

**DECISIONS OF 81ST MEETING OF MEDICAL DEVICE BOARD
HEALTH ON 06-03-2025**

ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S#	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi,Pakistan (ELI-00090) Date of R&I 02 nd June 2022 Fee: PKR 25000/- Slip: 76684480205 Dated: 20-06-2024	Legal Manufacturer: M/s Guangdong Genial Technology Co., Ltd, Manufacturing Site: I-6-05-02 11th Road, Area B, Guangfozhao Economic Cooperation Zone, Zhagang Town, Huaiji County, Zhaoqing City, Guangdong Province, 526437, China FSC Validity: 13-04-2024.	Brand name: “GENIAL” Generic: Digital Thermometer Model: T15, T15B & T15SC Class: B LOA Validity: 31-2-2023 Shelf life: 05 years ISO 13485 validity: 16- 09-2022	Deferred for the submission of valid Free sale certificate, ISO 13485 certificate, Letter of authorization & EC certificate and verification of fee challan
2.	M/s Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi,Pakistan (ELI-00090) Date of R&I 03 August 2022 Fee: PKR 25000/- Slip: 704587351 Dated: 28-07-2022	Legal Manufacturer: M/s Wenzhou Bokang Instruments Co., Ltd, Manufacturing Site: No.1500 Haining Road Haibin, Longwan 325024, Wenzhou, China FSC Validity: 10-03-2024 ISO 13485 validity: 01-04-2026 EC Certificate Validity: 27-04- 2024	Brand name: Electronic Sphygmomanometer Generic: Digital Sphygmomanometer Model: BK6032 & BK6052 Class: B LOA Validity: 16-05-2025 Shelf life: 05 years	Approved. Registration letter shall be issued after submission valid Free sale certificate & EC certificate.
3.	M/S SULTANSONS 133, KUTCHI GALI NO. 1, MARRIOT ROAD, KARACHI (ELI- 00051) Date of R&I 02 December 2024 Fee: PKR 31000/- Slip: 3522771811 Dated: 22-11-2024	(LEGAL MANUFACTURER) Anhui Ganor Medical Device Co., Ltd (Manufacturing site) No.1,Industrial Park, Datong Town 239300,Tianchang City, Anhui Province, China FSC: Validity 18.10.2025	CLASSIC + Disposable Sterile Connecting Tube Type: (WITH ANKAUER) Class: B Shelf Life: 05 Years EC Certificate Validity:31.12.2028 ISO 13485 Validity: 10.09.2026	Approved.
4.	M/S SULTANSONS 133, KUTCHI GALI NO. 1, MARRIOT ROAD, KARACHI	Legal Manufacturer JIANGSU YUYUE Medical Instruments co., ltd. (Manufacturing site) No. 36 West Yandu Road, Yandu New District, Yancheng Jiangsu	CLASSIC Infrared Thermometer CLASS: B Code/Size:	Approved. Registration letter shall be issued after submission valid Free sale certificate & EC certificate.

	(ELI- 00051) Date of R&I 09-12-2021 Fee: PKR 31000/- Slip: 426179628012 Dated: 01-12-2021	224005,P.R.China FSC: Validity 07-06-2024 ISO 13485 Validity: 14-07-2025	YHW1, YHW-2, YHW-3, YHW-4, YHW-5, YHW-6 Shelf Life: N/A EC Certificate Validity: 27-05-2024 LOA Validity 19-05-2027	
5.	M/S SULTANSONS 133, KUTCHI GALI NO. 1, MARRIOT ROAD, KARACHI (ELI- 00051) Date of R&I 17-03-2023 Fee: PKR 31000/- Slip: 699070944142 Dated: 13-02-2023	Legal Manufacturer FUJIAN BESTWAY. (Manufacturing site) No. 138 Guanpu Road, Fuzhou, China FSC: Validity 05-06-2027 ISO 13485 Validity: 26-10-2027	CLASSIC PLUS Disposable Endotracheal Tube Sterile Without Cuff CLASS: B Code/Size: (2.0,2.5,3.0,3.5,4.0,4 .5,5.0,5.5,6.0, 6.5,7.0,7.5,8.0,8.5,9. 0,9.5,10.0,10.5, 11.0) WITHOUT CUFF (2.0,2.5,3.0,3.5,4.0,4 .5,5.0,5.5,6.0, 6.5,7.0,7.5,8.0,8.5,9. 0,9.5,10.0,10.5, 11.0)	Approved
6.	M/S Popular International Pvt. Ltd. 141 KMCHS Karachi (ELI- 00091) Date of R&I 20-10-2022 Fee: PKR 25000/- Slip: 55588823 Dated: 07-10-2022	Details of manufacturer and models / accessories given in the below row	Product / family Name: CAPNOSTREAM 35 Generic: CO2 Monitoring System Class: C LOA Validity: Valid until revoked CFG Validity: 10/05/2024 ISO 13485 16/04/2025 EC Certificate: 31/12/2028	Approved. Registration letter shall be issued after submission of valid certificate to foreign Government & differential fee as per Class C (medical group: family)
Legal Manufacturer: COVIDIEN LLC. 15 HAMPSHIRE STREET, MANSFIELD MA 02048, USA. Contract Manufacturer: Sanmina, Huntsville, AL 13000 Memorial Pkwy Sw UNTSVILLE, AL USA35803 Models of CAPNOSTREAM 35: PM35MN03: Capnostream35 Portable Respiratory Monitor PM35BTY03: Capnostream35 removable battery PM35CHG03 / PM35CHG: Capnostream35 external battery charger PM35VAA03: Capnostream35 Vesa adapter assembly		Accessories for CAPNOSTREAM 35: Legal Manufacturer RESPIRONICS MEDICAL PRODUCTS (SHENZHEN) CO., LTD. Block 6 & 7, No. 129, 2nd Industrial Avenue Tang Xia Yong Village, Yan Luo Subdistrict, Bao An District SHENZHEN, Guangdong CHINA 518105 Volcano Corporation by Volcarica S.R.L. BRAND NAME Coyol Free Zone and Business Park Building B37 Coyol, Alajuela COSTA RICA none Accessories for CAPNOSTREAM 35: 10087 409: Capnography Sensor, Reusable 10078386: Neonatal & pediatric CO ₂ airway adapter, Disposable. 10078387: Pediatric & Adult CO ₂ airway adapter, Disposable 10083942: Pediatric & Adult CO ₂ airway adapter, Reusable 10083943: Neonatal & pediatric CO ₂ airway adapter, Reusable 10047078: Proximal Flow Sensor, Neonatal 10005002: Neonatal flow & CO ₂ Sensor, Disposable		
7.	M/S National Enterprises. 409, 4th floor Al-Sehat	Legal Manufacturer Disa Medinotec (Pty) Ltd.	Trachealator Rx Non-Occlusive Airway	Deferred for submission of

	<p>Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi (ELI- 00043)</p> <p>Date of R&I 18-10-2024</p> <p>Fee: PKR 6000/- Slip: 2449476902 Dated: 01-10-2024</p>	<p>(Manufacturing site) Stand 171, Northlands Business Park, Bush Telegraph Street, Northriding, Johannesburg, 2169, South Africa</p> <p>FSC: Validity 06-02-2025</p> <p>ISO 13485 Validity: 26-04-2025</p>	<p>Dilation Catheter - Sterile CLASS: A Code/Size: TRD1-06030, TRD1-07030 TRD1-08030, TRD1-09030 TRD1-10030, TRD1-12040 TRD1-14540, TRD1-16040 TRD1-18040 Shelf Life: 03 years LOA Validity 01-01-2027 EC Certificate Validity: 26-04-2027</p>	<p>Declaration of conformity to confirm the risk class of this device in Europe.</p>
8.	<p>M/S Sanyoh International. Flat #8 Block 19. Allah Dad plaza, G8 Markaz, Islamabad (ELI- 01179)</p> <p>Date of R&I 08-01-2024</p> <p>Fee: PKR25000/- Slip: 18617777676 Dated: 28-12-2023</p>	<p>Legal Manufacturer EMBOSS MEDICAL LIMITED. (Manufacturing site) 128 City Road, London, EC1V 2NX, United Kingdom</p> <p>FSC: Validity 08-08-2028</p> <p>ISO 13485 Validity: 26-04-2025</p>	<p>Product: Circumplast® Generic: Circumcision Device Class: B Size: CIRC-11 → 11mm CIRC-12 → 12mm CIRC-13 → 13mm CIRC-95 → 9.5mm Shelf life: 05 years LOA Validity: Valid until revoked ISO 13485 16/05/2025 EC Certificate: 08/08/2027</p>	<p>Approved</p>
9.	<p>M/S Rech International. 247/B, Block 6 PECHS Shahrah-e-Faisal Karachi (ELI- 00257)</p> <p>Date of R&I 6-March-2024</p> <p>Fee: PKR 25000/- Slip: 82579984739 Dated: 26-02-2024</p>	<p>Legal Manufacturer M/s Beijing Medkon Medical Devices Co, Ltd Floor 1 and 2 Building 1, Floor 1and 2 Building 5, 8 Yunteng Rd., Miyun Economic Development Zone, Miyun District, 101500 Beijing, P.R. China</p> <p>FSC: Validity 18-03-2026</p> <p>ISO 13485 Validity: 26-04-2025</p>	<p>Brand: Medkon pulse Lavage system Generic: Disposable Battery powered Surgical / Orthopedic Pulse Lavage System Class: B</p> <p>Shelf life: NA LOA Validity: 20th October 2025 ISO 13485: 29-01-2027 EC Certificate validity: 04-12-2029</p>	<p>Approved</p>
10.	<p>M/S Rech International. 247/B, Block 6 PECHS Shahrah-e-Faisal Karachi (ELI- 00257)</p> <p>Date of R&I August-2024</p> <p>Fee: PKR 25000/- Slip: 624215267 Dated: 29-07-2024</p>	<p>Legal Manufacturer M/s Jiangsu Changmei Medtech Co., Ltd. Add: No.27 Xinke West Road, Luoyang, Wujin District, Changzhou 213104, Jiangsu, China</p> <p>FSC: Validity 18-03-2026</p> <p>ISO 13485 Validity: 01-07-2027</p> <p>LOA Validity: 30-06-2025</p> <p>ISO 13485 validity: 29-01-2027</p>	<p>Brand: Jiangsu Changmei Generic: Medtech Khyphoplasty system Class: B MD Group: system Models: Kyphoplasty Tool Kit: KT-00-01、KT-00-02、KT00-03、KT-00-04、KT-00-05、KT-00-06 Balloon Inflator: BI20 (25、30、35、40) A-(10、15、20、25) Kyphoplasty Balloon Catheter</p>	<p>Approved</p>

		EU QMS validity: Year 2029	KB10, KB15, KB20, KB25, KB10S, KB15S, KB20S, KB25S Shelf life: 03 years	
11.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore. (ELI- 00993) Fee: PKR 5000/- Slip: 8644815427 Dated: 24/11/2022	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park, Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom	Brand: GPH Generic: MICROTOME BLADE Class: A Models: JDD-1100- 00A Shelf life: 03 years	Approved
12.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore. (ELI- 00993) Fee: PKR 5000/- Slip: 524655405372 Dated: 24/11/2022	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park, Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom	Brand: GPX Generic: MICROTOME BLADE Class: A Models: JDD-1000- 00A Shelf life: 03 years	Approved
13.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore. (ELI- 00993) Fee: PKR 5000/- Slip: 57841442 Dated: 24/01/2023	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park, Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom	Brand: CELLSTOR 5L – 10% NEUTRAL BUFFERED FORMALIN Generic: Formalin Class: A Models: BAF-0010- 25A-PK Shelf life: 03 years	Approved
14.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore. (ELI- 00993) Fee: PKR 5000/- Slip: 11613143 Dated: 24/01/2023	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park, Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom	Brand: EOSIN Y STAIN 1% (ALCOHOLIC) – 1L Generic: EOSIN Class: A Models: RBC-0201- 00A-PK Shelf life: 03 years	Approved
15.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore. (ELI- 00993) Fee: PKR 5000/- Slip: 615639551 Dated: 24/01/2023	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park, Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom	Brand: EOSIN Y STAIN 1% (AQUEOUS) – 1L Generic: EOSIN Class: A Models: RBC-0201- 00A-PK Shelf life: 03 years	Approved
16.	M/S Health Imaging System 319 Imperial Garden Paragon City, Lahore.	Legal Manufacturer M/s CellPath Ltd. Mochdre Enterprise Park,	Brand: HARRIS HAEMATOXYLIN STAIN (ORTHO) – 1 L	Approved

