PTA5-35-80-10-14.0 PTA5-35-80-10-2.0 PTA5-35-80-10-3.0 PTA5-35-80-10-4.0 PTA5-35-80-10-6.0 PTA5-35-80-10-8.0 PTA5-35-80-12-10.0 PTA5-35-80-12-12.0 PTA5-35-80-12-14.0 PTA5-35-80-12-2.0 PTA5-35-80-12-4.0 PTA5-35-80-12-8.0 PTA5-35-80-3-10.0 PTA5-35-80-3-12.0 PTA5-35-80-3-14.0 PTA5-35-80-3-17.0 PTA5-35-80-3-2.0 PTA5-35-80-3-20.0 PTA5-35-80-3-4.0 PTA5-35-80-3-6.0 PTA5-35-80-3-8.0 PTA5-35-80-4-10.0 PTA5-35-80-4-12.0 PTA5-35-80-4-14.0 PTA5-35-80-4-17.0 PTA5-35-80-4-2.0	
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		PTA5-35-80-4-20.0 PTA5-35-80-4-4.0 PTA5-35-80-4-6.0 PTA5-35-80-4-8.0 PTA5-35-80-5-10.0 PTA5-35-80-5-12.0 PTA5-35-80-5-14.0 PTA5-35-80-5-17.0 PTA5-35-80-5-2.0 PTA5-35-80-5-20.0 PTA5-35-80-5-4.0 PTA5-35-80-5-6.0 PTA5-35-80-5-8.0 PTA5-35-80-6-10.0 PTA5-35-80-6-12.0 PTA5-35-80-6-14.0 PTA5-35-80-6-17.0 PTA5-35-80-6-2.0 PTA5-35-80-6-20.0 PTA5-35-80-6-4.0 PTA5-35-80-6-6.0 PTA5-35-80-6-8.0 PTA5-35-80-7-10.0 PTA5-35-80-7-12.0 PTA5-35-80-7-14.0 PTA5-35-80-7-17.0 PTA5-35-80-7-2.0 PTA5-35-80-7-2.5 PTA5-35-80-7-20.0 PTA5-35-80-7-4.0 PTA5-35-80-7-6.0 PTA5-35-80-7-8.0 PTA5-35-80-8-10.0 PTA5-35-80-8-12.0 PTA5-35-80-8-14.0 PTA5-35-80-8-17.0 PTA5-35-80-8-2.0 PTA5-35-80-8-20.0 PTA5-35-80-8-4.0 PTA5-35-80-8-6.0 PTA5-35-80-8-8.0 PTA5-35-80-9-10.0 PTA5-35-80-9-12.0 PTA5-35-80-9-14.0 PTA5-35-80-9-2.0 PTA5-35-80-9-3.0 PTA5-35-80-9-4.0 PTA5-35-80-9-6.0 PTA5-35-80-9-8.0		
8.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg	Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA	Liver Access and Biopsy Needle Set Trans-jugular Set Class: B	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along

	<p>IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 03/09/2024 Fee Challan No: 14949940 PKR: 25,030/-</p>	<p>47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <ul style="list-style-type: none"> • ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 <p>EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes: LABS-100-01 LABS-100-J-01 LABS-200-01 LABS-200-J-01</p>	<p>with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>
9.	<p>M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 18/10/2024 Fee Challan No: 863152189 PKR: 31,030/-</p>	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <ul style="list-style-type: none"> • ISO 13485: 	<p>Ring Transjugular Intrahepatic Access Set Trans-jugular Set Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes: RTPS-100 RTPS-100-10.0.</p>	<p>Deferred for submission of the followings:</p> <p>1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>

