

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

DECISIONS OF 98TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)

HELD ON 04-09-2025

98th 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 04th September, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	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.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
8.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)
9.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through

		videolink)
10.	Asif Jalil, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Zia Ullah	Deputy Director-V
6.	Mr. Muhammad Ashfaq	Deputy Director-VI
7.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
8.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
9.	Mr. Muhammad Amin	Deputy Director-IX

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants.

Import License Agenda

Evaluator Name: Muhammad Amin (Evaluator-IX)

New Applications

S.#	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: Enhance Healthcares Pvt Ltd Office Address: Office 237/B 1st Floor Railway Officer Colony Walton Road Lahore Cantt Godown Address: House 237- B , First Floor Railway Officer Colony Walton Road Lahore Cantt, Lahore Challan No: 17703838 /- Fee: Rs 25000 /- Date of Submission: 06 August 2025	Name: Rubaila Ejaz CNIC No: 3520283583466 Qualification: Pharm D Experience: Branch Pharmacist (from January 2023 to February 2024)	Designation: CEO Name: Imran Hakim CNIC No: 3520112672231 Address: House NO. E-841 Peer Colony no. 2 , gulshadia Masjid Walton Cantt. Lahore. Designation: Director Name: Jawad Mustjab Ahmed Khan CNIC No: 3520296509053 Address: House No 6, Bokahri Street Rustam Park Near	Rejected. The board considered the recommendation of inspector and rejected establishment license to import for not complying with the conditions of license under Medical Devices Rules, 2017 and DRAP Act, 2012

	Tracking ID: MDMC-250806-12022		Mor Samanabad Multan Road Lahore	
2	Name of Establishment: Dental Providers - DENPRO Office Address: SmileUp Dental & Aesthetic Clinic, Main Bhimber Road, Kotla Arab Ali Khan, Gujrat Godown Address: SmileUp Dental and Aesthetic Clinic, Bhimber road, Mian chohan, Kotla arab ali khan, Gujrat Challan No: 558912532974 /- Fee: Rs 25000 /- Date of Submission: 22 July 2025 Tracking ID: MDMC-250722-10653	Name: Saad Ghaus CNIC No: 3540439459541 Qualification: BS Microbiology M.Phil Experience: Participation (from December 2023 to December 2023)	Designation: CEO Name: Muhammad Ghias Ismat CNIC No: 3420151661851 Address: Post Office Peroshah, Tehsil and District Gujrat Designation: Partner Name: Muhammad Muizz Gul CNIC No: 3230389083233 Address: Ward no 4 near girls college road Kot Addu Designation: Partner Name: Muhammad Taimoor Younas CNIC No: 8110279679693 Address: Ward no 1 Muhallah rasoolpur colony Bhimber	Approved
3	Name of Establishment: MEDICARE IMPEX PRIVATE LIMITED Office Address: PLOT NO. 17-D, COMMERCIAL MARKET, 4TH FLOOR, PHASE XII, DHA EME SECTOR, Godown Address: Plot No. 17-D, Commercial Market 4th-Floor, Phase XII, DHA EME Sector , Multan Road , lahore,Pakistan, Lahore	Name: Muhammad Umar Farooq CNIC No: 3510267426447 Qualification: Microbiologist Experience: Microbiologist (from July 2021 to N/A)	Designation: CEO Name: HAMZA SAJJAD CNIC No: 3520286084973 Address: HOUSE NO. 350, BLOCK E, DHA EME SECTOR, MULTAN ROAD, LAHORE, PUNJAB, PAKISTAN. Designation: Director Name: SAJJAD AHMAD	Approved

Challan No: Rs 446166295000 /- Fee: Rs 26100 /- Date of Submission: 07 August 2025 Tracking ID: MDMC-250807- 12116	CNIC No: 3520229775921 Address: HOUSE NO. 350, BLOCK E, DHA EME SECTOR, MULTAN ROAD, LAHORE, PUNJAB, PAKISTAN.
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Local Manufacturer License Agenda

Evaluator Name: Muhammad Amin (Evaluator-IX)

New Applications

S.#	Name of Establishment along with address	Details of Qualified Technical Person	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: ARSONS PHARMACEUTICAL INDUSTRIES (PVT) LIMITED (UNIT-II) Office Address: 2 KM LAKHAN K ROAD, OFF MULTAN ROAD, TEHSIL PATTOKI, DISTRICT KASUR- LAHORE Factory Address: 2 KM LAKHAN K ROAD, OFF MULTAN ROAD, TEHSIL PATTOKI, DISTRICT KASUR, Lahore Challan No: Rs 35881440382 Fee: Rs 128500 /- Date of Submission: 06 August 2025 Tracking ID: MDMC- 250806-11970	Production Incharge: Name: Miss Maliha Asmatullah CNIC No: 3510222653584 Qualification: Miss Maliha Asmatullah Experience: Production Manager (from December 2024 to N/A) Quality Control Incharge: Name: Miss Sonia Sabir CNIC No: 3510337827592 Qualification: Miss Sonia Sabir Experience: Quality Control Incharge (from November 2024 to N/A)	Designation: CEO Name: Doctor Muhammad Arshad Javed CNIC No: 3520296503269 Address: H. No, 135-F, Sector EME, DHA Multan Road, Lahore, Lahore City, District Lahore Pakistan Designation: Director Name: Muhammad Shahid Mukhtar CNIC No: 3520202200385 Address: H. No 42, Block Indus Green Forts-2 Form Housing Scheme Lahore Designation: Director Name: Muhammad Ali Arshad CNIC No:	Deferred. The Board considered the request of the firm to delay inspection due to heavy rains in inspection region and acceded to request due to ongoing weather conditions. The applicant shall inform inspection panel as soon as the conditions get normal and accordingly return the application to DRAP.

			9150601288617 Address: H. No, 135-F EME Sector DHA Multan Road, Lahore, Lahore City, District Lahore Pakistan.	
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Product Agenda

LOCAL MANUFACTURER AGENDA FOR CLASS B MEDICAL DEVICES

Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

New Applications

Sr.No	Name & Address of Establishment	Name of Medical Devices with Class, Shelf life, codes, Size	Minutes/Decision
1	Name and address of the manufacturer along with ELM no: ELM-0102 Monitor Health International (Pvt) Ltd , Head office: Office 1010, 10th Floor, Haly Tower, DHA Phase II, Lahore, Lahore Name of Approved facility/section: N/A, Fee Challan No.: 048647899911 Rs: 26100 Date of submission: 06 August 2025 Tracking ID: MDMR-20250806-00032	Brand name: Monitor Health Hypodermic needle Generic Name: Hypodermic needle Class B Device/Accessories Name: Hypodermic Needles Shelf life/service life: 60 Months. Sizes/Codes: UUDS JSNR 16G,18G,19G,20G,21G,22G,2 3G,24G,25G,26G,27G,28G,29 G,30G Specify grouping: Single	Approved with shelf life 2 years

IMPORT AGENDA FOR CLASS A MEDICAL DEVICES

Evaluator Name: Waqar Ahmed (Evaluator-II)

New Applications

S#	Name & Address of	Name & Address of Legal Manufacturer,	Name of Medical Device/ Shelf	Minutes/Decisi
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	Importer	Manufacturer, Manufacturing Site	Life/ Codes/ Sizes (if any)	on
1	<p>Mian Enterprises</p> <p>Office No. UG-400 Deans Trade Center Islamia Road, Peshawar</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 89726953</p> <p>Date of submission: 30 July 2025</p> <p>Tracking ID: MDMR- 20250730-00010</p>	<p>Manufacturer</p> <p>Tecfen Medical</p> <p>Address: 6100 Hollister Avenue, Building 3, Unit 3A/3B, Santa Barbara, California 93117, USA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-10</p> <p>Validity Date: 2027-08-09</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-03-29</p> <p>Validity Date: 2026-03-28</p> <p>Issuing Authority: USFDA</p> <p>Attestation Status: Apostiled</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-02</p> <p>Notarization Status: Notarized, by state of California</p>	<p>Brand Name:</p> <p>Tecfen Medical PVA Eye Spears</p> <p>Generic Name:</p> <p>PVA Eye Spears</p> <p>Class A</p> <p>Device/Accessori es Name: PVA Eye Spears</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): QPV091N/25 Foils (1 x 5) = 125 pcs per Box</p> <p>Specify grouping: Single</p> <p>Storage condition: 0°C to 37°C</p>	Approved
2	<p>NI Healthcare products (Pvt) Ltd</p> <p>Office #A Unit 10 Survey No. 263 Damlotte Road, District Malir ,Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 72367428834</p> <p>Date of submission: 01 August 2025</p> <p>Tracking ID: MDMR- 20250801-00004</p>	<p>Manufacturer</p> <p>MCREAT (GUANGZHOU) BIO- TECH CO.,LTD</p> <p>Address: 1rd-Floor B14 and B15 Huachuang Industry Area, Jinshan Cun, Shiji Town Panyu District,511450, Guangzhou, Guangdong China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-12-01</p> <p>Validity Date: 2027-11-30</p> <p>Notarization Status: Notarized by CCPIT.</p> <p>FSC: Submitted</p>	<p>Brand Name:</p> <p>Mcreat Suction Tooth Brush</p> <p>Generic Name:</p> <p>Suction Tooth Brush</p> <p>Class A</p> <p>Device/Accessori es Name: Mcreat Suction Toothbrush</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): TYPE- I/Adult I</p> <p>Specify grouping:</p>	Approved

		<p>Issue Date: 2024-05-22</p> <p>Validity Date: 2026-05-21</p> <p>Issuing Authority:</p> <p>Attestation Status: Apostille</p> <p>Issue Date: 2024-05-22</p> <p>Validity Date: 2026-05-21</p> <p>Issuing Authority:</p> <p>Attestation Status: Apostille</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-12-01</p> <p>Validity Date: 2027-11-30</p> <p>Notarization Status: duly notarized from the country of origin.</p>	<p>Single</p> <p>Storage condition: This product should be stored in a dry, ventilated, heat-proof place without corrosive gases.</p>	
3	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6</p> <p>P.E.C.H.S Karachi East</p> <p>75400, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 0398806478</p> <p>Date of submission: 05 August 2025</p> <p>Tracking ID: MDMR-20250805-00016</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Ventana Medical Systems</p> <p>Address: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2022-11-03</p> <p>Validity Date: 2027-11-02</p> <p>Issuing Authority: Baden Württemberg</p>	<p>Brand Name: Ventana MSLN (SP74) Assay</p> <p>Generic Name: Ventana MSLN (SP74) Assay</p> <p>Class A</p> <p>Device/Accessories Name: Ventana MSLN (SP74) Assay</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 08508011001</p> <p>Specify grouping: Single</p> <p>Storage condition: 2 - 8°C</p>	Approved