	<p>(ELI- 00993)</p> <p>Fee: PKR 5000/- Slip: 062981639128 Dated: 24/01/2023</p>	<p>Newtown, Powys, SY16 4LE, Mid Wales, United Kingdom</p>	<p>Generic: HAEMATOXYLIN Class: A Models: RBA-4213- 00A-PK Shelf life: 03 years</p>	
17.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 5000/- Slip: 58662134802 Dated: 27/09/2022</p>	<p>Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US</p> <p>LOA Validity: 31-12-2025</p> <p>FSC Validity: 31-05-2025</p> <p>ISO 13485 Validity: 12-03-2027</p> <p>EC Certificate issue date: 05-01-2021</p>	<p>B40602 - TN, DXH 520 CP HEMATOLOGY INSTRUMENT (HEMATOLOGY ANALYZER)</p> <p>B40603 - DxH 560 AL HEMATOLOGY ANALYZER (HEMATOLOGY ANALYZER)</p> <p>C00345 - SALES GROUP REMFG TN, UNICEL DXH 800 REMANUFACTURED UNITIZED (HEMATOLOGY ANALYZER)</p> <p>C23655 - SALES GROUP TN, DXH 900 (HEMATOLOGY ANALYZER)</p> <p>C34520 - TN, DxH 690T HEMATOLOGY SYSTEM (HEMATOLOGY ANALYZER)</p> <p>C23656 - SALES GROUP TN, DXH SMS II (HEMATOLOGY ANALYZER)</p> <p>A95702 - S/A, SMS PRINTER CARTRIDGE (SMS PRINTER)</p> <p>A95865 - R PROD, DXH 800/600/900/ PMI KIT (PMI KIT)</p>	Approved.
18.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 06/01/2023 Fee: PKR 5000/- Slip: 44024481688 Dated: 03/01/2023</p>	<p>Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae- myeon, Chungcheon-si, Gang- won-do 24398, KOREA</p> <p>LOA Validity: 01-01-2026</p> <p>FSC issue date: 05-10-2022</p>	<p>FPRRO34 - EZ POC Analyzer (Chemistry Analyzer)</p> <p>FPRRO09 - i-Chamber (Chemistry Analyzer)</p> <p>FPRRO07 - Thermal Printer (Printer)</p> <p>CFPO-161 - Handy Ray</p>	Approved.

		ISO 13485 Validity: 31-10-2025 EC Certificate Validity: 22-07-2026	(Sampler) Class: A Shelf life:	
19.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 06/01/2023 Fee: PKR 5000/- Slip: 297221148887 Dated: 03/01/2023	Legal Manufacturer DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC issue date: 27-03-2023 ISO 13485 Validity: 31-11-2025 DOC Issue date : 27-07-2022	960910 - Respons 910 (Chemistry analyzer) 960920 - Respons 920 (Chemistry analyzer) 960921 - Respons 920 with ISE (Chemistry analyzer) 965900 - Respons 940 (Chemistry analyzer) 965910 - Respons 940 with ISE (Chemistry analyzer) 187009910920 - Respons Containers Twin large (Accessories) 187009910921 - Respons Containers Twin small (Accessories) 187009910923 - Respons Containers Mono (Accessories)	Approved.
20.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 03453640473 Dated: 21/05/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC validity : 24-06-2025 ISO 13485 Validity: 31-12-2025 DOC Issue date : 13-12-2022	010102008801 010102002301 010102002401 010102002201 010102002801 010102002901 010102003001 010102003101 010102003201 010102003301 - Biossays C8 (Automatic Biochemistry Analyzer) Class: A Shelf life: 010102008801 – 10 years 010102002301 – 10 years 010102002401 – 10 years 010102002201 –	Approved the firm will submit brand name

			10 years 010102002801 – 10 years 010102002901 – 10 years 010102003001 – 10 years 010102003101 – 10 years 010102003201 – 10 years 010102003301 – 10 years	
21.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 04709745 Dated: 21/06/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 ISO 13485 Validity: 31-12-2025 DOC Issue date : 13-12-2022	130299004M - Starter 1+2 (230 ml) (substrate reagent) 130299027M - Starter 1+2 (1.5 ml) (substrate reagent) Class: A Codes/Sizes: 130299004M (230 ml) 130299027M (1.5 ml) Shelf life: 130299004M – 1 year 130299027M - 1 year	Approved. the firm will submit brand name
22.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 04709745 Dated: 21/06/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 DOC Issue date : 13-12-2022	130299006M Light Check (Chemiluminescent substrate reagent IVD) Class: A Codes/Sizes: 130299006M (5*2ml) Shelf life: 130299006M – 2 year ISO 13485 Validity: 31-12-2025	Approved. the firm will submit brand name
23.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 82934309757 Dated: 21/06/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025	630003 - Reaction Modules (Chemiluminescent substrate reagent IVD) Class: A Codes/Sizes: 630003 (6*64) Shelf life: 630003 – 2 year ISO 13485 Validity: 31-12-2025 FSC issue date : 29-09-2022	Approved. the firm will submit brand name
24.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9,	Legal Manufacturer Shenzhen New Industries	130299007M – System Tubing Cleaning	Approved. the firm will submit brand

	Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 128595619260 Dated: 21/06/2024	Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 DOC Issue date : 13-12-2022	Solution (Chemiluminescent substrate reagent IVD) Class: A Codes/Sizes: 130299007M (1'500ml) Shelf life: 130299007M – 1 year ISO 13485 Validity: 31-12-2025	name
25.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 1673002166 Dated: 21/02/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China	63000040 – BIOSSAYS 240 PLUS (Automatic Biochemistry Analyzer) Class: A Shelf life: 63000040 – 5 year LOA Validity : 30-12-2025 FSC issue date : 29-09-2022	Approved. the firm will submit brand name
26.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 7642139301 Dated: 21/02/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022	130208000201 – MAGLUMI Disposable Tips (96 tips) (MAGLUMI Disposable Tips (96 tips)) Class: A Codes/Sizes: 130208000201 (96 tips) Shelf life: 130208000201 – 20 month	Approved the firm will submit brand name
27.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 8775637532 Dated: 21/02/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 ISO 13485 Validity: 31-12-2025 DOC Issue date : 13-12-2022	23020018 – MAGLUMI 600 (Fully-auto chemiluminescence immunoassay analyzer) 23020003 - MAGLUMI 800 (Fully-auto chemiluminescence immunoassay analyzer) 23020006 - MAGLUMI 2000 (Fully-auto chemiluminescence immunoassay analyzer)	Approved the firm will submit brand name

			Class: A Shelf life: 23020018 - 10 years 23020003 - 10 years 23020006 - 10 years	
28.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 07768005254 Dated: 21/02/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 ISO 13485 Validity: 31-12-2025 DOC Issue date : 13-12-2022	23020007 – MAGLUMI 2000 PLUS (Fully-auto chemiluminescence immunoassay analyzer) 23020037 - MAGLUMI 4000 PLUS (Fully-auto chemiluminescence immunoassay analyzer) Class: A Shelf life: 23020007 - 10 years 23020037 - 10 years	Approved the firm will submit brand name
29.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 4726595331 Dated: 21/02/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity : 30-12-2025 FSC issue date : 29-09-2022 ISO 13485 Validity: 31-12-2025 DOC Issue date : 13-12-2022	10101003301 - MAGLUMI X3 (Fully-auto chemiluminescence immunoassay analyzer) 10101008801 - MAGLUMI X8 (Fully-auto chemiluminescence immunoassay analyzer) 010101002501 - MAGLUMI X8 Immunoassay module (Single Track) * 1 + Sample area * 1 (Fully-auto chemiluminescence immunoassay analyzer) 010101002301 - Maglumi X8 Immunoassay module (Three Tracks) *2 + decapper module*1+ Sample area * 1) (Fully-auto chemiluminescence immunoassay analyzer) 010101002101 - Maglumi X8 Immunoassay module (Three Tracks)*2+ Sample area * 1 (Fully-auto chemiluminescence immunoassay analyzer)	Approved the firm will submit brand name

			<p>010101001901 - Maglumi X8 Immunoassay module (Three Tracks) *1+ decapper module*1+ Sample area * 1 (Fully-auto chemiluminescence immunoassay analyzer) Class: A</p>	
30.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2024 Fee: PKR 5000/- Slip: 03351764588 Dated: 21/02/2024</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity : 30-12-2025</p> <p>FSC Validity : 24-06-2025</p> <p>ISO 13485 Validity: 31-12-2025</p> <p>DOC Issue date : 13-12-2022</p>	<p>010101006601 - Maglumi X6 Immunoassay module*1 (Fully-auto chemiluminescence immunoassay analyzer)</p> <p>010101006001 - Maglumi X6 Immunoassay module(Long Sample Arm)*1 (Fully-auto chemiluminescence immunoassay analyzer)</p> <p>010101006201 - MAGLUMI X6 Sample area *1+ Immunoassay module (Including short track) *1) (Fully-auto chemiluminescence immunoassay analyzer)</p> <p>010101006801 - MAGLUMI X6 (Sample area *1+ Immunoassay module (Including short track) *1) + Immunoassay module (Including long track) *1) (Fully-auto chemiluminescence immunoassay analyzer)</p> <p>010101006401 - MAGLUMI X6 (Sample area *1+ decapper module * 1+ Immunoassay module (Including short track) *1) (Fully-auto chemiluminescence immunoassay analyzer)</p> <p>10101007001 - MAGLUMI X6 (Sample area *1+ decapper</p>	<p>Approved the firm will submit brand name</p>

			<p>module * 1+ Immunoassay module (Including short track) *1) + Immunoassay module (Including Long Track)*1)</p> <p>Fully-auto chemiluminescence immunoassay analyzer (Fully-auto chemiluminescence immunoassay analyzer)</p>	
31.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>R&I detail 11/03/2024</p> <p>Fee: PKR 5000/- Slip: 19572633951 Dated: 21/02/2024</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity : 30-12-2025</p> <p>FSC issue date : 29-09-2022</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>130105000101 – MAGLUMI Reaction Cup (3*182cups) (MAGLUMI Reaction Cup (3*182cups))</p> <p>Class: A Codes/Sizes: 130105000101 (3*182cups)</p> <p>Shelf life: 130105000101 – 20 month</p> <p>DOC Issue date : 13-12-2022</p>	Approved the firm will submit brand name
32.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>R&I detail 11/03/2024</p> <p>Fee: PKR 5000/- Slip: 91165601 Dated: 21/02/2024</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity : 30-12-2025</p> <p>FSC issue date : 29-09-2022</p> <p>ISO 13485 Validity: 31-12-2025</p> <p>DOC Issue date : 13-12-2022</p>	<p>21060624 - MAGLUMI Waste Bag Apply to MAGLUMI 1000 Analyzer and MAGLUMI 2000 Analyzer (Waste Bag)</p> <p>21060625 - MAGLUMI Waste Bag Apply to MAGLUMI 1000 Analyzer and MAGLUMI 2000 Analyzer (Waste Bag)</p> <p>21060726 - MAGLUMI Waste Bag Apply to MAGLUMI 600 Analyzer and MAGLUMI 800 Analyzer (Waste Bag)</p> <p>130210000201 - MAGLUMI Waste Bag Apply to MAGLUMI 1000 Analyzer and MAGLUMI 2000 Analyzer (Waste Bag)</p>	Approved the firm will submit brand name
33.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd.</p>	<p>130299005M - Wash Concentrate (Consumables) 130299035M -</p>	Approved the firm will submit brand name

	<p>(ELI- 00619)</p> <p>R&I detail 11/10/2023</p> <p>Fee: PKR 5000/- Slip: 46818827324 Dated: 05/06/2023</p>	<p>No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity : 30-12-2025</p> <p>FSC issue date : 29-09-2022</p>	<p>Wash Concentrate (Consumables) Class: A Codes/Sizes: 130299005M (1x714mL) 130299035M (1x10L) Shelf life: 130299005M – 09 month 130299035M - 09 month</p>	
34.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 11/03/2023 Fee: PKR 5000/- Slip: 4305015568 Dated: 05/06/2023</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity : 30-12-2025</p> <p>FSC issue date : 29-09-2022</p> <p>ISO 13485 Validity: 31-12-2025</p> <p>DOC Issue date : 13-12-2022</p>	<p>1305990002 - Acid Wash (Consumables) 1305990006 - Acid Wash (Consumables) 1305990008 - Acid Wash (Consumables) 1305990007 - Acid Wash (Consumables) Class: A Codes/Sizes: 1305990002 (1x500g) 1305990006 (1x2000g) 1305990008 (2x60g) 1305990007 (2x40g)</p>	Approved the firm will submit brand name
35.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 24/06/2024 Fee: PKR 5000/- Slip: 0980078701 Dated: 21/05/2024</p>	<p>Legal Manufacturer Robert Riele GmbH & Co KG. Kurfuerstenstr. 75-79, 13467 Berlin Germany</p> <p>LOA Validity : 30-08-2028</p> <p>FSC issue date : 08-02-2024</p> <p>ISO 13485 Validity: 22-10-2025</p> <p>DOC Issue date : 12-02-2024</p>	<p>426237161P5053N - Photometer 505 (Photometer detection analyzer)</p> <p>Class: A Codes/Sizes: 426237161P5053N</p> <p>Shelf life: 426237161P5053N – 10 years</p>	Approved the firm will submit brand name
36.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>R&I detail 05/10/2022</p>	<p>Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US</p> <p>LOA Validity: 31-12-2025</p>	<p>COULTER LATRON CP-X CONTROL (LATRON CP-X CONTROL)</p> <p>COULTER LATRON CONTROL</p>	Approved.