		<p>Type: Scan copy of notarized copy Validity: 14-05-2027</p> <p>EC (FQA) certificate (MDR) :</p> <p>Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>		
10.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087) R&I Dated: 18/10/2024 Fee Challan No: 03571598 PKR: 31,030/-	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027</p> <p>EC (FQA) certificate (MDR) :</p> <p>Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Dilator Dilator</p> <p>Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes:</p> <p>JCD10.0-38-20 JCD11.0-38-20 JCD12.0-38-20 JCD13.0-38-30 JCD14.0-38-20 JCD16.0-38-20 JCD18.0-38-20 JCD20.0-38-20 JCD22.0-38-20 JCD24.0-38-20 JCD3.0-18-10 JCD4.0-18-10 JCD5.0-25-20 JCD5.0-35-20 JCD5.0-38-20 JCD5.5-18-15 JCD6.0-25-20 JCD6.0-35-20 JCD6.0-38-15 JCD6.0-38-20 JCD7.0-35-20 JCD7.0-38-20 JCD8.0-35-20 JCD8.0-38-15 JCD8.0-38-20 JCD9.0-35-11 JCD9.0-38-20</p>	<p>Deferred for submission of/ clarification of the following:</p> <ol style="list-style-type: none"> 1. The firm applied as family with multiple codes without family fee. 2. Justification of grouping is also required along with catalog. 3. LOA expired.
11.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg	Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA	<p>Neff Percutaneous Access Set with Hydrophilic Coating and Nitinol Wire Guide</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along

	<p>IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 10/10/2024</p> <p>Fee Challan No: 2728408681</p> <p>PKR: 31,030/-</p>	<p>47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 <p>EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Percutaneous access Set Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes: NPAS-100-RH-NT NPAS-104-RH-NT NPAS-104-RH-NT-JWG NPAS-105-RH-NT-U</p>	<p>with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>
12.	<p>M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 10/10/2024</p> <p>Fee Challan No: 2728408681</p> <p>PKR: 31,030/-</p>	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of 	<p>Neff Percutaneous Access Set with Hydrophilic Coating and Nitinol Wire Guide</p> <p>Percutaneous access Set Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 3 years</p> <p>Codes: NPAS-100-RH-NT NPAS-104-RH-NT NPAS-104-RH-NT-JWG NPAS-105-RH-NT-U</p>	<p>Deferred for submission of the followings:</p> <p>1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>

		<p>notarized copy Validity: 14-05-2027</p> <p>EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>		
13.	<p>M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 18/10/2024 Fee Challan No: 426079385 PKR: 31,030/-</p>	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 <p>EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Trocars Needle Biopsy access Needle Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 5 years</p> <p>Codes: DTN-18-10.0 DTN-18-15.0 DTN-18-15.0-LS DTN-18-15.0-U DTN-18-20.0 DTN-18-20.0-U DTN-19-10.0 DTN-21-15.0-U</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA.
14.	<p>M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated:</p>	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of</p>	<p>Roadrunner Uniglide Hydrophilic Wire Guide Vascular Wire Guides Class: B</p> <p>Applied as: Family</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be

	<p>18/10/2024 Fee Challan No: 4835783109 PKR: 31,030/-</p> <p>notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA</p> <p>Validity: 23-04-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027</p> <p>EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.</p>	<p>Shelf life: 3 years</p> <p>Codes:</p> <p>HPW-18-150 HPW-18-180 HPW-18-260 HPW-18-320 HPW-18-80 HPW-35-150 HPW-35-180 HPW-35-260 HPW-35-320 HPW-35-80 HPWA-18-150 HPWA-18-180 HPWA-18-260 HPWA-18-320 HPWA-18-80 HPWA-35-150 HPWA-35-180 HPWA-35-260 HPWA-35-320 HPWA-35-80 HPWAS-35-150 HPWAS-35-180 HPWAS-35-260 HPWAS-35-320 HPWAS-35-80 HPWS-35-150 HPWS-35-180 HPWS-35-260 HPWS-35-320 HPWS-35-80</p>	<p>required.</p> <p>2. Valid notarized LOA.</p> <p>3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>	
15.	<p>M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087)</p> <p>R&I Dated: 18/10/2024 Fee Challan No: 2912001371 PKR: 31,030/-</p>	<p>Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025</p> <p>Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA</p>	<p>Percutaneous Entry Thin Wall Needle One Part Entry access Needle Class: B</p> <p>Applied as: Family</p> <p>Shelf life: 5 years</p> <p>Codes:</p> <p>BSDN-18-7.0 BSDN-18-9.0 BSDN-19UT-7.0 SDN-18-15.0 SDN-18-5.0 SDN-18-5.0-UM SDN-18-7.0 SDN-18-7.0-U SDN-18-7.0-UM</p>	<p>Deferred for submission of the followings:</p> <p>1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required.</p> <p>2. Valid notarized LOA.</p> <p>3. Justification of Class as per MDR 2017 & accordingly revise its fee.</p>