		<p>regierungspräsidium karlsruhe</p> <p>Attestation Status: Embassy Attested</p> <p>Issue Date: 2022-11-03</p> <p>Validity Date: 2027-11-02</p> <p>Issuing Authority: Baden Württemberg regierungspräsidium karlsruhe</p> <p>Attestation Status: Embassy Attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-18</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2022-11-03</p> <p>Validity Date: 2027-11-02</p> <p>Issuing Authority: Baden Württemberg regierungspräsidium karlsruhe</p> <p>Attestation Status: Embassy Attested</p> <p>Issue Date: 2022-11-03</p> <p>Validity Date: 2027-11-02</p> <p>Issuing Authority: Baden Württemberg regierungspräsidium karlsruhe</p> <p>Attestation Status: Embassy Attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p>		
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		Validity Date: 2027-01-18 Notarization Status: Notarized		
4	<p>M.Y Surgical & Co. 86/R P.E.C.H.S Block 2, Allama Iqbal Road, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 2936335174</p> <p>Date of submission: 30 July 2025</p> <p>Tracking ID: MDMR- 20250730-00022</p>	<p>Manufacturer Sri Trang Gloves (Thailand) Public Company Limited</p> <p>Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-06-25</p> <p>Validity Date: 2028-06-25</p> <p>Notarization Status: MINISTRY OF FOREIGN AFFAIR THAILAND</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-05-29</p> <p>Validity Date: 2027-05-26</p> <p>Issuing Authority: FOOD AND DRUG ADMINISTRATION</p> <p>Attestation Status: MINISTRY OF FOREIGN AFFAIR THAILAND</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-05-30</p> <p>Validity Date: 2028-05-29</p> <p>Notarization Status: MINISTRY OF FOREIGN AFFAIR THAILAND</p>	<p>Brand Name: EFROMED</p> <p>Generic Name: LATEX EXAMINATION GLOVES</p> <p>Class A</p> <p>Device/Accessori es Name: LATEX EXAMINATION GLOVES</p> <p>POWDERED NON STERILE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Small, Medium, Large</p> <p>Specify grouping: Single</p> <p>Storage condition: DRY AND COOL</p>	Approved
5	<p>Aqib trading company pvt ltd Nowshera, Nowshera</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 982502727881</p> <p>Date of submission: 25 July 2025</p> <p>Tracking ID: MDMR- 20250725-00040</p>	<p>Manufacturer Nanjing 3H Medical Products Co., Ltd</p> <p>Address: located at NO.1, NO.5 Zhushan Road, Gaochun Economic Development Zone, Nanjing 211300 Jiangsu Province, P.R. China</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: AT-TAPE</p> <p>Generic Name: Non woven tape</p> <p>Class A</p> <p>Device/Accessori es Name: Non woven Adhesive Tape</p> <p>Shelf life/service</p>	Approved

		<p>Issue Date: 2024-09-30</p> <p>Validity Date: 2026-10-18</p> <p>Notarization Status: Norarized.</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date: 2030-04-02</p> <p>Issuing Authority: Lotus NL B.V</p> <p>Attestation Status: certified</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-04-11</p> <p>Validity Date: 2027-04-11</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2025-04-11</p> <p>Validity Date: 2027-04-11</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2025-04-11</p> <p>Validity Date: 2027-04-11</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-01-01</p> <p>Validity Date: 2030-01-01</p> <p>Notarization Status: Notarized</p>	<p>life: 60 Months</p> <p>Codes/Sizes (if any): N/A/HWFB001(1 .0×450)? HWFB002(1.25× 450)? HWFB003(2.5×4 50)? HWFB004(5×450)? HWFB005(7.5×4 50)? HWFB006(10×45 0)? HWFB007(26×45 0)? HWFB008(1×500)? HWFB009(1.25× 500)? HWFB010(2.5×5 00)? HWFB011(5×500)? HWFB012(7.5×5 00)? HWFB013(10×50 0)? HWFB014(26×50 0)? HWFB015(1×800)? HWFB016(1.25× 800)? HWFB017(2.5×8 00)? HWFB018(5×800)? HWFB019(7.5×8 00)? HWFB020(10×80 0)? HWFB021(26×80 0)? HWFB022 (1×914)? HWFB023(1.25× 914)? HWFB024(2.5×9 14)? HWFB025(5×914)? HWFB026(7.5×9</p>	
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			14)? HWFB027(10×91 4)? HWFB028(26×91 4)?HWFB029(1.0 ×1000)?HWFB03 0(1.25×1000)? HWFB031(2.5×1 000)? HWFB032(5.0×1 000)? HWFB033(7.5×1 000)? HWFB034(10×10 00)? HWFB035(1×137 0)? HWFB036(2.5×1 370)? HWFB037(5×137 0)? HWFB038(7.5×1 370)? HWFB039(10×13 70)? HWFB040(11.6× 20000)? HWFB041(6×100)? HWFB042(8×100)? HWFB043(5×6)? HWFB044(3×30) ? HWFB045(5×65) ? HWFB046(15×45 0)? HWFB047(15×50 0)? HWFB048(15×80 0)? HWFB049(15×91 4)? HWFB050(15×10 00)? HWFB051(15×13 70) (cm×cm) Specify grouping: Single Storage condition: The product should generally	
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			be stored in a clean, cool, dry and ventilated warehouse	
6	<p>Aqib trading company pvt ltd</p> <p>Nowshera, Nowshera</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 38089368476</p> <p>Date of submission: 26 July 2025</p> <p>Tracking ID: MDMR-20250726-00010</p>	<p>Manufacturer</p> <p>Jiangxi Hongda Medical Equipment Group Ltd.</p> <p>Address: 39 South Shengli Road, Jinxian County, Nanchang city. Jiangxi Province, China 331700</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-07-01</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-06-10</p> <p>Validity Date: 2029-06-10</p> <p>Issuing Authority: TUV SUD</p> <p>Attestation Status: certified</p> <p>FSC: Submitted</p> <p>Issue Date: 2023-11-02</p> <p>Validity Date: 2025-11-02</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2023-11-02</p> <p>Validity Date:</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>Issue Date: 2023-11-02</p> <p>Validity Date:</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p>	<p>Brand Name:</p> <p>BT-TEX (Powdered surface Examination Gloves)</p> <p>Generic Name:</p> <p>Single use powdered surface medical Examination Gloves (Natural Rubber)</p> <p>Class A</p> <p>Device/Accessories Name: Single use powdered surface medical Examination Gloves (Natural Rubber)</p> <p>Shelf life/service life: 60 Months</p> <p>Codes/Sizes (if any): XS, S, M, L, XL</p> <p>Specify grouping: Single</p> <p>Storage condition: Indoor storage in no corrosive gas, well0-ventilated and cleaned space</p>	Approved

		LOA: Submitted Issue Date: 2024-09-04 Validity Date: 2029-09-04 Notarization Status: notarized		
7	Aqib trading company pvt ltd Nowshera, Nowshera Fee: Rs 6000 /- Challan No.: 29302422128 Date of submission: 26 July 2025 Tracking ID: MDMR- 20250726-00008	Manufacturer Jiangxi Hongda Medical Equipment Group Ltd. Address: 39 South Shengli Road, Jinxian County, Nanchang city, Jiangxi Province, China 331700 ISO 13485: Submitted Issue Date: 2025-07-01 Validity Date: 2028-06-30 Notarization Status: notarized EC Certificate Issue Date: 2024-06-10 Validity Date: 2029-06-10 Issuing Authority: TUV SUD Attestation Status: certified FSC: Submitted Issue Date: 2023-11-02 Validity Date: 2025-11-02 Issuing Authority: certificate for exportation of medical products Attestation Status: certified Issue Date: 2023-11-02 Validity Date: 2025-11-02 Issuing Authority: certificate for exportation of medical products Attestation Status: certified Issue Date: 2023-11-02 Validity Date: 2025-11-02 Issuing Authority: certificate for exportation	Brand Name: BT-TEX (Powder Free Examination Gloves) Generic Name: Single use Powder Free medical Examination Gloves (Natural Rubber) Class A Device/Accessori es Name: Single use Powder Free medical Examination Gloves (Natural Rubber) Shelf life/service life: 60 Months Codes/Sizes (if any): XS, S, M, L, XL Specify grouping: Single Storage condition: Indoor storage in no corrosive gas, well-ventilated and cleaned space	Approved

		of medical products Attestation Status: certified LOA: Submitted Issue Date: 2024-09-04 Validity Date: 2029-09-04 Notarization Status: notarized		
8	GHAZALI BROTHERS 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, Karachi Fee: Rs 6000 /- Challan No.: 477153389 Date of submission: 23 July 2025 Tracking ID: MDMR- 20250723-00007	Manufacturer NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD Address: ROOM 1201-9, NO. 456 TAI'AN MIDDLE RD YINZHOU DISTRICT 315199 NINGBO, ZHEJIANG, CHINA ISO 13485: Submitted Issue Date: 2023-07-19 Validity Date: 2026-07-18 Notarization Status: CCPIT NO 253301A0/004281 DATED: MAR.26, 2025 FSC: Submitted Issue Date: 2025-01-01 Validity Date: 2025-12-31 Issuing Authority: U.S. Food and Drug Administration (FDA) Attestation Status: N/A Issue Date: 2025-01-01 Validity Date: 2025-12-31 Issuing Authority: U.S. Food and Drug Administration (FDA) Attestation Status: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm	Brand Name: YINGMED DISPOSABLE VACUUM BLOOD COLLECTION TUBE (EDTA K3) Generic Name: VACUUM BLOOD COLLECTION TUBE (EDTA K3) Class A Device/Accessories Name: DISPOSABLE VACUUM BLOOD COLLECTION TUBE (EDTA K3) Shelf life/service life: 3 Years Codes/Sizes (if any): 3ml Specify grouping: Single Storage condition: STORE IN DRY AND WELL- VENTILATED ROOM. TEMPERATURE UPTO 29C	Approved

		LOA: Submitted Issue Date: 2025-07-25 Validity Date: 2035-07-24 Notarization Status: NOTARIZATION BY CCPIT 253301A0/010797 DATED: JUL. 31, 2025		
9	Quality Medical Services H-49 Gordon College road, Rawalpindi Fee: Rs 6000 /- Challan No.: 93468682 Date of submission: 28 July 2025 Tracking ID: MDMR- 20250728-00034	Manufacturer Shenzhen Hugemed Medical Technical Development Co., Ltd. Address: 401, 501, Building 4 Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong 518112, China ISO 13485: Submitted Issue Date: 2023-03-23 Validity Date: 2025-12-21 Notarization Status: CCPIT FSC: Submitted Issue Date: 2023-10-23 Validity Date: 2025-10-22 Issuing Authority: CCPIT Attestation Status: APOSTILLE LOA: Submitted Issue Date: 2025-03-18 Validity Date: 2026-03-18 Notarization Status: CCPIT	Brand Name: HugeMed Medical Generic Name: Video Laryngoscope, Model # VL4R Class A Device/Accessories Name: Video Laryngoscope Shelf life/service life: 3 Years Codes/Sizes (if any): VL4R/ Specify grouping: Single Storage condition: Dry Place	Approved
10	Roche Pakistan Limited 1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi Fee: Rs 6000 /-	Legal Manufacturer (as per FSC) Roche Diagnostics GmbH Address: Sandhofer Str.116, 68305 Mannheim,	Brand Name: Accessory Kit BMK Special Stains Generic Name:	Approved

	Challan No.: 00539789 Date of submission: 05 August 2025 Tracking ID: MDMR-20250805-00028	Germany Manufacturing Site (as per FSC) Ventana Medical Systems, Inc. Address: 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA ISO 13485: Submitted Issue Date: 2024-06-30 Validity Date: 2027-06-29 Notarization Status: Notarized FSC: Submitted Issue Date: 2025-03-26 Validity Date: 2030-03-25 Issuing Authority: Baden Württemberg Attestation Status: Embassy Attested LOA: Submitted Issue Date: 2023-01-18 Validity Date: 2027-01-17 Notarization Status: Notarized ISO 13485: Submitted Issue Date: 2024-06-30 Validity Date: 2027-06-29 Notarization Status: Notarized FSC: Submitted Issue Date: 2025-03-26 Validity Date: 2030-03-25 Issuing Authority: Baden Württemberg Attestation Status: Embassy Attested LOA: Submitted	Accessory Kit BMK Special Stains Class A Device/Accessories Name: Accessory Kit BMK Special Stains Shelf life/service life: Months Codes/Sizes (if any): 06564909001 Specify grouping: Single Storage condition: Not Applicable	
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		<p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p>		
11	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 940128198951</p> <p>Date of submission: 05 August 2025</p> <p>Tracking ID: MDMR- 20250805-00020</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Ventana Medical Systems, Inc.</p> <p>Address: 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-20</p> <p>Validity Date: 2027-08-19</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-11-18</p> <p>Validity Date: 2029-11-17</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-20</p> <p>Validity Date: 2027-08-19</p> <p>Notarization Status: Notarized</p>	<p>Brand Name:</p> <p>BenchMark GX, AFM, 100V Assembly</p> <p>Generic Name:</p> <p>BenchMark GX, AFM, 100V Assembly</p> <p>Class A</p> <p>Device/Accessori es Name: BenchMark GX, AFM, 100V Assembly</p> <p>Shelf life/service life: Months</p> <p>Codes/Sizes (if any): 05894646001</p> <p>Specify grouping: Single</p> <p>Storage condition: 20 - 30°C</p>	Approved