	Fee: PKR 25000/- Slip: 69808498 Dated: 27-09-2022	FSC Validity: 31-05-2025 DOC Issue date: 16-03-2018 ISO 13485 Validity: 12-03-2027	(LATRON CONTROL) Class B Codes/Sizes: 628024 - (8 x 4MI) 7546914 - (5 x 16MI) Shelf Life: 628024 - 12 Months 7546914 - 12 Months	
37.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 20562771 Dated: 27-09-2022	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC issue date: 23-10-2024 DOC issue date: 20-05-2022 ISO 13485 Validity: 12-03-2027	COULTER BODY FLUID CONTROL (BODY FLUID CONTROL) COULTER DxH RETIC PACK (RETIC PACK) COULTER RETIC-X CELL CONTROL (RETIC-X CELL CONTROL) Class B Shelf Life: 120 days Codes/Sizes 628030 (4 x 3.5 MI Level 1 4 x 3.5 MI Level 2 4 x 3.5 MI Level 3) 628021 (1 x 380 MI Level 1 1 x 1900 MI Level 2) 628028 (4 x 3.5 MI Level 1 4 x 3.5 MI Level 2 4 x 3.5 MI Level 3)	Approved.
38.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 201171758	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC issue date: 23-10-2024 DOC issue date: 09-05-2022 ISO 13485 Validity: 12-03-2027	628029 - COULTER LIN-X LINEARITY CONTROL 628022 - COULTER DxH CLEANER (CLEANER) 628023 - COULTER DxH CLEANER (CLEANER) Class B Shelf Life: 628029 - 120 days 628022 - 3 Months 628023 - 3 Months Codes/Sizes 628029 (12 x 3.3MI) 628022 (1 x 5 L)	Approved.

			628023 (1 x 10 L)	
39.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 1565283204	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC Validity: 31-05-2025 DOC Issue date: 17-01-2022 ISO 13485 Validity: 12-03-2027	628027 - COULTER 6C CELL CONTROL (6C CELL CONTROL) A59925 - COULTER 6C CELL CONTROL (6C CELL CONTROL) C07297 - COULTER 6C PLUS CELL CONTROL (6C PLUS CELL CONTROL) Class B Shelf Life: 628027 - 95 Days A59925 - 95 Days C07297 - 95 Days	Approved.
40.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 5648654612	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC issue date: 23-10-2024 DOC issue date: 25-05-2022 ISO 13485 Validity: 12-03-2027	COULTER DxH DILUENT (DILUENT) COULTER DxH CELL LYSE (CELL LYSE) COULTER DxH CELL LYSE (CELL LYSE) Class B Shelf Life: 628017 60 Days 628018 60 Days 628019 60 Days Codes/Sizes 628017 (1 x 10 L) 628018 (1 x 1 L) 628019 (1 x 1 L)	Approved.
41.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 1004282717	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC Country of Origin issue date: 23-10-2024 DOC issue date: 20-05-2022 ISO 13485 Validity: 12-03-2027	COULTER S-CAL CALIBRATOR KIT (CALIBRATOR KIT) COULTER DxH DIFF PACK (DIFF PACK) DxH 500 SERIES CALIBRATOR (SERIES CALIBRATOR) Class B Shelf Life: 628026 - 73 Days 628020 - 73 Days B36880 - 73 Days	Approved.

42.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 961792241448	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC Country of Origin issue date: 27-03-2024 DOC issue date: 24-05-2022 ISO 13485 Validity: 12-03-2027	DxH 500 SERIES DILUENT (SERIES DILUENT) DxH 500 SERIES LYSE (SERIES LYSE) DxH 500 SERIES CLEANER (SERIES CLEANER) DxH 500 SERIES CONTROL (SERIES CONTROL) Class B Shelf Life: 60 Days 60 Days 3 Months 16 Days	Approved.
43.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 7689241348	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC Country of Origin Validity: 31-05-2025 DOC issue date: 06-02-2019 ISO 13485 Validity: 12-03-2027	COULTER TRUCOLOR WRIGHT STAIN (WRIGHT STAIN) COULTER TRUCOLOR WRIGHT-GIEMSA STAIN (WRIGHT-GIEMSA STAIN) COULTER TRUCOLOR WRIGHT STAIN BUFFER (WRIGHT STAIN BUFFER) COULTER TRUCOLOR WRIGHT-GIEMSA STAIN BUFFER (WRIGHT-GIEMSA STAIN BUFFER)	Approved.
44.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 05/10/2022 Fee: PKR 25000/- Slip: 59813607075	Legal Manufacturer Beckman Coulter Inc. 250 South Kraemer Blvd, CA 92821 Brea, US LOA Validity: 31-12-2025 FSC Country of Origin Validity: 31-05-2025 ISO 13485 Validity: 12-03-2027	GC002 - DXH 500 G-CAL (G-CAL) B01276 - GLWR, CUSTOM, 25x75x1MM, GLASS MICROSCOPE SLIDE, BOTH ENDS PAINTED, SQUARE (GLASS MICROSCOPE SLIDE)	Approved.
45.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae- myeon, Chungcheon-si, Gang- won-do 24398, KOREA LOA Validity: 01-01-2026	EZ POC Anti-CCP Plus (anti-CCP Plus) Class B Shelf Life: 20 Months Codes/Sizes:	Approved subject to submission of differential fee.

	<p>R&I detail 16/09/2024</p> <p>Fee: PKR 25000/- Slip: 350635769861 Dated: 19/08/2024</p>	<p><u>FSC</u> issue date: 07-10-2022</p> <p><u>OR</u> <u>EC Certificate</u> Validity: 22-07-2026</p> <p><u>ISO 13485</u> Validity: 31-10-2025</p>	EZPC-25 ((25 tests))	
46.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail 16/09/2024</p> <p>Fee: PKR 25000/- Slip: 774177953061 Dated: 19-08-2024</p>	<p>Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA</p> <p>LOA Validity: 01-01-2026</p> <p>FSC issue date: 07-10-2022</p> <p>EC Certificate Validity: 22-07-2026</p> <p>ISO 13485 Validity: 31-10-2025</p>	<p>EZ POC β-hCG (Beta-Human Chorionic Gonadotropins)</p> <p>EZ POC LH (Luteinizing hormone)</p> <p>EZ POC FSH (Follicle Stimulating Hormone)</p> <p>Class B</p> <p>Shelf Life: EZPC-11 - 20 months EZPC-17 - 20 months EZPC-19 - 20 months</p> <p>Codes/sizes: EZPC-11 (25 tests) EZPC-17 (25 tests) EZPC-19 (25 tests)</p>	Approved subject to submission of differential fee.
47.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail 16/09/2024</p> <p>Fee: PKR 25000/- Slip: 9942042147 Dated: 19-08-2024</p>	<p>Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA</p> <p>LOA Validity: 01-01-2026</p> <p>FSC issue date: 07-10-2022</p> <p>EC Certificate Validity: 22-07-2026</p> <p>ISO 13485 Validity: 31-10-2025</p>	<p>EZ POC Calprotectin (Calprotectin)</p> <p>Class B Shelf Life: 20 months</p> <p>Codes/Sizes EZPC-49</p>	Approved subject to submission of differential fee.
48.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail 16/09/2024</p> <p>Fee: PKR 25000/-</p>	<p>Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA</p> <p>LOA Validity: 01-01-2026</p>	<p>EZ POC Cortisol (Cortisol)</p> <p>Class B Shelf Life:20 months</p> <p>Codes/Sizes EZPC-28 (25 tests)</p>	Approved subject to submission of differential fee.

	Slip: 759163138060 Dated: 19-08-2024	FSC issue date: 07-10-2022	EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	
49.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 937758595583 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnaemyeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022	EZ POC Cystatin C (Cystatin C) Class B Shelf Life: 20 months Codes/Sizes EZPC-33 (25 tests) EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
50.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 5152331214 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnaemyeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022	EZ POC ASO (Anti-Streptolysin O (ASO)) Class B Shelf Life: 20 months Codes/Sizes EZPC-24 (25 tests) EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
51.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 81741231 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnaemyeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022 EC Certificate Validity: 22-07-2026	EZ POC HbA1c (HbA1c) Class B Shelf Life: 20 months Codes/Sizes EZPC-3 (25 tests) ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
52.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 853776257 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnaemyeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022 EC Certificate Validity: 22-07-2026	EZ POC Vitamin D (Vitamin D) Class B Shelf Life: 20 Months Codes/Sizes EZPC-9 (25 tests)	Approved subject to submission of differential fee.

		ISO 13485 Validity: 31-10-2025		
53.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 33584593334 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022	EZ POC Ferritin (Ferritin) Class B Shelf Life: 20 months Codes/Sizes EZPC-18 (25 tests) EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
54.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 1105984748 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022	EZ POC H.pylori SA (Helicobacter pylori SA) Class B Shelf Life: 20 months Codes/Sizes EZPC-39 (25 tests) EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
55.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 40103436463 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022	EZ POC Microalbumin (Microalbumin) Class B Shelf Life: 20 months Codes/Sizes EZPC-14 (25 tests) EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	Approved subject to submission of differential fee.
56.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 041189006 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022 EC Certificate Validity: 22-07-2026	EZ POC PRL (Prolactin (PRL)) EZ POC Progesterone (Progesterone) EZ POC Testosterone (Testosterone) Class B Shelf Life: EZPC-8 - 20 months EZPC-12 - 20 months EZPC-27 - 20 months	Approved the firm will submit differential fee.for EZ POC PRL (Prolactin (PRL)) and seperate fee for EZ POC Progesterone (Progesterone) and EZ POC Testosterone (Testosterone) as per revised SRO

		ISO 13485 Validity: 31-10-2025	Codes/Sizes EZPC-8 (25 tests) EZPC-12 (25 tests) EZPC-27 (25 tests)	
57.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 16/09/2024 Fee: PKR 25000/- Slip: 606449117827 Dated: 19-08-2024	Legal Manufacturer Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gangwon-do 24398, KOREA LOA Validity: 01-01-2026 FSC issue date: 07-10-2022 EC Certificate Validity: 22-07-2026 ISO 13485 Validity: 31-10-2025	EZ POC TSH (Thyroid stimulating hormone (TSH)) EZ POC T3 (Triiodothyronine (T3)) EZ POC T4 (Thyroxine T4) Class B Shelf Life: EZPC-1 - 20 months EZPC-10 - 20 months EZPC-5 - 20 months Codes/Sizes EZPC-1 (25 Tests) EZPC-10 (25 Tests) EZPC-5 (25 Tests)	Approved the firm will submit differential fee.for EZ POC TSH (Thyroid stimulating hormone (TSH)) and seperate fee for EZ POC T3 (Triiodothyronine (T3)) EZ POC T4 (Thyroxine T4) as per revised SRO
58.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 47310169 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	ALAT (GPT) FS (IFCC mod.) (Alanine Aminotransferase (glutamic pyruvic transaminase)) Class B Shelf Life: 15 Months Codes/Sizes: 127019910021 /5x20mL/1x25mL 127019910023 /1x800mL/1x200mL 127019910026 /5x80mL/1x100mL 127019910704 /8x50mL/8x12.5mL 127019910917 /8x60mL/8x15mL 127019910920 /4x200 Test 127019910962 /1380 Test	Approved
59.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 905619332307 Dated: 24-09-2024	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country	ASAT (GOT) FS (IFCC mod.) (Aspartate Aminotransferase (glutamic oxaloacetic transaminase))) Class B Shelf Life: 15 Months Codes/Sizes: 126019910021	Approved

	Fee: PKR 31000/-	Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	/5x20mL/1x25mL 126019910023 /1x800mL/1x200mL 126019910026 /5x80mL/1x100mL 126019910704 /8x50mL/8x12.5mL 126019910917 /8x60mL/8x15mL 126019910920 /4x200 Test 126019910962 /1380 Test	
60.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 80183729 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	GLDH FS DGKC (Glutamate dehydrogenase) Class B Shelf Life: 22 Months Codes/Sizes: 124119910021 /5x20mL/1x25mL 124119910930 /4x20mL/2x10mL	Approved
61.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 0425157762 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Glucose Hexokinase FS (Glucose Hexokinase) Class B Shelf Life: 24 Months Codes/Sizes: 125119910021 /5x20mL/1x25mL 125119910023 /1x800mL/1x200mL 125119910026 /5x80mL/1x100mL 125119910704 /8x50mL/8x12.5mL 125119910917 /8x60mL/8x15mL 125119910920 /4x200 Test 125119910962 /2280 Test 125119910963 /2280 Test	Approved
62.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 449466242753 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	HbA1c net FS (Hemoglobin A1c) Class B Shelf Life: 12 Months Codes/Sizes: 133489910920 /4x200 Test 133489910921 /4x100 Test 133489910930 /3x18mL/3x6mL 133489910962 /6x300 Test 133489910964 /2x160 Tests	Approved.