		Validity: 23-04-2026 <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.	SDN-18-9.0 SDN-19UT-7.0 SDN-20-2.5 SDN-20-4.0 SDN-20-5.0-UM SDN-20-7.0-UM SDN-21-15.0-U SDN-21-2.5 SDN-21-20.0 SDN-21-4.0 SDN-21-4.0-U SDN-21-5.0-UM SDN-21-7.0 SDN-21-7.0-U SDN-21-7.0-UM	
16.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087) R&I Dated: 20/11/2024 Fee Challan No: 693255917695 PKR: 31,030/- LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025 Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026 <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.	Rosen Curved Wire Guide Vascular Wire Guides Class: B Applied as: Family Shelf life: 5 years Codes: THSCF-35-145-1.5-ROSEN THSCF-35-180-1.5-ROSEN THSCF-35-220-1.5-ROSEN THSCF-35-260-1.5-ROSEN THSCF-35-80-1.5-ROSEN	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.	
17.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg	Cook Incorporated Address: 750 Daniels Way, Bloomington, IN USA 47404	Roadrunner PC Wire Guide The Firm Vascular Wire Guides	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along

	IV, Lahore Pakistan. (ELI-00087) R&I Dated: 20/11/2024 Fee Challan No: 55701185814 PKR: 31,030/-	47404 LOA Type: Scan copy of notarized copy. Validity date: 29-11-2025 Certificate to Foreign Government (CFG) Type: Scan copy of Apostille & notarized copy. Issued By: USFDA Validity: 23-04-2026 • ISO 13485: Type: Scan copy of notarized copy Validity: 14-05-2027 EC (FQA) certificate (MDR) : Type: Scan copy of notarized copy. Validity: 28-05-2024. Extension letter attached.	Class: B Applied as: Family Shelf life: 5 years Codes: RPC-35-145 RPC-35-180 RPC-35-260 RPC-35-80	with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized LOA. 3. Justification of Class as per MDR 2017 & accordingly revise its fee.
18.	M/s Verizon Address: 60-D F.C.C Zahoor Elahi Road, Gulberg IV, Lahore Pakistan. (ELI-00087) R&I Dated: 24/02/2025 Fee Challan No: 97266907 PKR: 62,030/-/-	Beijing LidaKang Technology Co., Ltd. Address as per Form-7A: No. 19 Dongying Road, Zhaofeng Industrial Zone, Zhaoquanying Town, Shunyi District, 101300 Beijing, China. Address as per FSC: 3 rd Floor, Building No. 3, No. 19 Dongying Road, Zhaofeng Industrial Zone, Zhaoquanying Town, Shunyi, Beijing, China. LOA Type: Scan copy of notarized copy. Validity date: 11-10-2027	Revision Knee Prosthesis System Knee Prosthesis Class: D Applied as: System Shelf life: 5 years Codes: 52001-1L 52001-2L 52001-3L 52001-4L 52001-5L 52001-6L 52001-1R 52001-2R 52001-3R 52001-4R 52001-5R	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Valid notarized ISO 13485, EC (FQA) & EC (Design Examination Certificate). 3. Justification of difference in address of manufacturer in Form-7A & other documents. 4. Valid FSC of country of origin issued by the concerned Regulatory Authority or FSC of any reference country.