		FSC: Submitted Issue Date: 2024-11-18 Validity Date: 2029-11-17 Issuing Authority: Baden Württemberg Attestation Status: Embassy Attested LOA: Submitted Issue Date: 2023-01-18 Validity Date: 2027-01-17 Notarization Status: Notarized		
12	HOSPICARE SYSTEMS Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e- Faisal, Karachi-75350, Pakistan, Karachi Fee: Rs 6000 /- Challan No.: 8253361586 Date of submission: 02 August 2025 Tracking ID: MDMR- 20250802-00008	Legal Manufacturer (as per FSC) Philips Medizin Systeme Böblingen GmbH Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY Manufacturing Site (as per FSC) Gebr. Schwarz GmbH Address: Zepfenhaner Strasse 35 78628 Rottweil Deutschland ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized FSC: Submitted Issue Date: 2025-06-18 Validity Date: 2030-06-17 Issuing Authority: Baden Wurttemberg Germany Attestation Status: Attested from Embassy of Pakistan LOA: Submitted Issue Date: 2025-06-11	Brand Name: Avalon CL Belt Clip Generic Name: CL Belt Clip Class A Device/Accessori es Name: Avalon CL Belt Clips Shelf life/service life: 5 Years Codes/Sizes (if any): 989803184851 Specify grouping: Single Storage condition: -20 to 60 C	Approved

		<p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Attested from Embassy of Pakistan</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>FSC: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Attested from Embassy of Pakistan</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>		
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AGENDA FORMAT FOR CLASS B, C & D MEDICAL DEVICES

Evaluator Name: Sadaf Ahmad (Evaluator-III)

New Applications

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	<p>Aqib trading company pvt ltd</p> <p>Nowshera, Nowshera</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 68216427</p> <p>Date of submission: 26 July 2025</p> <p>Tracking ID: MDMR-20250726-00006</p>	<p>Manufacturer</p> <p>Jiangxi Hongda Medical Equipment Group Ltd.</p> <p>Address: 39 South Shengli Road, Jinxian County, Nanchang city. Jiangxi Province, China 331700</p> <p>ISO 13485: Submitted</p> <p>Issue Date:</p> <p>Validity Date: 2028-06-30</p> <p>Notarization Status: notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-06-10</p> <p>Validity Date: 2029-06-10</p> <p>Issuing Authority: TUV SUD</p> <p>Attestation Status: certified</p> <p>FSC</p> <p>Issue Date: 2023-11-02</p> <p>Validity Date:</p> <p>Issuing Authority: certificate for exportation of medical products</p> <p>Attestation Status: certified</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-09-04</p> <p>Validity Date: 2029-09-04</p> <p>Notarization Status: notarized</p>	<p>Brand Name:</p> <p>AT-TRANS</p> <p>Generic Name:</p> <p>Blood Transfusion Set for Single Use</p> <p>Class B</p> <p>Device/Accessories Name: Blood Transfusion Set for Single Use</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Model A, Model B/0.7mm 0.8mm 0.9mm 1.2mm</p> <p>Specify grouping: Single</p> <p>Storage condition: This product should be stored in a dry, ventilated, no corrosive gas and clean environment. it is strictly forbidden to store it in the same warehouse with chemicals and wet items.</p>	<p>Approved Model A.</p>
2	<p>HI-MOD Technologies</p> <p>House No. 13, Rahman Park, Near PEPSI</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Medical Econet GmbH</p>	<p>Brand Name:</p> <p>MEDICAL ECONET</p>	<p>Approved</p>

	<p>Factory, Gulberg-II, Lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 9453080589</p> <p>Date of submission: 12 August 2025</p> <p>Tracking ID: MDMR-20250812-00001</p>	<p>Address: Im Erlengrund 16 46149 Oberhausen Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-02-16</p> <p>Validity Date: 2027-02-15</p> <p>Notarization Status: Yes</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-03</p> <p>Validity Date:</p> <p>Issuing Authority: Bezirksregierung Dusseldorf</p> <p>Attestation Status: Yes</p> <p>FSC</p> <p>Issue Date: 2024-12-03</p> <p>Validity Date:</p> <p>Issuing Authority: Bezirksregierung Dusseldorf</p> <p>Attestation Status: Yes</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-12-09</p> <p>Validity Date: 2026-12-31</p> <p>Notarization Status: Yes</p>	<p>Generic Name: Electrocardiograph</p> <p>Class B</p> <p>Device/Accessories Name: ELECTROCARD IOGRAPH</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): CARDIO E3/</p> <p>Specify grouping: Single</p> <p>Storage condition: -20°C~+55°C</p>	
3	<p>Human Health Care</p> <p>61 A Revenue Employees Cooperative Housing Society M A Johar Town Lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 73533717018</p> <p>Date of submission: 11 August 2025</p> <p>Tracking ID: MDMR-20250811-00030</p>	<p>Manufacturer</p> <p>Guangzhou Ajax Medical Equipment Co., Ltd.</p> <p>Address: Building No.2, Dagang industrial zone, Shilou Town, Panyu District, Guangzhou, P.R. China</p>	<p>Brand Name: Guangzhou Ajax Medical Equipment Co., Ltd</p> <p>Generic Name: DENTAL UNIT</p> <p>Class B</p> <p>Device/Accessories Name: DENTAL UNIT</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): MODEL: AJ12, AJ10, AJ11, AJ15, AJ16, AJ17, AJ18, AJ19,</p>	<p>Deferred. Brand name should be mentioned clearly. The applicant need to inform which one dental unit system to be considered for this application along with differential fee as per revised SRO for System. Fields in the application form will be amended accordingly</p>

			AJ22, AJ25, AJ26, AJ28/ Specify grouping: System Storage condition: NA	
4	Hearing Care Services Islamabad, Islamabad Fee: Rs 52200 /- Challan No.: 120197705998 Date of submission: 12 August 2025 Tracking ID: MDMR- 20250812-00029	<p>Manufacturer Sonova AG Address: Laubisrütistrasse 28, CH-8712 Stäfa, Switzerland Manufacturing Site (as per FSC) Sonova Hearing (Suzhou) Co.,Ltd Address: No.78, Qi Ming Road, Comprehensive Bonded Zone Suzhou Industrial Park, Jiangsu Province 215126, P.R. China Manufacturing Site (as per FSC) Sonova Operations Center Vietnam Co.Ltd. Address: No.29A VSIP Street 8 Vietnam Singapore Industrial Park, Thuan An Town, Binh Duong Province, Vietnam</p> <p>ISO 13485: Submitted Issue Date: 2023-04-15 Validity Date: 2026-04-14 Notarization Status: Yes EC Certificate: Submitted Issue Date: 2025-01-08 Validity Date: 2028-01-08 Issuing Authority: Swiss Agency for Therapeutic Products Attestation Status: Apostille</p>	<p>Brand Name: Vista V Generic Name: Hearing Aids Class B Device/Accessori es Name: Vista V R Shelf life/service life: 5 Years Codes/Sizes (if any): Vista V 1,3,5,7,9/ Device/Accessori es Name: Vista V RT Telecoil Shelf life/service life: 5 Years Codes/Sizes (if any): Vista V1 ,3,5,7,9 RT/ Device/Accessori es Name: Vista V- PR Shelf life/service life: 5 Years Codes/Sizes (if any): Vista V 1,3,5,7,9 -PR/ Device/Accessori es Name: Vista V- UP Ultra Power Shelf life/service life: 5 Years</p>	Deferred. The applicant need to inform which one hearing Aid to be considered for this application and apply separately for other types. Fields in the application form will be amended accordingly

		<p>Yes</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-15</p> <p>Validity Date: 2029-11-14</p> <p>Notarization Status: Yes</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-04-15</p> <p>Validity Date: 2026-04-14</p> <p>Notarization Status: Yes</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-01-08</p> <p>Validity Date: 2028-01-08</p> <p>Issuing Authority: Swiss Agency for Therapeutic Products</p> <p>Attestation Status: Apostille Yes</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-15</p> <p>Validity Date: 2029-11-14</p> <p>Notarization Status: Yes</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-04-15</p> <p>Validity Date: 2026-04-14</p> <p>Notarization Status: Yes</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-01-08</p> <p>Validity Date: 2028-01-08</p> <p>Issuing Authority: Swiss Agency for Therapeutic Products</p> <p>Attestation Status: Apostille Yes</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-15</p>	<p>Codes/Sizes (if any): Vista V 1,3,5,7,9 -UP/</p> <p>Device/Accessories Name: Vista V-SP</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista V 1,3,5,7,9 - SP/</p> <p>Device/Accessories Name: Vista V-M</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista V 1,3,5,7,9 -M/</p> <p>Device/Accessories Name: Vista V RS</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista V 3,5,7,9 RS L/R/</p> <p>Device/Accessories Name: Vista V 312</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista V1,3,5,7,9 312/</p> <p>Specify grouping: Family</p> <p>Storage condition: room Temperate</p>	
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		Validity Date: 2029-11-14 Notarization Status: Yes		
5	Hearing Care Services Islamabad, Islamabad Fee: Rs 52200 /- Challan No.: 14118209123 Date of submission: 12 August 2025 Tracking ID: MDMR- 20250812-00011	<p>Manufacturer Sonova AG Address: Laubisrütistrasse 28, CH-8712 Stäfa, Switzerland</p> <p>Manufacturing Site (as per FSC) Sonova Hearing (Suzhou) Co.,Ltd Address: No.78, Qi Ming Road, Comprehensive Bonded Zone Suzhou Industrial Park, Jiangsu Province 215126, P.R. China</p> <p>Manufacturing Site (as per FSC) Sonova Operations Center Vietnam Co.Ltd. Address: No.29A VSIP Street 8 Vietnam Singapore Industrial Park,Thuan An Town, Binh Duong Province,Vietnam</p> <p>ISO 13485: Submitted Issue Date: 2024-09-20 Validity Date: 2028-02-28 Notarization Status: yes</p> <p>EC Certificate: Submitted Issue Date: 2025-01-08 Validity Date: 2028-01-08 Issuing Authority: Swiss Agency for Therapeutic Products</p> <p>Attestation Status: Yes</p> <p>FSC LOA: Submitted Issue Date: 2024-11-15</p>	<p>Brand Name: Vista B</p> <p>Generic Name: Hearing Aids</p> <p>Class B</p> <p>Device/Accessori es Name: Vista B- R</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista B 1- R,Vista B 3- R,Vista B 5-R ,Vista B 7-R, Vista B 9-R/</p> <p>Device/Accessori es Name: Vista B- RT TeleCoil</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista B1 R- T,Vista B3 R-T, Vista B5 R-T, Vista B7 R-T, Vista B9 R-T/</p> <p>Device/Accessori es Name: Vista B 312</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Vista B1 312, Vista B3 312, Vista B5 312, Vista B7 312,Vista B9 312/</p> <p>Device/Accessori</p>	Deferred. The applicant need to inform which one hearing Aid to be considered for this application and apply separately for other types. Fields in the application form will be amended accordingly