		ISO 13485 Validity: 21-11-2025		
63.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 66160577055 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Total bile acids 21 FS (Total bile acids) Class B Shelf Life: 12 Months Codes/Sizes: 122389910920/ 800 (4 x 200) 122389910921/ 4x50 Test 122389910930/ 4x12mL/2x8Ml	Approved.
64.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 79932502113 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Total protein FS (Total protein) Class B Shelf Life: 24 Months Codes/Sizes: 123119910021 /5x20mL/1x25mL 123119910023 /1x800mL/1x200mL 123119910026 /5x80mL/1x100mL 123119910704 /8x50mL/8x12.5mL 123119910917 /8x60mL/8x15mL 123119910920 /4x200 Test 123119910962 /1890 Test	Approved.
65.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 0596456027 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Urea FS (Urea) Class B Shelf Life: 24 Months Codes/Sizes: 131019910021 /5x20mL/1x25mL 131019910023 /1x800mL/1x200mL 131019910026 /5x80mL/1x100mL 131019910704 /8x50mL/8x12.5mL 131019910917 /8x60mL/8x15mL 131019910920 /4x200 Test 131019910962 /2280 Test 131019910963 /2280 Test	Approved.
66.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany	Uric acid FS TBHBA (Uric acid) Class B Shelf Life: 18 Months	Approved.

	R&I detail -07/11/2024 Slip: 162348831758 Dated: 24-09-2024 Fee: PKR 31000/-	LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Codes/Sizes: 130219910021 /5x20mL/1x25mL 130219910023 /1x800mL/1x200mL 130219910026 /5x80mL/1x100mL 130219910704 /8x50mL/8x12.5mL	
67.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -07/11/2024 Slip: 438745438929 Dated: 24-09-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Uric acid FS TOOS (Uric acid) Class B Shelf Life: 24 Months Codes/Sizes: 130019910021 /5x20mL/1x25mL 130019910023 /1x800mL/1x200mL 130019910026 /5x80mL/1x100mL 130019910704 /8x50mL/8x12.5mL 130019910917 /8x60mL/8x15mL 130019910920 /4x200 Test 130019910962 /1890 Test	Approved.
68.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 566687467 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 <u>FSC</u> FSC of Reference Country Issue Date: 20-09-2022 <u>ISO 13485</u> Validity: 21-11-2025	Albumin FS (Albumin) Class B Shelf Life: 24 Months Codes/Sizes: 102209910021 /6x25mL 102209910023 /1x1000mL 102209910026 /6x100mL 102209910704 /8x50mL 102209910917 /10x60mL 102209910923 /4x200 Test 102209910960 /980 Test 102209910967 /1500 Test	Approved.
69.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 61326825247 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485	Alkaline phosphatase FS IFCC 37 °C (Alkaline phosphatase) Class B Shelf Life: 15 Months Codes/Sizes: 104419910021 /5x20mL/1x25mL 104419910023 /1x800ml/1x200mL 104419910026 /5x80mL/1x100mL 104419910704 /8x50mL/8x12.5mL 104419910917	Approved.

		Validity: 21-11-2025	/8x60mL/8x15mL 104419910920 /4x200 Test 104419910930 /4x20mL/2x10mL 104419910962 /1320 Test	
70.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 9529193170 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Alpha-Amylase CC FS (Alpha-Amylase) Class B Shelf Life: 24 Months Codes/Sizes: 105019910021 /5x20mL/1x25mL 105019910023 /1x800mL/1x200mL 105019910026 /5x80mL/1x100mL 105019910704 /8x50mL/8x12.5mL 105019910921 /4x120 Test 105019910930 /4x20mL/2x10mL 105019910964 /900 Test	Approved.
71.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 07482517 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Pancreatic amylase CC FS (Pancreatic amylase) Class B Shelf Life: 24 Months Codes/Sizes: 105519910021 /5x20mL/1x25mL 105519910023 /1x800mL/1x200mL 105519910921 /4x120 Test 105519910930 /4x20mL/2x10mL 105519910964 /900 Test	Approved.
72.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 48589223058 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 OR ISO 13485 Validity: 21-11-2025	Ethanol FS (Ethanol) Class B Shelf Life: 18 Months Codes/Sizes: 108819910921 /4x120 Test 108819910930 /4x20mL/2x10mL 108819910964 /540 Test	Approved.
73.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity:	Bicarbonate FS (Bicarbonate) Class B Shelf Life: 18 Months	Approved.

	Slip: 5843836761 Dated: 24-08-2024 Fee: PKR 25000/-	15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 OR ISO 13485 Validity: 21-11-2025	Codes/Sizes: 109509910021 /6x25mL 109509910026 /6x100mL 109509910917 /10x60mL 109509910923 /4x200 Test 109509910930 /6x20mL 109509910961 /960 Test	
74.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 67352283331 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Calcium AS FS (Calcium) Class B Shelf Life: 24 Months Codes/Sizes: 111309910021 /6x25mL 111309910023 /1000mL 111309910026 /6x100mL 111309910704 /8x50mL	Approved.
75.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 67602132 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Glucose GOD FS (Glucose oxidase) Class B Shelf Life: 24 Months Codes/Sizes: 125009910021/ 6x25mL 125009910023 /1x1000mL 125009910026 /6x100mL 125009910704 /8x50mL 125009910717 /6x100mL 125009910917 /10x60mL 125009910923 /4x200 Test	Approved.
76.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 65655058046 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Gamma-GT FS (Szasz mod./IFCC stand.) (Gamma-glutamyl transferase) Class B Shelf Life: 15 Months Codes/Sizes: 128019910021 /5x20mL/1x25mL 128019910023 /1x800mL/1x200mL 128019910026 /5x80mL/1x100mL 128019910704 /8x50mL/8x12.5mL 128019910917 /8x60mL/8x15mL 128019910920 /4x200 Test 128019910930 /4x20mL/2x10mL 128019910962 /2280 Test 128019910963 /2280 Test	Approved.

77.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 207251230 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Homocysteine FS (Homocysteine) Class B Shelf Life: 06 Weeks Codes/Sizes: 134099910930 /4x12.5mL/1x8mL/1x6mL	Approved.
78.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 414246209616 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	ISE Urine Diluent respons® (Urine Diluent) Class B Shelf Life: 12 months Codes/Sizes: 136009910921 /4x30mL	Approved.
79.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 603007396 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	β-Hydroxybutyrate 21 FS (β-Hydroxybutyrate) Class B Shelf Life: 24 Months Codes/Sizes: 137119910921 /4x120 Test 137119910930 /4x20mL/2x10mL 137119910964 /540 Test	Approved.
80.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 67411814076 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	Prealbumin FS (Prealbumin) Class B Shelf Life: 24 Months Codes/Sizes: 102929910921 /4x100 Test 102929910935 /2x20mL/1x8mL 102929910966 /200 Test	Approved.
81.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028	Complement C3c FS (Complement Component 3) Class B Shelf Life: 24 Months Codes/Sizes: 118029910921 /4x100 Test 118029910930	Approved.

	Slip: 93971412461 Dated: 24-08-2024 Fee: PKR 25000/-	FSC FSC of Reference Country Issue Date: 20-09-2022	/4x20mL/2x8mL 118029910935 /2x20mL/1x8mL 118029910966 /200 Test	
82.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 267828898821 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	Immunoglobulin A FS (Immunoglobulin A) Class B Shelf Life: 24 Months Codes/Sizes: 172029910921 /4x80 Test 172029910930 /4x20mL/2x8mL 172029910935 /2x20mL/1x8mL 172029910964 /540 Test	Approved.
83.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 35512675354 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	Immunoglobulin M FS (Immunoglobulin M) Class B Shelf Life: 24 Months Codes/Sizes: 172229910921 /4x80 Test 172229910930 /4x20mL/2x8mL 172229910935 /2x20mL/1x8mL 172229910964 /540 Test	Approved.
84.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 8743111406 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Immunoglobulin E FS (Immunoglobulin E) Class B Shelf Life: 24 Months Codes/Sizes: 172399910921 /4x80 Test 172399910926 /2x80xTest 172399910930 /2x20mL/2x10mL 172399910966 /200 Test	Approved.
85.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 392272747 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	Ferritin SR (Ferritin) Class B Shelf Life: 18 Months Codes/Sizes: 172459910921/ 4x80 Test 172459910926 /2x80 Test	Approved.
86.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A.	Legal Manufacturer DiaSys Diagnostic Systems GmbH	Total protein Standard FS (Total protein standard)	Approved.

	Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 4592195668 Dated: 24-08-2024 Fee: PKR 25000/-	Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Total protein UC Standard FS (Total protein UC Standard) Class B Shelf Life: 36 Months 24 Months Codes/Sizes: 123009910030 /6x3mL 102609910030 /6x3mL	
87.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -01/08/2024 Slip: 57143941016 Dated: 24-08-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	CRP U-hs FS (High sensitivity C-reactive protein) Class B Shelf Life: 18 Months Codes/Sizes: 170459910920 /4x100 Test	Approved.
88.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 24859431718 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 <u>FSC</u> FSC of Reference Country Issue Date: 20-09-2022 <u>ISO 13485</u> Validity: 21-11-2025	Bilirubin Auto Direct FS (Bilirubin Auto Direct) Class B Shelf Life: 18 Months Codes/Sizes: 108219910021 /5x20mL/1x25mL 108219910023 /1x800mL/1x200mL 108219910026 /5x80mL/1x100mL 108219910704 /8x50mL/8x12.5mL 108219910920 /4x200 Test 108219910930 /4x20mL/2x10mL 108219910964 /900 Test	Approved subject to differential fee
89.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 214799528761 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Bilirubin Auto Total FS (Bilirubin Auto Total) Class B Shelf Life: 18 Months Codes/Sizes: 108119910021 5x20mL/1x25mL 108119910023 1x800mL/1x200mL 108119910026 5x80mL/1x100mL 108119910704 8x50mL/8x12.5mL 108119910917	Approved subject to differential fee