	<p>Certificate for Exportation of Medical Products</p> <p>Type: Scan copy of Apostille & notarized copy.</p> <p>Issued By: Not clear</p> <p>Validity: 23-04-2026</p> <p>• ISO 13485:</p> <p>Type: Scan copy of notarized copy</p> <p>Validity: 12-12-2025</p> <p>EC (FQA) certificate (MDR) :</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity: 27-05-2024.</p> <p>EC (Design Examination) certificate:</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity: 27-05-2024.</p>	52001-6R 52002-1 52002-2 52002-3 52002-4 52002-5 52002-6 52003-1-9 52003-1-11 52003-1-13 52003-1-15 52003-1-18 52003-1-21 52003-2-9 52003-2-11 52003-2-13 52003-2-15 52003-2-18 52003-2-21 52003-3-9 52003-3-11 52003-3-13 52003-3-15 52003-3-18 52003-3-2 52003-4-9 52003-4-11 52003-4-13 52003-4-15 52003-4-18 52003-4-21 52003-5-9 52003-5-11 52003-5-13 52003-5-15 52003-5-18 52003-5-21 52003-6-9 52003-6-11 52003-6-13 52003-6-15 52003-6-18 52003-6-21 52004-10-80 52004-12-80 52004-14-80 52004-16-80 52004-18-80 52004-10-120 52004-12-120 52004-14-120 52004-16-120 52004-18-120	.
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		52010-15-30 52011-2-25 52011-4-25 52011-6-25 52005-1-5 52005-2-5 52005-3-5 52005-4-5 52005-5-5 52005-6-5 52005-1-10 52005-2-10 52005-3-10 52005-4-10 52005-5-10 52005-6-10 52006-1-5 52006-1-5 52006-2-5 52006-3-5 52006-4-5 52006-5-5 52006-6-5 52006-1-10 52006-2-10 52006-3-10 52006-4-10 52006-5-10 52006-6-10 52007-1L-5 52007-2L-5 52007-3L-5 52007-4L-5 52007-5L-5 52007-6L-5 52007-1L-10 52007-2L-10 52007-3L-10 52007-4L-10 52007-5L-10 52007-6L-10 52007-1R-5 52007-2R-5 52007-3R-5 52007-4R-5 52007-5R-5 52007-6R-5 52007-1R-10 52007-2R-10 52007-3R-10 52007-4R-10 52007-5R-10 52007-6R-10	
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			Instruments: W0910008 W0910009 W0910010	
19.	M/S Universal Dental Pvt. Ltd, 17- Mcleod Road, Lahore. ELI-00071 R & I Details: Dossier Submission Date : 24-06-2025 Fee Challan: No: 62264114 Dated: 23-06-2025.	ZOGEAR Medical Co., Ltd. Address : No 166 Industrial Concentration Area Dayi Town Yizheng City , Jiangsu Province , China LOA Type: Scan copy of notarized copy. Validity date: 01-05-2027 Certificate for Exportation of Medical Products Type: Scan copy of non-notarized copy. Issued By: Not clear Validity: 21-12-2025 • ISO 13485: Type: Scan copy of notarized copy Validity: 06-05-2026	Dental Alginate Impression Material (Alginate Impression Material) Class: A Applied as: Single Shelf life: 30 months Codes: TM029-1 TM029-2	Deferred for submission of the followings: 1. Justification of grouping as per MDR 2017 along with submission of catalog for the applied product & if justified family fee as per current SRO will also be required. 2. Revised Form-7A dully signed by the authorized person. 3. Valid FSC of country of origin issued by the concerned Regulatory Authority with applied codes or FSC of any reference country with applied codes.
20.	M/S Global Marketing Services. (ELI-00109) R&I Dated: 2/06/2025 Fee Challan No: 367485449521 PKR: 62,000/-	Biomerieux, Inc 100 Radolphe Street Durham, North Carolina 27712-USA. LOA Type: Scan copy of notarized copy. Validity date: 31-03-2026 FSC Type: Scan copy of Apostille & notarized copy. Issued By: CCI Paris Issuance Date: 02-07-2025 Validity: Not mentioned	BacT/ALERT® FA Plus Culture Bottles Class: C Applied as: Single Shelf life: 12 months Codes: 410851	Approved.

	<ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy Validity: 17-12-2027</p>		
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Item No. II (B): REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

Evaluator: Rana Ahsan Ul Haq Attar (Deputy Director)

DEFERRED CASES AGENDA:

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<p>M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore</p> <p>ELI-00147</p> <p>Date of R & I 27-06-2025</p> <p>Fee: 6,000/- Slip # 386760094</p>	<p>Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China</p> <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostilled Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: 	<p>Brand name: BRUN Ballon Inflation Device Set</p> <p>Generic Name: Balloon Inflation Device Set</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Code/sizes (as per FSC & Application): BR-BID-130A, BR-BID-130AL, BR-BID-II26A, BR-BID-II30A, BR-BID-III30A, BR-BID-130B, BR-BID-II2BA, BR-BID-130BL, BR-BID-III30B, BR-BID-130C, BR-BID-130CL, BR-BID-II26C, BR-BID-II30C, BR-BID-III30C, BR-BID-130D, BR-BID-II26D, BR-BID-II30D, BR-BID-130E, BR-BID-130EL, BR-BID-II26E, BR-BID-II30E, BR-BID-III30E, BR-BID-130F, BR-BID-II26F, BR-BID-II30F, BR-BID-III30F, BR-BID-130L, BR-BID-II26, BR-BID-III30, BR-BID-140, BR-BID-140L, BR-BID-II30, BR-BID-IV30</p>	Approved subject to submission of the fee for extra codes.

		Type: Copy Notarization: By CCPIT Validity: 12-09-2028	Service Life: 3 Years	
2.	M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R & I 27-06-2025 Fee: 31,000/- Slip # 3467162744	Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 	Brand name: BRUN Manifolds Generic Name: Manifolds Applied as: Single Class: B Code/sizes (as per FSC & Application): Service Life: 3 Years	Approved.
3.	M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R & I 27-06-2025 Fee: 31,000/- Slip # 98205538650	Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China <ul style="list-style-type: none"> • LOA: 	Brand name: BRUN Guidewires Generic Name: Guidewires Applied as: Single Class: B Code/sizes (as per FSC &	Approved subject to submission of fee for the extra codes.

	<p>Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027</p> <p>• FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028</p> <p>• ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026</p> <p>• CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028</p>	<p>Application:</p> <p>Firm has submitted the following codes</p> <p>BR-GWC025-150J, BR-GWC025-150S, BR-GWC025-260S, BR-GWC025-260J, BR-GWC032-150S, BR-GWC032-150J, BR-GWC035-150S, BR-GWC035-150J, BR-GWC038-150S, BR-GWC038-150J, BR-GWC035-260S, BR-GWC035-260J, BR-GWC038-260S, BR-GWC038-260J, BR-NGW018-45J, BR-NGW021-45J, BR-NGW025-45J, BR-NGW018-60J, BR-NGW021-60J, BR-NGW025-60J, BR-NGW021-150S, BR-NGW021-150J, BR-NGW025-150S, BR-NGW025-150J, BR-NGW032-45J, BR-NGW035-45J, BR-NGW038-45J, BR-NGW032-60J, BR-NGW035-60J, BR-NGW038-60J, BR-NGW032-150J, BR-NGW035-150J, BR-NGW038-150J.</p> <p>Service Life: 3 Years</p>		
4.	<p>M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore</p> <p>ELI-00147</p> <p>Date of R & I 27-06-2025</p> <p>Fee: 31,000/- Slip # 5905805985</p>	<p>Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China</p> <p>• LOA: Type: Copy Notarization: By</p>	<p>Brand name: BRUN Connecting Tubings (Pressure Extension Line)</p> <p>Generic Name: Connecting Tubes</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per FSC & Application):</p>	Approved subject to submission of the fee for extra codes.

		<p>CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027</p> <ul style="list-style-type: none"> • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 	<p>-</p> <p>Now firm has applied following codes only.</p> <p>BR-CT1.80-90, BR-CT1.80-120, BR-CT1.80-150, BR-CT2.00-90, BR-CT2.00-120, BR-CT2.00-150, BR-CT2.70-90, BR-CT2.70-120, BR-CT2.70-150, BR-CT3.00-90, BR-CT3.00-120, BR-CT3.00-150, BR-CT3.65-90, BR-CT3.65-120, BR-CT3.65-150, BR-CT3.20-90A, BR-CT3.20-120A, BR-CT3.20-150A, BR-CT3.20-180A, BR-CT3.20-200A, BR-CT3.65-90B, BR-CT3.65-120B, BR-CT3.65-150B, BR-CT3.65-180B, BR-CT3.65-200B,</p> <p>Service Life: 3 Years</p>	
5.	<p>M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore</p> <p>ELI-00147</p> <p>Date of R& I 27-06-2025</p> <p>Fee: 31,000/- Slip # 54732192</p>	<p>Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Enterpreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China</p> <ul style="list-style-type: none"> • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 	<p>Brand name: BRUN Introducer Sheath Set</p> <p>Generic Name: Introducer Sheath</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per FSC & Application):</p> <p>BR-RA0407, BR-RA0507, BR-RA0607, BR-RA0707, BR-RA0411, BR-RA0511, BR-RA0611, BR-RA0711, BR-RA0416, BR-RA0516, BR-RA0616, BR-RA0716, BR-RA0423, BR-RA0523, BR-RA0623, BR-RA0723, BR-FA0409, BR-FA0511</p>	Approved subject to submission of the fee for extra codes.