		<p>Validity Date: 2029-11-15 Notarization Status: yes ISO 13485: Submitted Issue Date: 2024-09-20 Validity Date: 2028-02-28 Notarization Status: yes EC Certificate: Submitted Issue Date: 2025-01-08 Validity Date: 2028-01-08 Issuing Authority: Swiss Agency for Therapeutic Products Attestation Status: Yes FSC LOA: Submitted Issue Date: 2024-11-15 Validity Date: 2029-11-15 Notarization Status: yes ISO 13485: Submitted Issue Date: 2024-09-20 Validity Date: 2028-02-28 Notarization Status: yes EC Certificate: Submitted Issue Date: 2025-01-08 Validity Date: 2028-01-08 Issuing Authority: Swiss Agency for Therapeutic Products Attestation Status: Yes FSC LOA: Submitted Issue Date: 2024-11-15 Validity Date: 2029-11-15 Notarization Status: yes</p>	<p>es Name: Vista B-PR Rechargeable Shelf life/service life: 5 Years Codes/Sizes (if any): Vista B 1-PR,Vista B 3-PR,Vista B 5-PR ,Vista B 7-PR, Vista B 9-PR/ Device/Accessories Name: Vista B-UP Ultra Power Shelf life/service life: 5 Years Codes/Sizes (if any): Vista B 1-UP,Vista B 3-UP,Vista B 5-UP ,Vista B 7-UP, Vista B 9-UP/ Device/Accessories Name: Vista B 312 Wireless Hybrid Shelf life/service life: 5 Years Codes/Sizes (if any): Vista B1 312 L/R DV3U, Vista B3 312 L/R DV3U, Vista B5 312 L/R DV3U, Vista B7 312 L/R DV3U,Vista B9 312 L/R DV3U/ Device/Accessories Name: Vista B 10A Omni Shelf life/service life: 5 Years Codes/Sizes (if any): Vista B1 10, Vista B3 10, Vista</p>	
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			B5 10, Vista B7 10,Vista B9 10/ Specify grouping: Family Storage condition: room Temperature	
6	Shams Enterprises 10 Medicine market kutchi gali no 1 mariot road karachi, Karachi Fee: Rs 32400 /- Challan No.: 86764976744 Date of submission: 11 August 2025 Tracking ID: MDMR- 20250811-00041	Manufacturer Beijing JinhuaKe Biological Technology Co., Ltd Address: Room 402, Building 3, No. 2 Xingye Street, Beijing Economic- Technological Development Area, 100176 Beijing, China ISO 13485: Submitted Issue Date: 2023-04-24 Validity Date: 2026-04-23 Notarization Status: NOTARIZED EC Certificate: Submitted Issue Date: 2024-10-14 Validity Date: 2026-10-13 Issuing Authority: BEIJING MUNICIPAL MEDICAL PRODUCT ADMINISTRATION Attestation Status: 12644884 APPOSTILED FSC LOA: Submitted Issue Date: 2025-06-13 Validity Date: 2030-06-12 Notarization Status: notarized	Brand Name: A1 SURGICS Generic Name: PREGNANCY TEST STRIPS Class B Device/Accessori es Name: pregnancy test strips Shelf life/service life: 36 Months Codes/Sizes (if any): N/A/1pc/pouch, 1pc/box, 2pcs/box, 5pcs/box, 10pcs/box, 15pcs/box, 20pcs/box, 25pcs/box, 50pcs/box, 100pcs/box Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved
7	Green Plus Services (PVT) Limited 251 Green House Street No 6 Gulrez III, Rawalpindi Fee: Rs 32400 /-	Manufacturer Guilin HBM Health Protections, Inc. Address: No.1-2, Shuijing East Road, Economic & Technological Development Area, 541805 Guilin,	Brand Name: MediGreen Generic Name: Surgical Gloves - Powder Free	Approved

	Challan No.: 783268851025 Date of submission: 18 August 2025 Tracking ID: MDMR- 20250818-00002	Guangxi, China ISO 13485: Submitted Issue Date: 2023-11-30 Validity Date: 2026-11-29 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2025-07-29 Validity Date: 2027-06-08 Issuing Authority: China Council for the Promotion of International Trade Attestation Status: Attested 31 July 2025 FSC LOA: Submitted Issue Date: 2025-07-29 Validity Date: 2027-07-07 Notarization Status: Notarized (Active)	Class B Device/Accessories Name: Surgical Latex Gloves, Powder Free Shelf life/service life: 5 Years Codes/Sizes (if any): N/A/Sizes: 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5 Specify grouping: Single Storage condition: 30°C	
8	MR Medical Pakistan Pvt Ltd Office no 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Islamabad Fee: Rs 32400 /- Challan No.: 2225407185 Date of submission: 19 August 2025 Tracking ID: MDMR- 20250819-00005	Legal Manufacturer (as per FSC) SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD Address: Mindray Buliding, Keji 12th Road South, High- Tech Industrial Park, Nanshan, 518057 Shenzhen PEOPLES REPUBLIC OF CHINA ISO 13485: Submitted Issue Date: 2023-09-01 Validity Date: 2026-08-31 Notarization Status: TUV SUD Product Services GmbH. Certification body. RidlerstraBe 65.80339 Munich. Germany EC Certificate: Submitted Issue Date: 2024-03-13	Brand Name: Mindray Generic Name: Electrocardiograph Class B Device/Accessories Name: Electrocardiograph Shelf life/service life: 5 Years Codes/Sizes (if any): Beneheart R3/ Specify grouping: Single Storage condition: -20-+60	Approved

		<p>Validity Date: 2026-03-12</p> <p>Issuing Authority: China Council for the Promotion of International Trade</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>Issue Date: 2023-08-05</p> <p>Validity Date: 2028-08-05</p> <p>Issuing Authority: Shanghai holding international corporation GmbH(Europe)</p> <p>Attestation Status: Embassy attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2022-04-14</p> <p>Validity Date: 2027-04-14</p> <p>Notarization Status: CHINA COUNCIL FOR THE PROMOTION OF INTERNATIONAL TRADES, CHINA COUNCIL OF INTERNATIONAL COMMERCE</p>		
9	<p>MR Medical Pakistan Pvt Ltd</p> <p>Office no 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Islamabad</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 7773939919</p> <p>Date of submission: 19 August 2025</p> <p>Tracking ID: MDMR-20250819-00006</p>	<p>Legal Manufacturer (as per FSC)</p> <p>SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD</p> <p>Address: Mindray Buliding, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen PEOPLES REPUBLIC OF CHINA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-09-01</p> <p>Validity Date: 2026-08-31</p> <p>Notarization Status: china council for the promotion of international trade</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-03-13</p>	<p>Brand Name: Mindray</p> <p>Generic Name: Electrocardiograph</p> <p>Class B</p> <p>Device/Accessories Name: Electrocardiograph</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Beneheart R12/</p> <p>Specify grouping: Single</p> <p>Storage condition:</p>	Approved

		<p>Validity Date: 2026-03-12</p> <p>Issuing Authority: china council for the promotion of international trade</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>Issue Date: 2023-08-23</p> <p>Validity Date: 2028-08-23</p> <p>Issuing Authority: Shanghai international holding corporation GmbH (Europe)</p> <p>Attestation Status: Embassy attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2022-04-14</p> <p>Validity Date: 2027-04-14</p> <p>Notarization Status: China council for the promotion of international trade, china chamber of international commerce</p>	-20-+60	
10	<p>MR Medical Pakistan Pvt Ltd</p> <p>Office no 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Islamabad</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 6704681840</p> <p>Date of submission: 19 August 2025</p> <p>Tracking ID: MDMR-20250819-00014</p>	<p>Legal Manufacturer (as per FSC)</p> <p>SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD</p> <p>Address: Mindray Buliding, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen PEOPLES REPUBLIC OF CHINA</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-09-01</p> <p>Validity Date: 2026-08-31</p> <p>Notarization Status: CHINA COUNCIL FOR THE PROMOTION OF INTERNATIONAL TRADE</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-03-13</p> <p>Validity Date: 2026-03-12</p>	<p>Brand Name: Mindray</p> <p>Generic Name: Electrocardiograph</p> <p>Class B</p> <p>Device/Accessories Name: Electrocardiograph</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Beneheart R12A/</p> <p>Specify grouping: Single</p> <p>Storage condition: -20-+60</p>	Approved

		<p>Issuing Authority: CHINA COUNCIL FOR THE PROMOTION OF INTERNATIONAL TRADE</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>Issue Date: 2023-08-23</p> <p>Validity Date: 2028-08-23</p> <p>Issuing Authority: Shanghai International holding corporation GmbH (Europe)</p> <p>Attestation Status: Embassy attested</p> <p>LOA: Submitted</p> <p>Issue Date: 2022-04-14</p> <p>Validity Date: 2027-04-14</p> <p>Notarization Status: CHINA COUNCIL FOR THE PROMOTION OF INTERNATIONAL TRADE</p>		
11	<p>Electromed Corporation</p> <p>53 Mall Avenue , 54 The Mall, Near Panorama Shopping Center , LAHORE, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 804380425791</p> <p>Date of submission: 21 August 2025</p> <p>Tracking ID: MDMR-20250821-00017</p>	<p>Manufacturer</p> <p>BMC (Tianjin) Medical Co., Ltd.</p> <p>Address: 2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, 301700 Tianjin, People's Republic of China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-07-13</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: Notarized by CCPIT, China</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-06-13</p> <p>Validity Date: 2026-06-12</p> <p>Issuing Authority: Tianjin Municipal Drug Administration</p>	<p>Brand Name: iVolve F1A</p> <p>Generic Name: Full Face Mask Class B</p> <p>Device/Accessories Name: iVolve F1A Full Face Mask</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMC-FM1A/Small, Medium, Large</p> <p>Specify grouping: Single</p> <p>Storage condition: -20°C to 55°C</p>	Approved

		<p>Attestation Status: Apostille</p> <p>FSC</p> <p>Issue Date: 2024-06-13</p> <p>Validity Date: 2026-06-12</p> <p>Issuing Authority: Tianjin Municipal Drug Administration</p> <p>Attestation Status: Apostille</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-07-28</p> <p>Validity Date: 2030-12-31</p> <p>Notarization Status: Notarized by CCPIT, China</p>		
12	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 50000 /-</p> <p>Challan No.: 88375472</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR-20250806-00011</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-11-06</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p> <p>Issuing Authority: Ministero Della Salute</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-10</p> <p>Validity Date: 2027-03-10</p> <p>Notarization Status: Duly Notarized</p>	<p>Brand Name: BMHE</p> <p>Generic Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Class B</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1105/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT /</p>	Approved

			<p>TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1107/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1110/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1112/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if</p>	
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			<p>any): BMHE 1115/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1305/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1307/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1310/</p> <p>Device/Accessories Name: BONE</p>	
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			<p>MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1312/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1315/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1410/</p> <p>Device/Accessori es Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p>	
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			<p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1415/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1505/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1507/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1510/</p>	
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			<p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1512/</p>	
			<p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1515/</p>	
			<p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1605/</p>	
			<p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE -</p>	

			<p>EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1607/</p> <p>Device/Accessories Name: BONE MARROW ASPIRATION NEEDLE - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHE 1807/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
13	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 50000 /-</p> <p>Challan No.: 9119900891</p> <p>Date of submission: 06 August 2025</p> <p>Tracking ID: MDMR-20250806-00013</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-11-06</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p> <p>Issuing Authority: Ministero Della Salute</p> <p>Attestation Status: Apostille</p>	<p>Brand Name: BMH</p> <p>Generic Name: BONE MARROW ASPIRATION NEEDLE</p> <p>Class B</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1105/</p>	Approved

		FSC LOA: Submitted Issue Date: 2025-03-10 Validity Date: 2027-03-10 Notarization Status: Duly Notarized	Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMH 1107/ Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMH 1110/ Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMH 1112/ Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMH 1115/ Device/Accessori	
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			<p>es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1305/</p> <p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1307/</p> <p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1310/</p> <p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1312/</p> <p>Device/Accessori es Name: BMH, BONE</p>	
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			<p>MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1315/</p>	
			<p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1410/</p>	
			<p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1415/</p>	
			<p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1505/</p>	
			<p>Device/Accessori es Name: BMH, BONE MARROW ASPIRATION</p>	