			8x60mL/8x15mL 108119910920 4x200 Test 108119910930 4x20mL/2x10mL 108119910962 1890 Test	
90.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 8438832812 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Calcium P FS (Calcium) Class B Shelf Life: 24 Months) Codes/Sizes: 111819910021 /5x20mL/1x25mL 111819910026 /5x80mL/1x100mL 111819910704 /8x50mL/8x12.5mL 111819910917 /8x60mL/8x15mL 111819910920 /4x200 Test 111819910962 /1890 Test	Approved subject to differential fee
91.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 5644361443 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	Chloride 21 FS (Chloride) Class B Shelf Life: 12 Months Codes/Sizes: 112219910021 /5x20mL/1x25mL 112219910921 /4x50 Test	Approved subject to differential fee
92.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 77418378 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Cholesterol FS (Cholesterol) Class B Shelf Life: 24 Months Codes/Sizes: 113009910021 /6x25mL 113009910023 /1x1000mL 113009910026 /6x100mL 113009910704 /8x50mL 113009910717 /6x100mL 113009910917 /10x60mL 113009910923 /4x200 Test 113009910960 /2120 Test 113009910967 /1920 Test	Approved subject to differential fee
93.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 33170690	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028	Cholinesterase FS (Cholinesterase) Class B Shelf Life: 18 Months Codes/Sizes: 114019910021	Approved subject to differential fee

	Dated: 02-09-2024 Fee: PKR 25000/-	FSC FSC of Reference Country Issue Date: 20-09-2022	/5x20mL/1x25mL 114019910921 /4x120 Test 114019910930 /4x20mL/2x10mL 114019910962 /1890 Test	
94.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 344473189407 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Creatinine FS (Creatinine) Class B Shelf Life: 24 Months Codes/Sizes: 117119910021 /5x20mL/1x25mL 117119910023 /1x800mL/1x200mL 117119910026 /5x80mL/1x100mL 117119910704 /8x50mL/8x12.5mL 117119910917 /8x60mL/8x15mL 117119910920 /4x200 Test 117119910921 /4x50 Test 117119910962 /1890 Test	Approved subject to differential fee
95.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 53468091 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Creatinine PAP FS (Creatinine PAP) Class B Shelf Life: 12 Months Codes/Sizes: 117599910021 /4x20mL/2x20mL 117599910023 /1x800mL/1x400mL 117599910026 /4x100mL/2x100mL 117599910704 /8x40mL/8x20mL 117599910917 /8x30mL/8x15mL 117599910920 /4x180 Test 117599910962 /2040 Test 117599910963 /1800 Test	Approved subject to differential fee
96.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 62098213 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country	Iron FS Ferene (Iron FS Ferene) Class B Shelf Life: 24 Months Codes/Sizes: 119119910021 /5x20mL/1x25mL 119119910023 /1x800mL/1x200mL 119119910026	Approved subject to differential fee

		Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	/5x80mL/1x100mL 119119910704 /8x50mL/8x12.5mL 119119910917 /8x60mL/8x15mL 119119910921 /4x120 Test 119119910930 /4x20mL/2x10mL 119119910964 /900 Test	
97.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -16/09/2024 Slip: 31004923814 Dated: 02-09-2024 Fee: PKR 25000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	UIBC FS (Unsaturated iron binding capacity) Class B Shelf Life: 18 Weeks Codes/Sizes: 119219910921 /4x120 Test 119219910930 /4x20mL/2x10mL 119219910964 /540 Test	Approved subject to differential fee
98.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 8063332090 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Total protein UC FS (Total protein) Class B Shelf Life: 26 Months Codes/Sizes: 102109910021 /6x25mL 102109910026 /6x100mL 102109910921 /4x120 Test 102109910930 /6x20mL	Approved.
99.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 2881669174 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028	HDL Precipitant (High Density Lipoprotein Precipitant) LDL Precipitant (Low Density Lipoprotein Precipitant) Class B Shelf Life: 22 Months 22 Months Codes/Sizes: 135409990885 /250mL 143309990885 /250mL	Approved.
100.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 4842805141 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country	145709910113 - oneHbA1c Hemolyzing Solution (Hemoglobin A1c Hemolyzing solution) 179009910113 - G6PDH Hemolyzing Solution (Glucose-6-phosphate dehydrogenase Hemolyzing solution)	Approved.

		Issue Date: 20-09-2022	Class B Shelf Life: 18 Months 18 Months	
101.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 9525959491 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	102429910021- Albumin in Urine/CSF FS (Micro albumin) 102429910023 - Albumin in Urine/CSF FS (Micro albumin) (Microalbumin) Class B Shelf Life: 24 Months 24 Months Codes/Sizes: 102429910023 /1x1000mL/1x200mL 102429910021 /5x25mL/1x25mL 102429910921 /4x100 Test 102429910930 /4x20mL/2x8mL 102429910935 /2x20mL/1x8mL 102429910964 /600 Test	Approved.
102.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 42299201 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Complement C4 FS (Complement component C4) Class B Shelf Life: 24 Months Codes/Sizes: 118129910921 /4x100 Test 118129910930 /4x20mL/2x8mL 118129910935 /2x20mL/1x8mL 118129910966 /200 Test	Approved.
103.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -14/01/2025 Slip: 94555818531 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	oneHbA1c FS (Hemoglobin A1c) Class B Shelf Life: 18 Months Codes/Sizes: 133299910922 /4x100 Test 133299910927 /2x100 Test 133299910930 /3x20mL/2x10mL/1x10mL 133299910935 /2x15mL/1x10mL/1x5mL	Approved.
104.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim,	CRP FS (C-Reactive Protein) Class B	Approved.

	<p>(ELI- 00619)</p> <p>R&I detail -14/01/2025</p> <p>Slip: 2046708131 Dated: 24-12-2024 Fee: PKR 31000/-</p>	<p>Germany</p> <p>LOA Validity: 15-02-2028</p> <p>FSC FSC of Reference Country Issue Date: 20-09-2022</p> <p>ISO 13485 Validity: 21-11-2025</p>	<p>Shelf Life: 24 Months</p> <p>Codes/Sizes: 170029910021 /5x25mL/1x25mL 170029910023 /1x1000mL/1x200mL 170029910704 /8x50mL/8x10mL 170029910917 /8x60mL/8x12mL 170029910920 /4x200 Test 170029910930 /4x20mL/2x8mL 170029910935 /2x20mL/1x8mL 170029910962 /2280 Test 170029910963 /2280 Test</p>	
105.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail -14/01/2025</p> <p>Slip: 7630043446 Dated: 24-12-2024 Fee: PKR 31000/-</p>	<p>Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity: 15-02-2028</p> <p>FSC FSC of Reference Country Issue Date: 20-09-2022</p>	<p>Rheumatoid factor FS (Rheumatoid factor)</p> <p>Class B</p> <p>Shelf Life: 13 Months</p> <p>Codes/Sizes: 170229910021 /5x25mL/1x25mL 170229910921 /4x100 Test 170229910930 /4x20mL/2x8mL 170229910935 /2x20mL/1x8mL 170229910964 /600 Test</p>	Approved.
106.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail -14/01/2025</p> <p>Slip: 343973179 Dated: 24-12-2024 Fee: PKR 31000/-</p>	<p>Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity: 15-02-2028</p> <p>FSC FSC of Reference Country Issue Date: 20-09-2022</p>	<p>Ferritin FS (Ferritin)</p> <p>Class B</p> <p>Shelf Life: 12 weeks</p> <p>Codes/Sizes: 170599910930 /3x20mL/3x10mL 170599910935 /1x20mL/1x10mL 170599910964 /600 Test</p>	Approved.
107.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p> <p>(ELI- 00619)</p> <p>R&I detail -14/01/2025</p> <p>Slip: 596081671 Dated: 24-12-2024 Fee: PKR 31000/-</p>	<p>Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany</p> <p>LOA Validity: 15-02-2028</p> <p>FSC FSC of Reference Country Issue Date: 20-09-2022</p>	<p>Cystatin C FS (Cystatin C)</p> <p>Class B</p> <p>Shelf Life: 24 Months</p> <p>Codes/Sizes: 171589910921 /4x100 Test 171589910926 /2x100 Test 171589910930 /4x12mL/2x8mL 171589910966 /200 Test</p>	Approved.
108.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9,</p>	<p>Legal Manufacturer DiaSys Diagnostic Systems</p>	<p>Triglyceride FS Triglyceride FS 10'</p>	Approved.

	Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 4319963724 Dated: 24-12-2024 Fee: PKR 31000/-	GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	(Triglycerides) Class B Shelf Life: 24 Months Codes/Sizes: 157109910021 /6x25mL 157109910026/ 6x100mL 157109910023 /1x1000mL 157109910704 /8x50mL 157109910717 /6x100mL 157109910917 /10x60mL 157109910923 /4x200 Test 157109910960 /2120 Test 157109910967 /1920 Test	
109.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 92007697405 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	Cleaner A Cleaner B Cleaner respons 920 (Cleaner) Class B Shelf Life: 186109910923- 24 Months 186509910923- 24 Months 188309910885- 24 Months	Approved.
110.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 8552987704 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	HbA1c net Hemolyzing Solution (HbA1c net Hemolyzing Solution) Class B Shelf Life: 12 Months Codes/Sizes: 145909910113/ 1x500mL 145909910923/ 4x200 Test 145909910961/ 2x160 Tests 145909910967/ 4x450 Test	Approved.
111.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 48436578995 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022 ISO 13485 Validity: 21-11-2025	HDL-c direct FS (High Density Lipoprotein Cholesterol) Class B Shelf Life: 24 Months Codes/Sizes: 135619910021/ 5x20ml/1x25ml 135619910023 /1x800ml/1x200ml 135619910026 /5x80ml/1x100ml 135619910704 /8x50ml/8x12,5ml 135619910917 /8x60ml/8x15ml 135619910920 /4x200 Tests 135619910921 /4x120 Test 135619910930	Approved.

			/4x20ml/2x10ml 135619910962 /1890 Tests	
112.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 455838264513 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Lactate FS (Lactate) Class B Shelf Life: 18 Months Codes/Sizes: 140019910021 /5x20mL/1x25mL 140019910023 /1x800mL/1x200mL 140019910921 /4x120 Test 140019910930 /4x20mL/2x10mL 140019910964 /540 Test	Approved.
113.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 914797742 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	LDH 21 FS (Lactate dehydrogenase) Class B Shelf Life: 24 Months Codes/Sizes: 142519910021 /5x20mL/1x25mL 142519910704 /8x50mL/8x12.5mL 142519910920 /4x200 Test 142519910930 /4x20mL/2x10mL 142519910964 /900 Test	Approved.
114.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 949453505 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC Issue Date: 20-09-2022	LDL-c direct FS (Low Density Lipoprotein Cholesterol) Class B Shelf Life: 18 Months Codes/Sizes: 141319910021 /5x20ml/1x25ml 141319910026 /5x80mL/1x100mL 141319910921 /4x120 Test 141319910930 /4x20mL/2x10mL 141319910964 /900 Test	Approved.
115.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 877993316073 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country	Lipase DC FS (Lipase) Class B Shelf Life: 18 Months Codes/Sizes: 143219910021 /5x20mL/1x25mL 143219910023 /1x800mL/1x200mL 143219910921 /4x120 Test 143219910930	Approved.

		Issue Date: 20-09-2022	/4x20mL/2x10mL 143219910962 /1890 Test	
116.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 04534967759 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Magnesium XL FS (Magnesium) Class B Shelf Life: 24 Months Codes/Sizes: 146109910021 /6x25mL 146109910026 /6x100mL 146109910704 /8x50mL 146109910921 /4x120 Test 146109910930 /6x20mL 146109910961 /960 Test	Approved.
117.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -23/12/2024 Slip: 21152671112 Dated: 24-12-2024 Fee: PKR 31000/-	Legal Manufacturer DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim, Germany LOA Validity: 15-02-2028 FSC FSC of Reference Country Issue Date: 20-09-2022	Phosphate FS (Phosphate) Class B Shelf Life: 21 Months Codes/Sizes: 152119910021 /5x20mL/1x25mL 152119910704 /8x50mL/8x12.5mL 152119910920 /4x200 Test 152119910930 /4x20mL/2x10mL 152119910962 /1890 Test	Approved.
118.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -26/06/2024 Slip: 758449763863 Dated: 21-06-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC of Reference Country Issue: 29-09-2022 EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	AMA-M2 IgG (CLIA) (Autoimmune) Class B Shelf Life: 18 Months Codes/Sizes: 130217507M/ 100 tests/kit 130617507M/ 50 tests/kit	Approved.
119.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -26/06/2024 Slip: 66369068	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China	Serum Amyloid A (CLIA) (Serum Amyloid A) TNF- α (CLIA) (TNF-a) Class B Shelf Life:	Approved.