		<ul style="list-style-type: none"> • CE - EU Certificate: <p>Type: Copy Notarization: By CCPIT Validity: 12-09-2028</p>	BR-FA0611, BR-FA0711, BR-FA0811 BR-FA0911, BR-FA1011, BR-FA1211 BR-FA0419, BR-FA0523, BR-FA0623 BR-FA0723, BR-FA0823, BR-FA0923 BR-FA1023, BR-FA1223.	
6.	M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R & I 27-06-2025 Fee: 31,000/- Slip # 871539410213	<p>Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China</p> <ul style="list-style-type: none"> • LOA: <p>Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027</p> <ul style="list-style-type: none"> • FSC: Netherlands <p>Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028</p> <ul style="list-style-type: none"> • ISO – Certificate: <p>Type: Copy Notarization: By CCPIT Validity: 14-10-2026</p> <ul style="list-style-type: none"> • CE - EU Certificate: <p>Type: Copy Notarization: By CCPIT Validity: 12-09-2028</p>	<p>Brand name: BRUN Angiography Syringes and Accessories</p> <p>Generic Name: Angiography Syringes and Accessories</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per FSC & Application): BR-AS-CT-200-A01, BR-AS-CT-200/200-A02, BR-AS-CT-200-A03, BR-AS-CT-200/200-A04, BR-AS-CT-190-A05, BR-AS-CT-200-B01, BR-AS-CT-200/200-B02, BR-AS-CT-200-C01, BR-AS-CT-100/200-D02, BR-AS-CT-100-D01, BR-AS-CT-200-D03, BR-AS-CT-200-E01, BR-AS-CT-200/200-E02, BR-AS-CT-190/190-A06, BR-AS-CT-200/200-A08, BR-AS-DSA-150-A01, BR-AS-DSA-200-A03, BR-AS-DSA-60-A05, BR-AS-DSA-150-B01, BR-AS-DSA-150-B03, BR-AS-CT-200/200-C02, BR-AS-CT-100/100-D04, BR-AS-CT-200/200-D06, BR-AS-CT-60/200-D08,</p>	Approved following codes: BR-AS-CT-200-A01, BR-AS-CT-200-A03, BR-AS-CT-190-A05, BR-AS-CT-200-B01, BR-AS-CT-200-C01, BR-AS-CT-100-D01, BR-AS-CT-200-D03, BR-AS-CT-200-E01,

			BR-AS-MRI-65-E01, BR-AS-MRI-65/65-E02, BR-AS-DSA-130-A07, BR-AS-DSA-150-A09, BR-AS-MRI-65/65-A02, BR-AS-MRI-115/115-A04, BR-AS- MRI-65/115-A06, BR-AS-MRI-60-B01, BR-AS-MRI-60/60-B02, BR-AS-DSA-120-D01, BR-AS-MRI-60-D01, BR-AS-MRI-60/60-D02, BR-AS-MRI-65/200-E04. Service Life: 3 Years	
7.	Sonoscape Medical Corporation Pakistan, Office No. FF-21, 1st Floor Hayat Arsalah Heights, Commercial Block, CBR Town Phase 1, Islamabad (ELI-01301) R&I Date: 30-06-2025 Fee: 31,000/- Slip # 4879255436.	Name of Manufacturer: Sonoscape Medical Corporation, Address: Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Sub district, Nanshan District, Shenzhen, 518057, Guangdong P.R. China LOA: Type: Copy Notarization: No Validity: 31-12-2027 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 16-03-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 22-04-2028 Copy of EU Quality Management Certificate submitted.	Brand Name: Digital Color Doppler Ultrasound Diagnostic Machine Generic Name: Model: P10 Applied as: System Class: B Models/Code/sizes (as per FSC & application P10 Shelf life: --	Approved.

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