			<p>NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1507/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1510/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1515/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1607/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service</p>	
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			<p>life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1807/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1512/</p> <p>Device/Accessories Name: BMH, BONE MARROW ASPIRATION NEEDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMH 1605/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
14	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 50000 /-</p> <p>Challan No.: 45511622881</p> <p>Date of submission: 15 August 2025</p> <p>Tracking ID: MDMR-20250815-00023</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-06-11</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p>	<p>Brand Name: BMHR</p> <p>Generic Name: BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Class B</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION</p>	Approved

		<p>Issuing Authority: MINISTERO DELLA SALUTE</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-10</p> <p>Validity Date: 2027-03-10</p> <p>Notarization Status: Duly Notarized</p>	<p>NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1401/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1403/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1404/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p>	
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			<p>Codes/Sizes (if any): BMHR 1405/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1501/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1503/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1504/</p> <p>Device/Accessori</p>	
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			<p>es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1505/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1601/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1603/</p> <p>Device/Accessori es Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC</p>	
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			<p>HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1604/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1605/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR 1801/</p> <p>Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): BMHR</p>	
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			1803/ Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMHR 1804/ Device/Accessories Name: BMHR, BONE MARROW ASPIRATION NEEDLE - ERGONOMIC HANDLE Shelf life/service life: 5 Years Codes/Sizes (if any): BMHR 1805/ Specify grouping: Family Storage condition: Normal Room Temperature	
15	Nassir Trading Company Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi Fee: Rs 50000 /- Challan No.: 224318231 Date of submission: 15 August 2025	Manufacturer ADRIA SRL Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy ISO 13485: Submitted Issue Date: 2024-03-27 Validity Date: 2026-11-06 Notarization Status: Duly Notarized	Brand Name: ISTAN Generic Name: BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION Class B	Deferred for clarification/justification of applied product codes/models in single application and justification of applying system as family

	<p>Tracking ID: MDMR-20250815-00024</p>	<p>EC Certificate: Submitted Issue Date: 2025-03-28 Validity Date: 2030-03-28 Issuing Authority: Ministero Della Salute Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted Issue Date: 2025-03-10 Validity Date: 2027-03-10 Notarization Status: Duly Notarized</p>	<p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1401/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1403/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1404/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION</p>	
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			<p>SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1405/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1501/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1503/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p>	
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			<p>Codes/Sizes (if any): IST 1504/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1505/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1601/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1603/</p> <p>Device/Accessories Name: ISTAN,</p>	
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			<p>BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1604/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1605/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1801/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL</p>	
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			<p>VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1803/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1804/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM STERNAL VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): IST 1805/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
16	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: ISTAN</p> <p>Generic Name: BONE MARROW - STERNAL ASPIRATION</p>	<p>Deferred for clarification/justification of applied product codes/models in single application and justification of applying system as</p>

	<p>Fee: Rs 50000 /-</p> <p>Challan No.: 337937311277</p> <p>Date of submission: 15 August 2025</p> <p>Tracking ID: MDMR- 20250815-00025</p>	<p>Issue Date: 2024-03-27</p> <p>Validity Date: 2026-11-06</p> <p>Notarization Status: Duly Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-03-28</p> <p>Validity Date: 2030-03-28</p> <p>Issuing Authority: Ministero Della Salute</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-03-10</p> <p>Validity Date: 2027-03-10</p> <p>Notarization Status: Duly Notarized</p>	<p>SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Class B</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1401/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1403/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if</p>	family
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			<p>any): ISTE 1404/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1405/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1501/</p> <p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1503/</p>	
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			<p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1504/</p>	
			<p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1505/</p>	
			<p>Device/Accessories Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1601/</p>	
			<p>Device/Accessories Name: ISTAN, BONE</p>	

			<p>MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1603/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1604/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1605/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION</p>	
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			<p>SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1801/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1803/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1804/</p> <p>Device/Accessori es Name: ISTAN, BONE MARROW - STERNAL ASPIRATION SYSTEM - EXPLANT / TRANSPLANT</p>	
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			<p>VERSION</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): ISTE 1805/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
17	<p>Nassir Trading Company</p> <p>Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp Sindh Madrasa, Karachi., Karachi</p> <p>Fee: Rs 52200 /-</p> <p>Challan No.: 9506459653</p> <p>Date of submission: 21 August 2025</p> <p>Tracking ID: MDMR-20250821-00037</p>	<p>Manufacturer</p> <p>ADRIA SRL</p> <p>Address: Via Modena 46, 40017 San Giovanni in Persiceto (BO) – Italy</p> <p>ISO 13485</p> <p>EC Certificate</p> <p>FSC</p> <p>LOA</p>	<p>Brand Name: EVOTRAP</p> <p>Generic Name: BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Class B</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0710/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0707/</p> <p>Device/Accessories Name:</p>	Approved

			<p>EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0713/</p> <p>Device/Accessori es Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0715/</p> <p>Device/Accessori es Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0807/</p> <p>Device/Accessori es Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0810/</p>	
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			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0813/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0815/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0907/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0910/</p>	

			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0913/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 0915/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1107/</p>	
			<p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if</p>	

			<p>any): RDT 1110/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1113/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1115/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1307/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service</p>	
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			<p>life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1310/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1313/</p> <p>Device/Accessories Name: EVOTRAP, BONE MARROW BIOPSY WITH TRAP SYSTEM</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RDT 1315/</p> <p>Specify grouping: Family</p> <p>Storage condition: Normal Room Temperature</p>	
18	<p>Royal Medical</p> <p>Office No. 26th, 3rd Floor, United Trade Center, Plot No. 5, Block-6, Gulshan-e-Iqbal Karachi, Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 08559189</p> <p>Date of submission: 21 August 2025</p> <p>Tracking ID: MDMR-20250821-00019</p>	<p>Manufacturer</p> <p>Pharmamed Medikal Urunler San VE TIC LTD STI</p> <p>Address: Liman Sb Mh. B-1 Cd No 9, KONYAALTI, ANTALYA, TURKIYE</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-03-13</p> <p>Validity Date: 2025-11-04</p> <p>Notarization Status:</p>	<p>Brand Name: PHARMAMED</p> <p>Generic Name: EXTRA CORPOREAL TUBE SET</p> <p>Class B</p> <p>Device/Accessories Name: PHARMAMED- Extra Corporeal Tube Set</p>	Approved

		<p>Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-07</p> <p>Validity Date: 2028-05-07</p> <p>Issuing Authority: Ministry of Health Republic of Turkey</p> <p>Attestation Status: Apostilled</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-07</p> <p>Validity Date: 2030-08-07</p> <p>Notarization Status: Notarized</p>	<p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any): TTS0286/Standard</p> <p>Specify grouping: Set</p> <p>Storage condition: It must be stored under max 50°C/122°F in a cool and dry place.</p>	
19	<p>Royal Medical</p> <p>Office No. 26th, 3rd Floor, United Trade Center, Plot No. 5, Block-6, Gulshan-e-Iqbal Karachi, Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 6887826993</p> <p>Date of submission: 22 August 2025</p> <p>Tracking ID: MDMR-20250822-00005</p>	<p>Manufacturer</p> <p>Pharmamed Medikal Urunler San VE TIC LTD STI</p> <p>Address: Liman Sb Mh. B-1 Cd No 9, KONYAALTI, ANTALYA, TURKIYE</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-03-13</p> <p>Validity Date: 2025-11-04</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-07</p> <p>Validity Date: 2028-05-07</p> <p>Issuing Authority: Medicines and Medical Devices Agency of Turkiye</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-07</p> <p>Validity Date: 2030-08-07</p> <p>Notarization Status: Notarized</p>	<p>Brand Name: PHARMAMED</p> <p>Generic Name: EXTRA CORPOREAL Cardioplegia Set, Adult (1000ml)</p> <p>Class B</p> <p>Device/Accessories Name: PHARMAMED-EXTRA CORPOREAL Cardioplegia Set, Adult (1000ml)</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): 212/1000ml</p> <p>Specify grouping: Set</p> <p>Storage condition: Store in a cool and dry place.</p>	Approved

20	<p>gesundheit Concerns</p> <p>Plot no 36 , Second floor Marina Commercial Phase 4 Bahria Town, Islamabad</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 3989796528</p> <p>Date of submission: 25 August 2025</p> <p>Tracking ID: MDMR- 20250825-00024</p>	<p>Manufacturer</p> <p>Jiangsu Zhiyu Medical Instrument Co., Ltd.</p> <p>Address: No.88 Nan Yuan Road, Industrial Park, West Tiaixing 254000 Jiangsu, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-09-20</p> <p>Validity Date: 2027-09-22</p> <p>Notarization Status: Duly CCPIT Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-07-15</p> <p>Validity Date: 2026-07-15</p> <p>Issuing Authority: Jiangsu Medical Products Administration (NMPA) - China</p> <p>Attestation Status:</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-06</p> <p>Validity Date: 2030-08-05</p> <p>Notarization Status: Duly CCPIT Notarized</p>	<p>Brand Name:</p> <p>GC</p> <p>Generic Name:</p> <p>Sterile Syringes for Single Use (with Needle)</p> <p>Class B</p> <p>Device/Accessori es Name: Sterile syringes for single use (with Needle)</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): N/A/1ml, 10ml & 20ml.</p> <p>Needle Specifications: 0.3mm, 0.33mm, 0.36mm, 0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm</p> <p>Specify grouping: Single</p> <p>Storage condition: Temperature: < 54 °C</p>	Approved
21	<p>gesundheit Concerns</p> <p>Plot no 36 , Second floor Marina Commercial Phase 4 Bahria Town, Islamabad</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 29955255</p> <p>Date of submission: 25 August 2025</p> <p>Tracking ID: MDMR- 20250825-00028</p>	<p>Manufacturer</p> <p>Jiangsu Zhiyu Medical Instrument Co., Ltd.</p> <p>Address: No.88 Nan Yuan Road, Industrial Park, West Tiaixing 254000 Jiangsu, P.R. China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-09-20</p> <p>Validity Date: 2027-09-22</p> <p>Notarization Status: Duly CCPIT Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-07-15</p>	<p>Brand Name:</p> <p>GC</p> <p>Generic Name:</p> <p>Sterile Syringes for Single Use (with Needle)</p> <p>Class B</p> <p>Device/Accessori es Name: Sterile syringes for single use (with Needle)</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): N/A/50ml,</p>	Approved

		<p>Validity Date: 2026-07-15</p> <p>Issuing Authority: Duly Apostilled</p> <p>Attestation Status:</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-08-06</p> <p>Validity Date: 2030-08-05</p> <p>Notarization Status: Duly CCPIT Notarized</p>	<p>Needle Specifications: 0.3mm, 0.33mm, 0.36mm, 0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm</p> <p>Specify grouping: Single</p> <p>Storage condition: Temperature: < 54 °C</p>	
22	<p>Safe Health Pakistan Bizcon</p> <p>Office # 18 & 19, 1st Floor, Dilkusha Chambers, Marstom Road, Karachi - 74400. Pakistan, Karachi</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 26538775407</p> <p>Date of submission: 13 August 2025</p> <p>Tracking ID: MDMR-20250813-00008</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Shandong Zhushi Pharmaceutical Group Co., Ltd.</p> <p>Address: Fanlou South Road, Development Zone, Shan Country</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2025-05-28</p> <p>Validity Date: 2028-05-27</p> <p>Notarization Status: Apostille CCPIT</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-07-24</p> <p>Validity Date: 2027-06-10</p> <p>Issuing Authority: Shandong Zhushi Pharmaceutical Group Co., Ltd.</p> <p>Attestation Status: Apostille CCPIT</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-12</p> <p>Validity Date: 2030-06-11</p> <p>Notarization Status: Apostille CCPIT</p>	<p>Brand Name:</p> <p>Infusion Set For Single use With Needle</p> <p>Generic Name:</p> <p>Infusion Set For Single use With Needle</p> <p>Class B</p> <p>Device/Accessories Name: Infusion Set</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): SY01 (Air Intake Type), SY02 (Non-air Intake Type)/0.36X15RWLB, 0.45X15RWLB, 0.55X20RWLB, 0.6X25TWLB, 0.7X25TWLB, 0.8X28TWLB, 0.9X28TWLB, 1.2X30TWLB</p> <p>Specify grouping: Family</p> <p>Storage condition: Room Temperature</p>	<p>Deferred for submission of Brand name AND type to be considered for this application.</p>

23	<p>Mr Dental Supply Pvt Ltd</p> <p>LG-41, 42, 43 Land Mark Plaza, Jail Road, Lahore, Lahore</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 53327017294</p> <p>Date of submission: 11 August 2025</p> <p>Tracking ID: MDMR-20250811-00053</p>	<p>Manufacturer</p> <p>Drendel+Zweiling DIAMANT GmbH</p> <p>Address: Schurenbreder Weg 27 D-32689 Kalletal, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-12-20</p> <p>Validity Date: 2026-01-08</p> <p>Notarization Status: Apostille Attestation</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-04-30</p> <p>Validity Date: 2029-04-30</p> <p>Issuing Authority: The European Parliament and of the Council, Germany</p> <p>Attestation Status: Apostille Attestation</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-04-10</p> <p>Validity Date: 2026-12-31</p> <p>Notarization Status: Apostille Attestation</p>	<p>Brand Name: D+Z</p> <p>Generic Name: Cavity and Crown Preparation Rotating Diamond</p> <p>Class B</p> <p>Device/Accessories Name: Diamond, coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046150D1/</p> <p>Device/Accessories Name: Diamond, coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046151D1/</p> <p>Device/Accessories Name: Diamond, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 051637D1/</p> <p>Device/Accessories Name: Diamond, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046152D1/</p> <p>Device/Accessories Name:</p>	Approved
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			<p>Diamond, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046153D1/</p> <p>Device/Accessories Name: Diamond, super coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041531D1/</p> <p>Device/Accessories Name: Diamond, super coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046244D1/</p> <p>Device/Accessories Name: Diamond, coarse, cylinder</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 046246D1/</p> <p>Device/Accessories Name: Diamond, medium, cylinder SF-21</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041588D1/</p> <p>Device/Accessori</p>	
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			<p>es Name: Diamond,super coarse,cylinder</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041479D1/</p> <p>Device/Accessori es Name: Diamond, extra fine, tapered TF- 21EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041673D1/</p> <p>Device/Accessori es Name: Diamond,extra fine,tapered rd TR-21EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041680D1/</p> <p>Device/Accessori es Name: Diamond, fine, tapered round TR- 21F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041631D1/</p> <p>Device/Accessori es Name: Diamond, medium, torpedo SO-20</p> <p>Shelf life/service life: 10 Years</p>	
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			<p>Codes/Sizes (if any): 041655D1/</p> <p>Device/Accessories Name: Diamond, coarse, cylinder</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 042970D1/</p> <p>Device/Accessories Name: Diamond, medium, tapered</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 048592D1/</p> <p>Device/Accessories Name: Diamond, medium, tapered</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 048950D1/</p> <p>Device/Accessories Name: Diamond, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 10005984/</p> <p>Device/Accessories Name: Diamond, fine, tapered TF-21F</p> <p>Shelf life/service life: 10 Years</p>	
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			<p>Codes/Sizes (if any): 041608D1/</p> <p>Device/Accessories Name: Diamond, fine, tapered round CR-21F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041630D1/</p> <p>Specify grouping: Family</p> <p>Storage condition: Room Temperature Device</p>	
24	<p>Mr Dental Supply Pvt Ltd</p> <p>LG-41, 42, 43 Land Mark Plaza, Jail Road, Lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 85919444550</p> <p>Date of submission: 13 August 2025</p> <p>Tracking ID: MDMR-20250813-00032</p>	<p>Manufacturer Drendel+Zweiling DIAMANT GmbH</p> <p>Address: Schurenbreder Weg 27 D-32689 Kalletal, Germany</p> <p>ISO 13485</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-04-30</p> <p>Validity Date: 2029-04-30</p> <p>Issuing Authority: The European Parliament and of the Council, Germany</p> <p>Attestation Status: Apostille Attestation</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-04-10</p> <p>Validity Date: 2026-12-31</p> <p>Notarization Status: Apostille Attestation</p>	<p>Brand Name: D+Z</p> <p>Generic Name: Crown Preparation and Preparation of Restoration Materials Rotating Diamond Class B</p> <p>Device/Accessories Name: Diamond, extra fine, bud</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041452D1/</p> <p>Device/Accessories Name: Diamond, extra fine, bud</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if</p>	Approved

			<p>any): 041453D1/</p> <p>Device/Accessories Name: Diamond, extra fine, egg</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041457D1/</p> <p>Device/Accessories Name: Diamond, extra fine, egg</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041458D1/</p> <p>Device/Accessories Name: Diamond, extra fine, tapered TC-21EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041549D1/</p> <p>Device/Accessories Name: Diamond, extra fine, tapered</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041500D1/</p> <p>Device/Accessories Name: Diamond, extra fine, tapered TC-11EF</p> <p>Shelf life/service</p>	
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			<p>life: 10 Years</p> <p>Codes/Sizes (if any): 041550D1/</p> <p>Device/Accessories Name: Diamond, extra fine, flame FO-42EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041553D1/</p> <p>Device/Accessories Name: Diamond, extra fine, flame FO-21EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041552D1/</p> <p>Device/Accessories Name: Diamond, extra fine, flame FO-22EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041551D1/</p> <p>Device/Accessories Name: Diamond, extra fine, flame</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041510D1/</p> <p>Device/Accessories Name:</p>	
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			<p>Diamond, extra fine, bud</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041451D1/</p> <p>Device/Accessories Name: Diamond, extra fine, flame</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041506D1/</p> <p>Device/Accessories Name: Diamond, fine, tapered TC-21F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041543D1/</p> <p>Device/Accessories Name: Diamond, fine, tapered TC-11F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041544D1/</p> <p>Device/Accessories Name: Diamond, fine, flame FO-22F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041545D1/</p> <p>Device/Accessori</p>	
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			<p>es Name: Diamond, fine, bud FO-30F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041556D1/</p> <p>Device/Accessori es Name: Diamond, fine, flame FO-21F</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041650D1/</p> <p>Device/Accessori es Name: Diamond, extra fine, bud FO- 30EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041664D1/</p> <p>Device/Accessori es Name: Diamond, fine, egg</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 042483D1/</p> <p>Specify grouping: Family</p> <p>Storage condition: Room Temperature Device</p>	
25	Mr Dental Supply Pvt Ltd LG-41, 42, 43 Land	Manufacturer Drendel+Zweiling DIAMANT GmbH	<p>Brand Name: D+Z</p> <p>Generic Name:</p>	Approved

	<p>Mark Plaza, Jail Road, Lahore, Lahore</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 709762060</p> <p>Date of submission: 14 August 2025</p> <p>Tracking ID: MDMR- 20250814-00002</p>	<p>Address: Schurenbreder Weg 27 D-32689 Kalletal, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-12-20</p> <p>Validity Date: 2026-01-08</p> <p>Notarization Status: Apostille Attestation</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-04-30</p> <p>Validity Date: 2029-04-30</p> <p>Issuing Authority: The European Parliament and of the Council, Germany</p> <p>Attestation Status: Apostille Attestation</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-04-10</p> <p>Validity Date: 2026-12-31</p> <p>Notarization Status: Apostille Attestation</p>	<p>Cavity Preparation Rotating Diamond</p> <p>Class B</p> <p>Device/Accessori es Name: Diamond, super coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041463D1/</p> <p>Device/Accessori es Name: Diamond, super coarse, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041467D1/</p> <p>Device/Accessori es Name: Diamond, s- coarse, inver. cone</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041469D1/</p> <p>Device/Accessori es Name: Diamond, coarse, inver. cone</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041470D1/</p> <p>Device/Accessori es Name: Diamond, medium, round</p>	
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			<p>BR-45</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041565D1/</p> <p>Device/Accessories Name: Diamond, medium, round BR-46</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041566D1/</p> <p>Device/Accessories Name: Diamond, medium, round BR-41</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041567D1/</p> <p>Device/Accessories Name: Diamond, medium, round BR-31</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041568D1/</p> <p>Device/Accessories Name: Diamond, medium, inverted cone SI-46</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041576D1/</p>	
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			<p>Device/Accessories Name: Diamond, medium, inverted cone SI-47</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041577D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, inverted cone SI-48</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041578D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, cylinder SF-41</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041586D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, cylinder SF-31</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041587D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, pear EX-</p>	

			<p>26</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041696D1/</p> <p>Device/Accessories Name: Diamond, extra fine, pear EX-21EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041697D1/</p> <p>Device/Accessories Name: Diamond, medium, round</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 042489D1/</p> <p>Device/Accessories Name: Dia., coarse, inverted cone</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 043744D1/</p> <p>Device/Accessories Name: Dia., coarse, inverted cone</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 043745D1/</p> <p>Device/Accessori</p>	
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			es Name: Diamond, super coarse, round Shelf life/service life: 10 Years Codes/Sizes (if any): 052279D1/ Specify grouping: Family Storage condition: Room Temperature Device	
26	Mr Dental Supply Pvt Ltd LG-41, 42, 43 Land Mark Plaza, Jail Road, Lahore, Lahore Fee: Rs 31000 /- Challan No.: 3868409624 Date of submission: 14 August 2025 Tracking ID: MDMR- 20250814-00003	Manufacturer Drendel+Zweiling DIAMANT GmbH Address: Schurenbreder Weg 27 D-32689 Kalletal, Germany ISO 13485: Submitted Issue Date: 2022-12-20 Validity Date: 2026-08-01 Notarization Status: Apostille Attestation EC Certificate: Submitted Issue Date: 2024-04-30 Validity Date: 2029-04-30 Issuing Authority: The European Parliament and of the Council, Germany Attestation Status: Apostille Attestation FSC LOA: Submitted Issue Date: 2024-04-10 Validity Date: 2026-12-31 Notarization Status: YES	Brand Name: D+Z Generic Name: Crown Preparation Rotating Diamond Class B Device/Accessori es Name: Diamond, coarse, torpedo Shelf life/service life: 10 Years Codes/Sizes (if any): 041514D1/ Device/Accessori es Name: Diamond, coarse, torpedo Shelf life/service life: 10 Years Codes/Sizes (if any): 041515D1/ Device/Accessori es Name: Diamond, coarse, torpedo Shelf life/service life: 10 Years	Approved

			<p>Codes/Sizes (if any): 041516D1/</p> <p>Device/Accessories Name: Diamond, coarse, torpedo</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041518D1/</p> <p>Device/Accessories Name: Diamond, medium, bud FO-32</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041557D1/</p> <p>Device/Accessories Name: Diamond, medium, bud FO-27</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041559D1/</p> <p>Device/Accessories Name: Diamond, medium, double cone EX-11</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041582D1/</p> <p>Device/Accessories Name: Diamond,</p>	
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			<p>medium, cylinder SF-11</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041590D1/</p> <p>Device/Accessories Name: Diamond, medium, cylinder SF-12</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041591D1/</p> <p>Device/Accessories Name: Diamond, medium, cylinder SF-13</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041592D1/</p> <p>Device/Accessories Name: Diamond, coarse, tapered TF-13C</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041614D1/</p> <p>Device/Accessories Name: Diamond, medium, tapered TF-11</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041618D1/</p>	
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			<p>Device/Accessories Name: Diamond, medium, tapered TF-13</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041619D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, tapered TF-12</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041621D1/</p>	
			<p>Device/Accessories Name: Diamond, coarse, wheel WR-13C</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041661D1/</p>	
			<p>Device/Accessories Name: Diamond, extra fine, tapered TF- 12EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041676D1/</p>	
			<p>Device/Accessories Name: Diamond, medium, tapered round TR-11</p>	

			<p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041920D1/</p> <p>Device/Accessories Name: Diamond,extra fine,tapered rd TR-11EF</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 041922D1/</p> <p>Device/Accessories Name: Diamond, coarse,cylinder</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 042950D1/</p> <p>Device/Accessories Name: Diamond, coarse, cylinder</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 042951D1/</p> <p>Specify grouping: Family</p> <p>Storage condition: Room Temperature Device</p>	
27	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 545398359</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>ISO 13485: Submitted</p>	<p>Brand Name: Cobas Albumin Gen.2</p> <p>Generic Name: ALB2</p>	Approved

	<p>Date of submission: 15 August 2025</p> <p>Tracking ID: MDMR-20250815-00019</p>	<p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2022-07-11</p> <p>Validity Date: 2027-07-10</p> <p>Issuing Authority: Baden Wurttemberg</p> <p>Attestation Status: Embassy Legalized / Embassy Attested</p> <p>FSC</p> <p>Issue Date: 2022-07-11</p> <p>Validity Date: 2027-07-10</p> <p>Issuing Authority: Baden Wurttemberg</p> <p>Attestation Status: Embassy Attested/Embassy Legalized</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-25</p> <p>Validity Date: 2028-01-24</p> <p>Notarization Status: Notarized</p>	<p>Class B</p> <p>Device/Accessories Name: ALB2</p> <p>Shelf life/service life: 18 Months</p> <p>Codes/Sizes (if any): 05166861190/750 Tests</p> <p>Specify grouping: Single</p> <p>Storage condition: 15 - 25°C</p>	
28	<p>K.M Enterprises</p> <p>KM Mansion 605-D block M.A Johar Town lahore, Lahore</p> <p>Fee: Rs 32400 /-</p> <p>Challan No.: 73212549959</p> <p>Date of submission: 25 August 2025</p> <p>Tracking ID: MDMR-20250825-00023</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Euromed for Medical industries, Egypt</p> <p>Address: Area No. 10 Block. 1 Free Zone, Nasr City, Cairo, Egypt.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2022-08-01</p> <p>Validity Date: 2025-07-16</p> <p>Notarization Status: Yes (Applied for Renewal ISO 13485)</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-01-18</p> <p>Validity Date: 2026-01-18</p>	<p>Brand Name: Euro Flow</p> <p>Generic Name: I.V. Cannula Two Way, With Wings & With Injection Port</p> <p>Class B</p> <p>Device/Accessories Name: Euro Flow I.V. Cannula</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): Two Way, With Wings & With Injection Port/14, 16, 18,</p>	Approved

		<p>Issuing Authority: Egyptian Drug Authority, Egypt</p> <p>Attestation Status: Yes</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-04-15</p> <p>Validity Date: 2030-04-14</p> <p>Notarization Status: Yes</p> <p>Notarized</p>	<p>20, 22, 24, 26G</p> <p>Specify grouping: Single</p> <p>Storage condition: 20C - 25C</p>	
29	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6</p> <p>P.E.C.H.S Karachi East</p> <p>75400, Karachi</p> <p>Fee: Rs 50000 /-</p> <p>Challan No.: 980963373</p> <p>Date of submission: 22 August 2025</p> <p>Tracking ID: MDMR-20250822-00027</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH.</p> <p>Address: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-19</p> <p>Validity Date: 2030-05-18</p> <p>Issuing Authority: Baden-Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2026-01-22</p> <p>Notarization Status: Notarized</p>	<p>Brand Name: Cobas Bilirubin Total Gen.3</p> <p>Generic Name: BILT3</p> <p>Class B</p> <p>Device/Accessories Name: BILT3</p> <p>Shelf life/service life: 18 Months</p> <p>Codes/Sizes (if any): 10421410190/250</p> <p>Device/Accessories Name: BILT3</p> <p>Shelf life/service life: 18 Months</p> <p>Codes/Sizes (if any): 10421428190/600</p> <p>Device/Accessories Name: BILT3</p> <p>Shelf life/service life: 18 Months</p> <p>Codes/Sizes (if any): 10421436190/1050</p> <p>Specify grouping: Cluster</p> <p>Storage condition:</p>	Approved

		ISO 13485: Submitted Issue Date: 2024-06-30 Validity Date: 2027-06-29 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2025-05-19 Validity Date: 2030-05-18 Issuing Authority: Baden-Württemberg Attestation Status: Embassy Attested FSC LOA: Submitted Issue Date: 2023-01-18 Validity Date: 2026-01-22 Notarization Status: Notarized	2 - 8°C	
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Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

New Applications

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	HOSPICARE SYSTEMS Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi-75350, Pakistan, Karachi Fee: Rs 31000 /- Challan No.: 789324022869 Date of submission: 03 August 2025 Tracking ID: MDMR-20250803-00003	Legal Manufacturer (as per FSC) Philips Medizin Systeme Böblingen GmbH Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY ISO 13485: Submitted Issue Date: 2024-10-29 Validity Date: 2027-10-28 Notarization Status: Notarized EC Certificate: Submitted Issue Date: 2025-06-18	Brand Name: Avalon CL Fetal & Maternal Pod Generic Name: Fetal & Maternal Pod Class C Device/Accessories Name: Avalon CL Fetal & Maternal Pod Shelf life/service life: 4 Years Codes/Sizes (if any): 866488/ Specify grouping: Single Storage condition: 20 to	Deferred. Firm need to provide proof of changes in establishment licence particulars.

		<p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Embassy of Pakistan attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>	60 C	
2	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 6777878674</p> <p>Date of submission: 12 August 2025</p> <p>Tracking ID: MDMR-20250812-00044</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ 85755 USA.</p> <p>Address: Inc. 1910 E. Innovation Park Drive Tucson, AZ 85755 USA.</p> <p>Manufacturing Site (as per FSC)</p> <p>Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ 85755 USA.</p> <p>Address: Inc. 1910 E. Innovation Park Drive Tucson,</p>	<p>Brand Name:</p> <p>CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody</p> <p>Generic Name:</p> <p>CONFIRM anti-CD3 (2GV6) Rabbit Monoclonal Primary Antibody</p> <p>Class C</p> <p>Device/Accessories Name: CONFIRM anti-CD3 (2GV6) Rabbit</p>	Approved

		<p>AZ 85755 USA.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-04-17</p> <p>Validity Date: 2030-04-16</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-04-17</p> <p>Validity Date: 2030-04-16</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p>	<p>Monoclonal Primary Antibody</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 10243295001/50</p> <p>Specify grouping: Single</p> <p>Storage condition: 2 - 8 °C</p>	
3	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Ventana Medical Systems, Inc.</p> <p>Address: 1910 E. Innovation Park Dr. Tucson, AZ 85711</p>	<p>Brand Name:</p> <p>anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody</p> <p>Generic Name:</p>	Approved

	<p>Fee: Rs 62000 /-</p> <p>Challan No.: 2103347282</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00027</p>	<p>USA</p> <p>Manufacturing Site (as per FSC)</p> <p>Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ 85755 USA.</p> <p>Address: Inc. 1910 E. Innovation Park Drive Tucson, AZ 85755 USA.</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-20</p> <p>Validity Date: 2027-08-19</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-08-21</p> <p>Validity Date: 2026-08-20</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-08-20</p> <p>Validity Date: 2027-08-19</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-08-21</p> <p>Validity Date: 2026-08-20</p> <p>Issuing Authority: US FDA</p> <p>Attestation Status: Apostille</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p>	<p>anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody</p> <p>Class C</p> <p>Device/Accessories Name: anti-CD8 (SP239) Rabbit Monoclonal Primary Antibody</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 09780041001/50 Tests</p> <p>Specify grouping: Single</p> <p>Storage condition: 2 - 8 °C</p>	
4	Moody Global	Legal Manufacturer (as per	Brand Name:	Approved

	<p>Services</p> <p>Office no 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad., Islamabad</p> <p>Fee: Rs 64800 /-</p> <p>Challan No.: 8762202333</p> <p>Date of submission: 08 August 2025</p> <p>Tracking ID: MDMR-20250808-00022</p>	<p>FSC)</p> <p>Shenzhen Comen Medical Instruments Co., Ltd.</p> <p>Address: Floor 10, floor 11 section C of floor 12 of building 1A & floor 1 to floor 5 of building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R China</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-03-18</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: NOTARIZED- CHECK FILE SCANNED ISO</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2024-12-25</p> <p>Validity Date: 2026-01-21</p> <p>Issuing Authority: PEOPLES REPUBLIC OF CHINA</p> <p>Attestation Status: APOSTILLE</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2024-11-01</p> <p>Validity Date: 2029-10-31</p> <p>Notarization Status: NOTARIZED</p>	<p>COMEN</p> <p>Generic Name:</p> <p>Multi-parameter Patient Monitor</p> <p>Class C</p> <p>Device/Accessories Name: Multi-parameter Patient Monitor</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): K22pro/N/A</p> <p>Specify grouping: Single</p> <p>Storage condition: Storage Temperature: - 20°C to 70°C Humidity: 5% to 93%</p>	
5	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 2213207136</p> <p>Date of submission: 07 August 2025</p> <p>Tracking ID: MDMR-20250807-00053</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p>	<p>Brand Name:</p> <p>Elecsys PRO-C3</p> <p>Generic Name:</p> <p>Elecsys PRO-C3</p> <p>Class C</p> <p>Device/Accessories Name: Elecsys Pro-C3</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 09088423190/100 Tests</p>	Approved

		<p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-19</p> <p>Validity Date: 2030-05-18</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-19</p> <p>Validity Date: 2030-05-18</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p>	<p>Device/Accessories Name: CalSet Pro-C3</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 09088431190/4 x 1.0 mL</p> <p>Device/Accessories Name: PreciControl Pro-C3</p> <p>Shelf life/service life: 24 Months</p> <p>Codes/Sizes (if any): 09088440190/4 x 1.0 mL</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: 2 - 8°C</p>	
6	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrach-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Philips Medizin Systeme Böblingen GmbH</p> <p>Address: Hewlett-Packard Strasse 2, 71034 Böblingen, GERMANY</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p>	<p>Brand Name:</p> <p>Avalon CL Base Station</p> <p>Generic Name:</p> <p>Avalon Base Station</p> <p>Class C</p> <p>Device/Accessories Name: Avalon CL Base Station</p> <p>Shelf life/service life: 10</p>	Deferred. Firm need to provide proof of changes in establishment licence particulars.

	<p>98860878350</p> <p>Date of submission: 03 August 2025</p> <p>Tracking ID: MDMR-20250803-00002</p>	<p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Attested from embassy of Pakistan</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-10-29</p> <p>Validity Date: 2027-10-28</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-06-18</p> <p>Validity Date: 2030-06-17</p> <p>Issuing Authority: Baden Wurttemberg Germany</p> <p>Attestation Status: Attested from embassy of Pakistan</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2025-06-11</p> <p>Validity Date: 2030-05-12</p> <p>Notarization Status: Notarized</p>	<p>Years</p> <p>Codes/Sizes (if any): 866074/</p> <p>Specify grouping: Single</p> <p>Storage condition: 20 to 60 C</p>	
7	<p>Roche Pakistan Limited</p> <p>1st Floor, 37-B, Block 6 P.E.C.H.S Karachi East 75400, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 9024313492</p> <p>Date of submission:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site (as per FSC)</p> <p>Roche Diagnostics GmbH</p> <p>Address: Sandhofer Str.116,</p>	<p>Brand Name:</p> <p>PreciControl Rubella IgM</p> <p>Generic Name:</p> <p>PreciControl Rubella IgM</p> <p>Class C</p> <p>Device/Accessories</p>	Approved

	<p>06 August 2025</p> <p>Tracking ID: MDMR-20250806-00027</p>	<p>68305 Mannheim, Germany</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-19</p> <p>Validity Date: 2030-05-18</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2024-06-30</p> <p>Validity Date: 2027-06-29</p> <p>Notarization Status: Notarized</p> <p>EC Certificate: Submitted</p> <p>Issue Date: 2025-05-19</p> <p>Validity Date: 2030-05-18</p> <p>Issuing Authority: Baden Württemberg</p> <p>Attestation Status: Embassy Attested</p> <p>FSC</p> <p>LOA: Submitted</p> <p>Issue Date: 2023-01-18</p> <p>Validity Date: 2027-01-17</p> <p>Notarization Status: Notarized</p>	<p>Name: PreciControl Rubella IgM</p> <p>Shelf life/service life: 14 Months</p> <p>Codes/Sizes (if any): 09787518190/8 x 1.0 mL</p> <p>Specify grouping: Single</p> <p>Storage condition: 2 - 8°C</p>	
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Evaluator Name: Dr. Ghayour Ahmed (Evaluator-IV)

New Applications

S #	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Brief Description of the Medical Device	Evaluator Remarks	Minutes/Decision
1	<p>Global Marketing Services</p> <p>111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 776057514</p> <p>Date of submission: 04 August 2025</p> <p>Tracking ID: MDMR-20250804-00023</p>	<p>Manufacturer</p> <p>Lepu Medical Technology (Beijing) Co, Ltd.</p> <p>Address: No.37 Chaoqian Road, Changping District, Beijing, 102200, china</p> <p>ISO 13485: Submitted</p> <p>Issue Date: 2023-03-07</p> <p>Validity Date: 2026-03-06</p> <p>Notarization Status: Apostilled</p> <p>EC Certificate</p> <p>FSC: Submitted</p> <p>Issue Date: 2024-07-19</p> <p>Validity Date: 2025-12-17</p> <p>Issuing Authority: Beijing Municipal Medical Products Administration</p> <p>Attestation Status: Apostilled</p> <p>Issue Date: 2024-07-19</p>	<p>Brand Name:</p> <p>Hoper™ PTCA Balloon Dilatation Catheter</p> <p>Generic Name:</p> <p>PTCA Balloon Dilatation Catheter</p> <p>Class D</p> <p>Device/Accessories Name:</p> <p>Hoper™ PTCA Balloon Dilatation Catheter</p> <p>Shelf life/service life: 2 Years</p> <p>Codes/Sizes (if any):</p> <p>LPRX20009, LPRX20012, LPRX20016, LPRX20020, LPRX20024, LPRX20030, LPRX25009, LPRX25012, LPRX25016, LPRX25020, LPRX25024, LPRX25030, LPRX27009, LPRX27012, LPRX27016, LPRX27020, LPRX27024, LPRX27030, LPRX30009, LPRX30012,</p>	<p>Hoper™ PTCA balloon dilatation catheter which serves to expand coronary artery is mainly used in Percutaneous Coronary Intervention (PCI). It can relieve angina and lengthen life by improving blood flow of coronary artery.</p>	<p>The LOA is locally notarized. The firm has provided Apostilled FSC of china and has provided 510(K) issued in 2013 which is issued for class II device in US. The firm has provided online link of the 510K online link is given below. 510(k) Premarket Notification The firm has not submitted Design examination certificate and has stated that The Design Examination Certificate is not applicable for this product. In its place, we have provided a manufacturer's declaration confirming the same. The firm has applied in family and has submitted fee of RS 62000/- and is not as</p>	<p>The board after deliberating decided to approve the product as the firm has provided 510(K) issued by USFDA which is also online verified subject to submission of differential fees for family.</p>

		Validity Date: 2025-12-17 Issuing Authority: Beijing Municipal Medical Products Administration Attestation Status: Locally Notarized LOA: Submitted Issue Date: 2025-07-11 Validity Date: 2028-12-31 Notarization Status: Notarized Locally	LPRX30016, LPRX30020, LPRX30024, LPRX30030, LPRX35009, LPRX35012, LPRX35016, LPRX35020, LPRX35024, LPRX35030, LPRX40009, LPRX40012, LPRX40016, LPRX40020, LPRX40024, LPRX40030/ Specify grouping: Family Storage condition: Temperature: 10 -30°C Humidity: ≤80%RH		per the new SRO.	
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Deferred Applications

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Brief Description of the Medical Device	Evaluator Remarks	Minutes/Decision
1	KASBN INTERNATIONAL 41-K, Gulberg-III, Lahore 54660 - Pakistan, Lahore Fee: Rs 31000 /- Challan No.: 6853546238 Date of submission: 24 July 2025 Tracking ID:	Legal Manufacturer (as per FSC) BIO COMPRESSION SYSTEMS INC. Address: 120 West Commercial Avenue, Moonachie, New Jersey 07074, USA	Brand Name: BIO COMPRESSION SYSTEM INC Generic Name: DVT PUMP Class B Device/Accessories Name: DVT PUMP Shelf life/service	DVT PUMP	D - 94 Remarks: Documents are valid. The firm has submitted the revised fee.	Approved

	MDMR-20250724-00004 - D-94	ISO 13485 EC Certificate FSC LOA	life: 5 Years Codes/Sizes (if any): IC-1545-DL/ Specify grouping: System Storage condition: ROOM TEMPERATURE			
2	KASBN INTERNATIONAL 41-K, Gulberg-III, Lahore 54660 - Pakistan, Lahore Fee: Rs 31000 /- Challan No.: 01139810303 Date of submission: 26 July 2025 Tracking ID: MDMR-20250726-00002 - D-94	Legal Manufacturer (as per FSC) Zimmer MedizinSysteme GmbH Address: Junkersstraße 9, 89231 Neu-Ulm, Germany ISO 13485 EC Certificate FSC LOA	Brand Name: Zimmer MedizinSysteme GmbH Generic Name: Shockwave Therapy Unit Class B Device/Accessories Name: (Shockwave Therapy Unit) Shelf life/service life: 10 Years Codes/Sizes (if any): enPuls Version 2.0/ Specify grouping: Single Storage condition: ROOM TEMPERATURE	Shockwave Therapy Unit	D - 94 Remarks: Now case is complete	Approved

Renewal Applications

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/ Decision
1	Product Registration Number/Enlistment: MDIR-0001773 K.M Enterprises KM Mansion 605-D block M.A Johar Town lahore,	Legal Manufacturer (as per FSC) Euromed For Medical Industries ,Egypt Area No.10 Block. Free Zone,Nasr City,	Brand Name: Euro Flow Generic Name: I.V.CANNULA (2 way) with	Deferred. The Board directed to return case to applicant to fill all fields of application form and in case of any approved variation from initial

	<p>Lahore</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 733357189329</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID: MDMR-20250901-14604</p>	<p>Cairo,Egypt.</p> <p>ISO 13485</p> <p>Issue Date: 2025-07-17</p> <p>Validity Date: 2028-07-16</p> <p>Notarization Status: Yes</p> <p>FSC</p> <p>Issue Date: 2024-01-18</p> <p>Validity Date: 2026-01-18</p> <p>Issuing Authority: Egypetion Drug Authority Cairo</p> <p>Attestation Status: Yes</p> <p>LOA</p> <p>Issue Date: 2025-04-15</p> <p>Validity Date: 2030-04-14</p> <p>Notarization Status: Yes</p>	<p>wings & with injection port 14,16,18,20,22,24, 26G</p> <p>Class B</p> <p>Device/Accessories Name: I.V.CANNULA (2 way) with wings & with injection port 14,16,18,20,22,24, 26G</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 9018.3940, with wings & with injection port 14,16,18,20,22,24, 26G</p> <p>Specify grouping: Single</p> <p>Storage condition: 20c - 30c</p>	<p>registration, fill fields with approved variation along with attachment of evidence of approved variation/approval letter.</p>
2	<p>Product Registration Number/Enlistment: MDIR-0001774</p> <p>K.M Enterprises</p> <p>KM Mansion 605-D block M.A Johar Town lahore, Lahore</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 113037442</p> <p>Date of submission: 01 September 2025</p> <p>Tracking ID: MDMR-20250901-14624</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Euromed For Medical Industries ,Egypt</p> <p>Area No.10 Block. Free Zone,Nasr City, Cairo,Egypt.</p> <p>ISO 13485</p> <p>Issue Date: 2025-07-17</p> <p>Validity Date: 2028-07-16</p> <p>Notarization Status: Yes</p> <p>FSC</p> <p>Issue Date: 2022-07-07</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: EGYPTIAN DRUG AUTHORITY</p> <p>Attestation Status: Yes</p> <p>LOA</p>	<p>Brand Name: EURO FOLEY SILICONE CATHETERS</p> <p>Generic Name: SILICONE CATHETERS 2 WAYS</p> <p>Class B</p> <p>Device/Accessories Name: EURO FOLEY SILICONE CATHETERS</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): 2-Way, All Sizes</p> <p>Specify grouping:</p>	<p>Deferred. The Board directed to return case to applicant to fill all fields of application form and in case of any approved variation from initial registration, fill fields with approved variation along with attachment of evidence of approved variation/approval letter.</p>

		Issue Date: 2025-04-15 Validity Date: 2030-04-14 Notarization Status: Yes	Single Storage condition: 30C	
3	<p>Product Registration Number/Enlistment: MDIR-0001822</p> <p>Global Marketing Services</p> <p>111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 70455103411</p> <p>Date of submission: 28 August 2025</p> <p>Tracking ID: MDMR-20250828-14419</p>	<p>Legal Manufacturer (as per FSC)</p> <p>M/s Biomerieux SA</p> <p>376 Chemin de l Orme 69280 Marcy l Etoile-France</p> <p>ISO 13485</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2027-11-07</p> <p>Notarization Status: Legalized</p> <p>FSC</p> <p>Issue Date: 2022-01-10</p> <p>Validity Date: 2030-10-01</p> <p>Issuing Authority: CCI PARIS ILE-DE-FRANCE INTERNATIONAL</p> <p>Attestation Status: Apostilled</p> <p>LOA</p> <p>Issue Date: 2025-04-03</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: Apostilled</p>	<p>Brand Name: VIDAS H. pylori IgG Test Kit</p> <p>Generic Name: H. pylori IgG Test Kit</p> <p>Class B</p> <p>Device/Accessories Name: VIDAS H. pylori IgG Test Kit</p> <p>Shelf life/service life: 11 months</p> <p>Codes/Sizes (if any): 30192</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: It should be stored at 2-8°C</p>	Deferred. The Board directed to return case to applicant to fill all fields of application form and in case of any approved variation from initial registration, fill fields with approved variation along with attachment of evidence of approved variation/approval letter.
4	<p>Product Registration Number/Enlistment: MDIR-0001823</p> <p>Global Marketing Services</p> <p>111,Hali Road westridge 1 Cantt rawalpindi,Pakistan, Rawalpindi</p> <p>Fee: Rs 15700 /-</p> <p>Challan No.: 3288922916</p> <p>Date of submission: 28 August 2025</p> <p>Tracking ID: MDMR-</p>	<p>Legal Manufacturer (as per FSC)</p> <p>M/s Biomerieux SA</p> <p>376 Chemin de l Orme 69280 Marcy l Etoile-France</p> <p>ISO 13485</p> <p>Issue Date: 2024-10-11</p> <p>Validity Date: 2027-11-07</p> <p>Notarization Status: Legalized</p> <p>FSC</p>	<p>Brand Name: VIDAS PTH (1-84) Test Kit</p> <p>Generic Name: PTH Test Kit</p> <p>Class B</p> <p>Device/Accessories Name: VIDAS PTH (1-84) Test Kit</p> <p>Shelf life/service life: 12 months</p> <p>Codes/Sizes (if</p>	Deferred. The Board directed to return case to applicant to fill all fields of application form and in case of any approved variation from initial registration, fill fields with approved variation along with attachment of evidence of approved variation/approval letter.

	20250828-14469	<p>Issue Date: 2022-01-10</p> <p>Validity Date: 2030-10-01</p> <p>Issuing Authority: CCI PARIS ILE-DE-FRANCE INTERNATIONAL</p> <p>Attestation Status: Apostilled</p> <p>LOA</p> <p>Issue Date: 2025-04-03</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: Apostilled</p>	<p>any): 422010</p> <p>Specify grouping: IVD Kit</p> <p>Storage condition: It should be stored at 2-8°C</p>	
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The meeting ended with vote of thanks from and to the Chair.

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