	<p>Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>12 months 12 months Codes/sizes: 130216005M/100 tests/kit 130616005M/50 tests/kit 130216006M/100 tests/kit 130616006M/ 50 tests/kit</p>	
120.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -26/06/2024</p> <p>Slip: 0031801043 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025</p> <p>FSC Validity: 24-06-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Gastrin-17 (CLIA) (Gastrin IVD)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes 130201522M/100 tests/kit 130601522M/50 tests/kit</p> <p>FSC RRA issue: 29-09-2022</p> <p>EC Certificate Validity: 14-12-2025</p>	Approved.
121.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -26/06/2024</p> <p>Slip: 187003829 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025</p> <p>FSC Validity: 24-06-2025</p> <p>FSC RRA issuance: 29-09-2022 EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Anti-TM (CLIA) (Anti-TM)</p> <p>Class B Shelf Life:18 months</p> <p>Codes/Sizes 130253008M/100 tests/kit 130653008M/50 tests/kit</p>	Approved.
122.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road,</p>	<p>Anti-HAV (CLIA) (Hepatitis A Antibody) HAV IgM (CLIA) (Hepatitis A Antibody)</p>	Approved.

	<p>R&I detail -26/06/2024</p> <p>Slip: 18879989 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Class B Shelf Life: 18 months Codes/Sizes 130210024M/100 tests/kit 130610024M/50 tests/kit 130210025M/100 tests/kit 130610025M/50 tests/kit</p>	
123.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 6691965783 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>AMH (CLIA) (Anti-Mullerian hormone)</p> <p>SHBG (CLIA) (Anti-Mullerian hormone)</p> <p>Androstenedione (CLIA) (Anti-Mullerian hormone)</p> <p>Class B Shelf Life: 18 months 18 months 18 months</p> <p>Codes/Sizes 130252014M, 130652014M/100 Test Kits, 50 Test Kits 130202515M, 130602515M/100 Test Kits, 50 Test Kits 130202516M, 130602516M/100 Test Kits, 50 Test Kits</p>	Approved.
124.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 2685893672 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC</p>	<p>Anti-Tg (CLIA) (Thyroid Antithyroglobulin Antibody)</p> <p>Thyroglobulin (CLIA) (Thyroglobulin)</p> <p>Anti-TPO (CLIA) (Anti-thyroid peroxidase)</p> <p>Class B Shelf Life: 18 months 18 months 18 months</p>	Approved.

		FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Codes/Sizes 130253007M, 130653007M/100 Test Kits, 50 Test Kits 130253006M, 130653006M/100 Test Kits, 50 Test Kits 130253011M, 130653011M/100 Test Kits, 50 Test Kits	
125.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 39533193794 Dated: 21-06-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	FA (CLIA) (Folic Acid) Vitamin B12 (CLIA) (Folic Acid) Class B Shelf Life: 18 Months Codes/Sizes 130263001M, 130663001M/100 Test kits, 50 Test kits 130263002M, 130663002M/100 Test kits, 50 Test kits	Approved.
126.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -30/04/2024 Slip: 7759295665 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	Growth Hormone (CLIA) (Cortisol) Class B Shelf Life: 18 months Codes/Sizes 130270001M, 130670001M/100 Test kits, 50 Test kits EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Approved.
127.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd.	H.pylori IgA (CLIA) (Anti-Helicobacter pylori immunoglobulin)	Approved.

	<p>(ELI- 00619) R&I detail -30/04/2024</p> <p>Slip: 08324756148 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>H.pylori IgM (CLIA) (Anti-Helicobacter pylori immunoglobulin)</p> <p>H.pylori IgG (CLIA) (Anti-Helicobacter pylori immunoglobulin)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes 130251028M, 130651028M/100 Test kits, 50 Test kits 130251027M, 130651027M/100 Test kits, 50 Test kits 130201521M, 130601521M/100 Test kits, 50 Test kits</p>	
128.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -30/04/2024</p> <p>Slip: 54239548 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Intact PTH (CLIA) (Parathyroid Hormone)</p> <p>25-OH Vitamin D (CLIA) (25-Hydroxyvitamin D)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes 130261001M, 130661001M/100 Test kits, 50 Test kits 130261004M, 130661004M/100 Test kits, 50 Test kits</p>	Approved
129.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -30/04/2024</p> <p>Slip: 510346180795 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin</p>	<p>Prolactin (CLIA) (Prolactin)</p> <p>Estradiol (CLIA) (Prolactin)</p> <p>Progesterone (CLIA) (Prolactin)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes</p>	Approved

		<p>Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>130252006M, 130652006M/100 Test kits, 50 Test kits 130252007M, 130652007M/100 Test kits, 50 Test kits 130252009M, 130652009M/100 Test kits, 50 Test kits</p>	
130.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 79406605399 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>TRAb (CLIA) (Thyroid uptake)</p> <p>T-Uptake (CLIA) (Thyroid uptake)</p> <p>Rev T3 (CLIA) (Thyroid uptake)</p> <p>Class B Shelf Life: 18 months Codes/Sizes 130253009M, 130653009M/100 Test kits, 50 Test kits 130203014M, 130603014M/100 Test kits, 50 Test kits 130253010M, 130653010M/100 Test kits, 50 Test kits</p>	Approved.
131.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -30/04/2024</p> <p>Slip: 88084454209 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Testosterone (CLIA) (Testosterone)</p> <p>DHEA-S (CLIA) (Dehydroepiandrosterone-sulfate)</p> <p>Class B Shelf Life: 18 months Codes/Sizes 130252010M, 130652010M/100 Test kits, 50 Test kits 130252012M, 130652012M/100 Test kits, 50 Test kits</p>	Approved.

132.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -30/04/2024</p> <p>Slip: 350669310611 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>TSH (CLIA) (Thyroid stimulating hormone)</p> <p>Total T3 (CLIA) (Triiodothyronine)</p> <p>Total T4 (CLIA) (Total Thyroxine)</p> <p>Class B Shelf Life: 24 months 18 months 18 months</p> <p>Codes/Sizes 130203023M, 130603023M/100 Test kits, 50 Test kits 130253003M, 130653003M/100 Test kits, 50 Test kits 130253002M, 130653002M/100 Test kits, 50 Test kits</p>	Approved.
133.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 301955516 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Aldosterone (CLIA) (Aldosterone)</p> <p>Direct Renin (CLIA) (Renin IVD)</p> <p>Class B Shelf Life: 18 months 18 months</p> <p>Codes/Sizes 130256007M,130656007M /100 Test kits, 50 Test kits 130206511M,130606511M/1 00 Test kits, 50 Test kits</p>	Approved.
134.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 836193892 Dated: 18-03-2024</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity:</p>	<p>Anti-Centromeres IgG (CLIA) (Centromeres)</p> <p>Anti-Histones IgG (CLIA) (Histones)</p> <p>Class B</p>	Approved.

	Fee: PKR 25000/-	30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Shelf Life: 18 months 12 months Codes/Sizes 130217506M,130617506M /100 Test kits, 50 Test kits 130217508M,130617508M /100 Test kits, 50 Test kits	
135.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 87279056868 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Anti-dsDNA IgG (CLIA) (Double-stranded DNA) ENA Screen (CLIA) (extractable nuclear antigens) Anti-Scl-70 IgG (CLIA) (Scl-70) Class B Shelf Life: 18 months 18 months 18 months Codes/Sizes 130217502M,130617502M /100 Test kits, 50 Test kits 130217504M ,130617504M /100 Test kits, 50 Test kits 130217505M,130617505M /100 Test kits, 50 Test kits	Approved.
136.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 648352839331 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate	Anti-MPO IgG (CLIA) (Myeloperoxidase) Anti-Cardiolipin IgG (CLIA) (Cardiolipin) Anti-Cardiolipin IgM (CLIA) (Cardiolipin) Class B Shelf Life: 18 months 12 months 12 months Codes/Sizes 130217015M,130617015M/1 00 Test kits, 50 Test kits 130217017M,130617017M/1 00 Test kits, 50 Test kits 130217016M,130617016M/1	Approved.

		Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	00 Test kits, 50 Test kits	
137.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 92368161811 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Anti-Rib-P IgG (CLIA) (Rib-P) Anti-Sm/RNP IgG (CLIA) (Sm/RNP) Anti-Sm IgG (CLIA) (Sm) Class B Shelf Life: 18 months 12 months 18 months Codes/Sizes 130217510M,130617510M/1 00 Test kits, 50 Test kits 130217511M,130617511M/1 00 Test kits, 50 Test kits 130217512M,130617512M/1 00 Test kits, 50 Test kits	Approved.
138.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 12148777 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Anti-SS-A/Ro IgG (CLIA) (SS-A/Ro) Anti-SS-B IgG (CLIA) (SS-B) Anti-Jo-1 IgG (CLIA) (Jo-1) Class B Shelf Life: 18 months 18 months 18 months Codes/Sizes 130217513M,130617513M/1 00 Test kits, 50 Test kits 130217514M,130617514M/1 00 Test kits, 50 Test kits 130217509M,130617509M/1 00 Test kits, 50 Test kits	Approved.
139.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China	Anti-β2-Glycoprotein 1 IgG (CLIA) (β2-Glycoprotein) Anti-β2-Glycoprotein 1 IgM (CLIA) (β2-Glycoprotein)	Approved.

	<p>Slip: 0967944883 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Class B Shelf Life: 12 months 12 months</p> <p>Codes/Sizes 130217018M,130617018M/100 Test kits, 50 Test kits 130217019M,130617019M/100 Test kits, 50 Test kits</p>	
140.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 1408722068 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC RRA issuance: 29-09-2022</p>	<p>EPO (CLIA) (Erythropoietin)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes 130213003M,130613003M/100 Test kits, 50 Test kits</p> <p>EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	Approved.
141.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024</p> <p>Slip: 7673912238 Dated: 18-03-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485</p>	<p>Osteocalcin (CLIA) (Osteocalcin)</p> <p>Total P1NP (CLIA) (P1NP)</p> <p>β-CTx (CLIA) (β-CTx)</p> <p>Class B Shelf Life: 18 months 18 months 18 months</p> <p>Codes/Sizes 130261003M,130661003M/100 Test kits, 50 Test kits 130211005M,130611005M/100 Test kits, 50 Test kits 130211006M ,130611006M/100 Test kits, 50 Test kits</p>	Approved.

		Validity: 31-12-2025		
142.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -24/06/2024 Slip: 5683337231 Dated: 18-03-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	PIIP NP (CLIA) (Procollagen N-terminal peptide) Cholyglycine (CLIA) (Cholyglycine) Class B Shelf Life: 18 months 18 months Codes/Sizes 130259002M,130659002M/100 Test kits, 50 Test kits 130259005M,130659005M/100 Test kits, 50 Test kits	Approved.
143.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 275648386 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	17 α -OH Progesterone (CLIA) (17 α -Hydroxyprogesterone) Class B Shelf Life: 18 months Codes/Sizes 130270004M, 130670004M/100 Test kits, 50 Test kits EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Approved.
144.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 17835931 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Albumin (CLIA) (Albumin) Class B Shelf Life: 18 months Codes/Sizes 130254002M, 130654002M/100 Test kits, 50 Test kits FSC Country of Origin Validity: 24-06-2025 FSC RRA issuance:	Approved.

			29-09-2022	
145.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 7935595151 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	ACTH (CLIA) (17 α -Hydroxyprogesterone) Class B Shelf Life: 18 months Codes/Sizes 130270003M, 130670003M/100 Test kits, 50 Test kits FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	Approved.
146.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 43565101527 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	ANA Screen (CLIA) (C-Reactive Protein) Class B Shelf Life: 18 months Codes/Sizes 130217503M, 130617503M/100 Test kits, 50 Test kits	Approved.
147.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 4629593214 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 EC Certificate Validity: 14-12-2025	Anti-CCP (CLIA) (C-Reactive Protein) Class B Shelf Life: 18 months Codes/Sizes 130217501M, 130617501M/100 Test kits, 50 Test kits FSC Country of Origin Validity: 24-06-2025	Approved.

		ISO 13485 Validity: 31-12-2025	FSC FSC of Reference Country Issue: 29-09-2022	
148.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 6077537168 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	Cortisol (CLIA) (Cortisol) Class B Shelf Life: 18 months Codes/Sizes 130270002M, 130670002M/100 Test kits, 50 Test kits EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Approved.
149.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 82863758 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	Ferritin (CLIA) (Ferritin) Class B Shelf Life: 24 months Codes/Sizes 130251001M, 130651001M/100 Test kits, 50 Test kits EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	Approved.
150.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 9327460447 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022	Free T3 (CLIA) (Triiodothyronine) Free T4 (CLIA) (Thyroxine) Class B Shelf Life: 18 months 18 months Codes/Sizes 130253005M, 130653005M/100 Test kits, 50 Test kits 130253004M, 130653004M/100 Test kits, 50 Test kits	Approved.

		OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025		
151.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 884710550012 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	FSH (CLIA) (Follicle stimulating hormone) LH (CLIA) (Luteinizing Hormone) Total β HCG (CLIA) (Beta-Human Chorionic Gonadotropin) Class B Shelf Life: 24 months 24 months 18 months Codes/Sizes 130252001M, 130652001M /100 Test kits, 50 Test kits 130252002M, 130652002M/100 Test kits, 50 Test kits 130252003M, 130652003M /100 Test kits, 50 Test kits	Approved.
152.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -06/02/2024 Slip: 650614689 Dated: 08-01-2024 Fee: PKR 25000/-	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China LOA Validity: 30-12-2025 FSC Country of Origin Validity: 24-06-2025 FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025 ISO 13485 Validity: 31-12-2025	IgE (CLIA) (Immunoglobulin E) IgM (CLIA) (Immunoglobulin M) Class B Shelf Life: 18 months 18 months Codes/Sizes 130258001M, 130258001M/100 Test kits, 50 Test kits 130258002M, 130658002M/100 Test kits, 50 Test kits	Approved.
153.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.	Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd.	IgG (CLIA) (Total immunoglobulin G) IgA (CLIA)	Approved.

	<p>(ELI- 00619) R&I detail -16/09/2024</p> <p>Slip: 002890870 Dated: 13-09-2024 Fee: PKR 31000/-</p>	<p>No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>(Total immunoglobulin G)</p> <p>Class B Shelf Life: 18 months 18 months</p> <p>Codes/Sizes 130258005M,130658005M/1 00 Test kits, 50 Test kits 130258004M,130658004M/1 00 Test kits, 50 Test kits</p>	
154.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -28/06/2024</p> <p>Slip:2188679586 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Laminin (CLIA) (Laminin)</p> <p>Col IV (CLIA) (IV collagen)</p> <p>Hyaluronic Acid (CLIA) (Hyaluronic)</p> <p>Class B Shelf Life: 18 months 18 months 18 months</p> <p>Codes/Sizes 130259004M,130659004M/1 00 Test kits, 50 Test kits 130259003M,130659003M/1 00 Test kits, 50 Test kits 130259001M,130659001M/1 00 Test kits, 50 Test kits</p>	Approved.
155.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -28/06/2024</p> <p>Slip: 1442402754 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin</p>	<p>IGF-I (CLIA) (Insulin-like-growth factor 1)</p> <p>IGFBP-3 (CLIA) (IGFBP-3)</p> <p>Class B Shelf Life: 18 months 18 months</p> <p>Codes/Sizes 130255007M,130655007M/1 00 Test kits, 50 Test kits</p>	Approved.

		<p>Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>130298505M,130698505M/100 Test kits, 50 Test kits</p>	
156.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -28/06/2024</p> <p>Slip: 10441772271 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022 OR EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	<p>Proinsulin (CLIA) (Proinsulin)</p> <p>ICA (CLIA) (antibody)</p> <p>Anti-IA2 (CLIA) (antigen 2 antibody)</p> <p>Class B Shelf Life: 18 months 18 months 18 months</p> <p>Codes/Sizes 130255004M,130655004M/100 Test kits, 50 Test kits 130205506M,130605506M/100 Test kits, 50 Test kits 130205508M,130605508M/100 Test kits, 50 Test kits</p>	Approved.
157.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -28/06/2024</p> <p>Slip:30756770892 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Validity: 24-06-2025</p> <p>FSC RRA issuance: 29-09-2022</p>	<p>Unconjugated Estriol (CLIA) (Unconjugated Estriol)</p> <p>Class B Shelf Life: 18 months</p> <p>Codes/Sizes 130252008M,130652008M/100 Test kits, 50 Test kits</p> <p>EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	Approved.
158.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail -28/06/2024</p>	<p>Legal Manufacturer Legal Manufacturer Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road,</p>	<p>Free Testosterone (CLIA) (Free-Testosterone)</p> <p>Class B Shelf Life: 18 months</p>	Approved.

	<p>Slip: 65539320280 Dated: 21-06-2024 Fee: PKR 25000/-</p>	<p>Pingshan District, 518122 Shenzhen, P.R.China</p> <p>LOA Validity: 30-12-2025</p> <p>FSC Country of Origin Validity: 24-06-2025</p> <p>FSC FSC of Reference Country Issue: 29-09-2022</p>	<p>Codes/Sizes 130252011M,130652011M/1 00 Test kits, 50 Test kits</p> <p>EC Certificate Validity: 14-12-2025</p> <p>ISO 13485 Validity: 31-12-2025</p>	
159.	<p>MEDICAL EQUIPMENT & SYSTEMS Address of Importer Adress: 60/61 F.C.C SYED MARATIB ALI ROAD GULBERG IV, LAHORE, 54000, PAKISTAN</p>	<p>Legal Manufacturer: PARAMOUNT BED CO., LTD. 14-5. 2-chome, H,gash,suna. Koto-ku. Tokyo 136-8670 Japan</p> <p>FSC Validity: Valid 24-07-2026</p> <p>LOA Validity: 31-12-2025</p> <p>ISO 13485 Validity: 31-05-2027</p> <p>ISO 9001 Validity: 27/03/2026</p>	<p>Paramount Beds:</p> <ul style="list-style-type: none"> • PA-6000-Series • A3 Type M series, A5 and A6 Series • PA -90000 Series • PA-60000 Series • PD-100 Bed • PD-200 Bed. <p>Class: A</p> <p>Shelf Life: N/A</p>	Approved
160.	<p>MEDICAL EQUIPMENT & SYSTEMS Address of Importer Adress: 60/61 F.C.C SYED MARATIB ALI ROAD GULBERG IV, LAHORE, 54000, PAKISTAN</p>	<p>Legal Manufacturer: PARAMOUNT BED CO., LTD. 14-5. 2-chome, H,gash,suna. Koto-ku. Tokyo 136-8670 Japan</p> <p>FSC Validity: Valid 24-07-2026</p> <p>LOA Validity: 31-12-2025</p> <p>ISO 13485 Validity: 31-05-2027</p> <p>ISO 9001 Validity: 27/03/2026</p>	<p>Paramount Stretchers:</p> <ul style="list-style-type: none"> • Emergency Stretcher PK-8000 • Stretcher PK-51000 Series • Stretcher trolley KK- 700 Series <p>Class: A</p> <p>Shelf Life: N/A</p>	Approved
161.	<p>MEDICAL EQUIPMENT & SYSTEMS</p>	<p>Legal Manufacturer:</p>	<p>Paramount Recliners:</p>	Approved

	Address of Importer Address: 60/61 F.C.C SYED MARATIB ALI ROAD GULBERG IV, LAHORE, 54000, PAKISTAN	PARAMOUNT BED CO., LTD. 14-5. 2-chome, H,gash,suna. Koto-ku. Tokyo 136-8670 Japan FSC Validity: Valid 24-07-2026 LOA Validity: 31-12-2025 ISO 13485 Validity: 31-05-2027 ISO 9001 Validity: 27/03/2026	<ul style="list-style-type: none"> Multiple medical recliners PA-8200 series Multiple medical recliners L'za series. Class: A Shelf Life: N/A	
162.	MEDICAL EQUIPMENT & SYSTEMS Address of Importer Address: 60/61 F.C.C SYED MARATIB ALI ROAD GULBERG IV, LAHORE, 54000, PAKISTAN	<u>Legal Manufacturer:</u> PARAMOUNT BED CO., LTD. 14-5. 2-chome, H,gash,suna. Koto-ku. Tokyo 136-8670 Japan FSC Validity: Valid 24-07-2026 LOA Validity: 31-12-2025 ISO 13485 Validity: 31-05-2027 ISO 9001 Validity: 27/03/2026	Bassinet cart series Class: A Shelf Life: N/A	Approved
163.	Amtronech, 560 A-Block, Faisal Town, Lahore ELI: 00173 416-P 5,000/-	<u>Legal Manufacturer:</u> D.O Weaver and Company, Inc. (doing business as "Weaver and Company") 565 Nucla Way, Unit B Aurora, Colorado 80011 USA. FSC:USA Date of valid: 31.12.2024	Nuprep (Skin Prep Gel) Class-A Shelf Life: 3 years	Approved subject to submission of LoA
164.	Amtronech, 560 A-Block, Faisal Town, Lahore ELI: 00173 417-P 5,000/-	<u>Legal Manufacturer:</u> D.O Weaver and Company, Inc. (doing business as "Weaver and Company") 565 Nucla Way, Unit B Aurora, Colorado 80011 USA. FSC:USA Date of valid: 31.12.2024	Ten20 (Conductive Paste) Class-A Shelf Life: 3 years	Approved subject to submission of LoA
165.	de Khon 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317 Challan of Rs. 50,000/- is attached.	<u>Legal Manufacturer</u> Enable Innovations S.r.l. with registered office at via Claudio Tolomeo 20/4 – 41012 Carpi (MO) Italy Attested FSC attached	EasyFlo nasal spray Code: SP2T-004 Class-A Shelf life: 36 months	Approved
166.	de Khon	<u>Legal Manufacturer</u>	NasaMyst nasal spray	Approved

	11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317 Challan # 967827275900 4/7/2022 of Rs.50,000/-	Enable Innovations S.r.l. with registered office at via Claudio Tolomeo 20/4 – 41012 Carpi (MO) Italy Attested FSC attached	Code: SP3-002 Class-A Shelf life: 36 months	
167.	de Khon 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317 Challan # 676479457320 4/7/2022 of Rs. 50,000/-	Legal Manufacturer Enable Innovations S.r.l. with registered office at via Claudio Tolomeo 20/4 – 41012 Carpi (MO) Italy Attested FSC attached	Revive nasal spray Code: SP1V-005 Class-A Shelf life: 36 months	Approved
168.	de Khon 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317 Challan # 15524977768 4/7/2022 of Rs. 50,000/-	Legal Manufacturer Enable Innovations S.r.l. with registered office at via Claudio Tolomeo 20/4 – 41012 Carpi (MO) Italy Attested FSC attached	TearFix Ophthalmic spray Code: SO1-004 Class-B Shelf life: 36 months	Approved
169.	de Khon 11-C, Old FCC, Ferozpur Road, Gulberg Lahore Pakistan ELI-00317 Challan # 219596856236 4/7/2022 of Rs. 50,000/-	Legal Manufacturer: Scope Ophthalmics with registered office at First Floor, Unit 4, Amberley Court, Whitworth Road, County Oak Way, Crawley, West Sussex RH11 7XL, UK Attested FSC attached	Vivio Junior Cough Syrup Code: PL0143 Class-B Shelf life: 36 months	Approved
170.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	AT-Tube Non Additive Vacuum Blood Collecting Tube Code: 3 ml Class-A Shelf Life: 3 years Fee: Rs. 5,000/- through slip no. 4402365442, dated 06.04.2022	Approved
171.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site	AT-Tube Tri Sodium Citrate Vacuum Blood Collecting Tube Code: 3 ml Class-A Shelf Life: 3 years	Approved

		Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	Fee: Rs. 5,000/ through slip no. 983816055281, dated 06.04.2022	
172.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	AT-Vein Sterile Blood Collecting needle Code: Type A, Type B Class-B Shelf Life: 5 years Fee: Rs. 31,000/ through slip no. 650564048433, 622149545980 (Differential Fee) Dated 11.12.2023 and 20.11.2024	Approved
173.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	AT-Hemo Blood Tubing Set for Hemodialysis Code: Model:20-A, 20-B, 22-A, 22- B, 30-A, 30-B Priority ALL Class- B Shelf Life: 5 years Fee: Rs. 31,000/ through slip no. 0981758935, Dated 20.11.2024	Approved
174.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to:	AT-Fist A.V. fistula Code: Type:(Fixed Wing, Revolving wing) Model: 1.2mm (18G), 1.4mm (17G), 1.6mm (16G) Class-B Shelf Life: 5 years Fee: Rs. 31,000/ through slip	Approved

		Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	no. 3443130611, Dated 28.11.2024	
175.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. NO.39 South Shengli RD. Jinxian county Jiangxi Province,China Original Legalized Free Sale Certificate (FSC) dated: People Republic of China Site Valid till 11.01.2026 ISO 13485 valid up to: Iso 13485 Notifying Body TUV SUD Valid till 30-Jun-25 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body TUV SUD extended LOA valid up to: September 3,2029	AT-lyzer Hemodialyzer Code: Low Flux: HD-10L, HD-L12, HD-L13, HD -L14, HD-L15, HD-L16, HD-L17, HD-L18, HD-L19, HD-L20. High Flux: HD-10L, HD-L12, HD-L13, HD -L14, HD-L15, HD-L16, HD-L17, HD-L18, HD-L19, HD-L20. Class-B Shelf Life: 5 years Fee: Rs. 31,000/ through slip no. 92827573698, Dated 28.11.2024	Approved
176.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: M/S Bergamot SDN. BHD.,_Unit 7 & 8, Jalan Sinaran, 43000 Kajang, Selangor, Malaysia Original Legalized Free Sale Certificate (FSC) dated: Malaysia Site Valid Till 12/11/2026 ISO 13485 valid up to: Iso 13485 Notifying Body BSI Valid till 27/11/2029 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body SATRA TECHNOLOGY extended LOA valid up to: December 3, 2029	AT-Tex Nitrile Powder Free Examination Gloves Code: XS, S, M, L, XL Class-A Shelf Life: 5 years Fee: Rs: 6,000/ through slip no. 65566173264, Dated 28.11.2024	Approved
177.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: M/S Bergamot SDN. BHD.,_Unit 7 & 8, Jalan Sinaran, 43000 Kajang, Selangor, Malaysia Original Legalized Free Sale Certificate (FSC) dated: Malaysia Site Valid Till 12/11/2026 ISO 13485 valid up to: Iso 13485 Notifying Body BSI	AT-Tex Latex Powder Examination Gloves Code: XS, S, M, L, XL Class-A Shelf Life: 5 years	Approved

		Valid till 27/11/2029 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body SATRA TECHNOLOGY extended LOA valid up to: December 3, 2029	Fee: Rs: 6,000/ through slip no. 53018270663, Dated 28.11.2024	
178.	Aqib Trading Company Pvt Ltd, Main GT Road Adamzai Akora Khattak Nowshera KPK ELI-00628	Legal manufacturer: M/S Bergamot SDN. BHD., Unit 7 & 8, Jalan Sinaran, 43000 Kajang, Selangor, Malaysia Original Legalized Free Sale Certificate (FSC) dated: Malaysia Site Valid Till 12/11/2026 ISO 13485 valid up to: Iso 13485 Notifying Body BSI Valid till 27/11/2029 FQ/CE Certificate valid up to: Ce/ Fqas Notifying Body SATRA TECHNOLOGY extended	AT-Tex Latex Powder free Examination Gloves Code: XS, S, M, L, XL Class-A Shelf Life: 5 years Fee: Rs: 6,000/ through slip no. 68073308676, Dated 28.11.2024	Approved
179.	M/s Miraj Corporation. ELI-00326. R&I Details 12/10/2022 Challan No: 196459246446.	Legal Manufacture GUILIN ZHONGHUI TECHNOLOGY CO., LTD Manufacturing Site (s): • Address: Lushan Industrial Park, Western City Economical Development Zone, Guilin 541199, P.R. China • Tel: 86- 773-5593907 Fax: 86-773- 2159586 LOA: Validity: 05-06-2026. FSC: Country of Origin: China. Validity: 17-08-2022. FSC: FSC of Reference Country (as mentioned in rule, 67) Validity: 17-08-2022. ISO 13485: Validity: 15-11-2024.	(Accu Answer) Urine Reagent Test Strips. Class B Shelf life: 24 Months. Codes/Sizes as per FSC	Approved subject to submission of valid CE or FSC of RRA
180.	M/s Nipro Medical Pvt Ltd 24CCA, Ex-park View, DHA Phase-8, Lahore, Pakistan (ELI-00530) R&I Dated: 03-02-2025 Fee Challan No.: 61701224449 Rs. 50,000/	Legal Manufacture Goodman Co. Ltd Address: 5F KDX Nagoya Sakae Building, 4-5-3 Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan. MD group: Family LOA Validity: 11-03-2029 FSC Validity: 24-08-2027	Okay II Y- connector set Class: B Shelf-life: 3 years Codes: YOKOA, YOKOB, YOKOC, YOKOD, YOKOE, YOKOF, YOKOG, YOKOH	Approved

181.	M/s SHAAD TRADERS 2 nd Floor, Ehsan Tower, Dalazak Road, Peshawar ELI-00809 R&I details 28-02-2025 Rs. 6000/- Deposit Slip No. 2078480941 27-02-2025	<u>Legal Manufacturer:</u> M/S AI GLOBE SDN BHD A1-2, BLOCK A, JALAN HARUAN 5/9, PUSAT KOMERSIAL OAKLAND II, 70300 SEREMBAN, NEGERI SEMBILAN, MALAYSIA <u>LOA</u> Validity: 21-02-2029 <u>FSC:</u> Country of Origin Validity: 06-08-2029	SHAAD GLOVES (NITRILE POWDER FREE GLOVES) Class-A Shelf Life: 03 years Codes/Sizes: XS, S, M, L, XL	Approved
182.	M/s SHAAD TRADERS 2 nd Floor, Ehsan Tower, Dalazak Road, Peshawar ELI-00809 R&I details 28-02-2025 Rs. 6000/- Deposit Slip No. 51069449 27-02-2025	<u>Legal Manufacturer:</u> M/S AI GLOBE SDN BHD A1-2, BLOCK A, JALAN HARUAN 5/9, PUSAT KOMERSIAL OAKLAND II, 70300 SEREMBAN, NEGERI SEMBILAN, MALAYSIA <u>LOA</u> Validity: 21-02-2029 <u>FSC:</u> Country of Origin Validity: 06-08-2029	SHAAD GLOVES (LATEX POWDERED GLOVE) Class-A Shelf Life: 03 years Codes/Sizes: XS, S, M, L, XL	Approved
183.	M/s SHAAD TRADERS 2 nd Floor, Ehsan Tower, Dalazak Road, Peshawar ELI-00809 R&I details 28-02-2025 Rs. 6000/- Deposit Slip No. 51069449 27-02-2025	<u>Legal Manufacturer:</u> M/S AI GLOBE SDN BHD A1-2, BLOCK A, JALAN HARUAN 5/9, PUSAT KOMERSIAL OAKLAND II, 70300 SEREMBAN, NEGERI SEMBILAN, MALAYSIA <u>LOA</u> Validity: 21-02-2029 <u>FSC:</u> Country of Origin Validity: 06-08-2029	SHAAD GLOVES (LATEX POWDER FREE GLOVE) Class-A Shelf Life: 03 years Codes/Sizes: XS, S, M, L, XL	Approved
184.	Khan trading agency Data Complex, Mouj darya Road, Lahore. EL100592 5861-P 31,000/-	<u>Legal Manufacturer:</u> Pro-Lab Diagnostics 3 Bassendale road, Bromborough, Wirral, CH62 3QL, U.K. Tel: +44 (0) 151 353 1613 Fax: +44 (0) 151 353 1614 www.pro-lab.co.uk . LOA issuance 23-10-2024 FSC Canada issuance 12-04-2023	Salmonella Agglutination Sera. PL6000 to PL.6250 Shigella Agglutination sera. PL.6900 To 6903 Class-B Shelf life: 3 years Codes as per FSC:	Approved
185.	Medequips SMC PVT Ltd Address of Importer: 30-SHAHRAH E QUAID E AZAM, LAHORE, 54000,	<u>Legal Manufacturer:</u> KONICA MINOLTA, INC., 2-7-2 Marunouchi, Chiyoda-ku, Tokyo, 100-7015, Japan	Digital Ultrasound System: <ul style="list-style-type: none"> • SONIMAGE MX1 • HS2 	Approved

	PAKISTAN Dossier Submitted to DRAP on 07/04/2022	FSC Validity: Valid 01-03-2026 LOA Validity: 31-03-2026 ISO 13485 Validity: 18/04/2025 ISO 9001 Validity: 11/04/2025	Class: B Shelf Life/Service life:	
186.	Medequips SMC PVT Ltd Address of Importer: 30-SHAHRAH E QUAID E AZAM, LAHORE, 54000, PAKISTAN Dossier Submitted to DRAP on 07/04/2022	Legal Manufacturer: KONICA MINOLTA, INC., 2-7- 2 Marunouchi, Chiyoda-ku, Tokyo, 100-7015, Japan FSC Validity: Valid 01-03-2026 LOA Validity: 31-03-2026 ISO 13485 Validity: 18/04/2025 ISO 9001 Validity: 11/04/2025	Direct Digitizer: <ul style="list-style-type: none">• REGIUS SIGMAII• AeroDR NS 1417• AeroDR 3 SKR 4000, SKR 3000. Class: B Shelf Life/Service life:	Approved
187.	Medequips SMC PVT Ltd Address of Importer: 30-SHAHRAH E QUAID E AZAM, LAHORE, 54000, PAKISTAN Dossier Submitted to DRAP on 07/04/2022	Legal Manufacturer: KONICA MINOLTA, INC., 2-7- 2 Marunouchi, Chiyoda-ku, Tokyo, 100-7015, Japan FSC Validity: Valid 01-03-2026 LOA Validity: 31-03-2026 ISO 13485 Validity: 18/04/2025 ISO 9001 Validity: 11/04/2025	Laser Imager: <ul style="list-style-type: none">• Drypro Sigma• Sigma II• Model 873 Class: A Shelf Life/Service life: 3years	Approved
188.	Medequips SMC PVT Ltd Address of Importer: 30-SHAHRAH E QUAID E AZAM, LAHORE, 54000, PAKISTAN. Dossier Submitted to DRAP on 07/04/2022	Legal Manufacturer: KONICA MINOLTA, INC., 2-7- 2 Marunouchi, Chiyoda-ku, Tokyo, 100-7015, Japan FSC Validity: Valid 01-03-2026 LOA Validity: 31-03-2026	Medical Imaging Films: <ul style="list-style-type: none">• SD-Q• SD-QM• SD-P• SD-PM• SD-S Class: A Shelf Life/Service life: 3years	Approved

		ISO 13485 Validity: 18/04/2025 ISO 9001 Validity: 11/04/2025		
189.	M/s Nipro Medical Pvt Ltd 24CCA, Ex-park View, DHA Phase-8, Lahore, Pakistan (ELI-00530) R&I Dated: 04-03-2025 Fee Challan No.: 1727803898 Rs. 50,000/	Legal Manufacturer: Infraredx , Inc Address: 28 Crosby Drive, Suite 100, Bedford, Massachusetts, 01730, USA MD group: Family LOA Validity: 08-11-2028 FSC Validity: 19-11-2025	Makoto Imaging System Codes: TVC-MC10, MC10i Class: C Shelf-life: N/A	Approved
190.	M/s Nipro Medical Pvt Ltd 24CCA, Ex-park View, DHA Phase-8, Lahore, Pakistan (ELI-00530) R&I Dated: 04-03-2025 Fee Challan No.: 209607723 Rs. 50,000/	Legal Manufacturer: Infraredx , Inc Address: 28 Crosby Drive, Suite 100, Bedford, Massachusetts, 01730, USA. MD Group: Single LOA Validity: 08-11-2028 FSC Validity: 19-11-2025	Dualpro Imaging Catheter Codes: TVC-C195-42 Class-B Shelf-life: 3 years	Approved
191.	M/s SBK INTERNATIONAL Address : 23, Valley Road, Street 3, West ridge 1, Rawalpindi ELI-00100 DRAP submitted documents at R & I on 20-02-2025 FEE CHALLAN No 45092313387 Paid on 6-2-2025	Legal Manufacturer: M/s /s Nantong Health & Beyond Hygenic Products Inc ADDRESS: No.118 Yuxian Road. North Town Street, Rugao City, Jiangsu Province, China. Manufacturing Site: Nantong Health & Beyond Hygenic Products Inc No.118 Yuxian Road. North Town Street, Rugao City, Jiangsu Province, China LOA Validity: 30-12-2029 FSC: Country of Origin Validity: 20-12-2026 EC Certificate Validity:	HEALTHCARE LUBRICATING JELLY Class B Shelf Life: 03 Years Codes / Sizes: 1. 3 grams 2. 5 grams 3. 42 grams 4. 57 grams 5. 82 grams 6. 113 grams	Approved

		31-12-2028 (letter attached) ISO 13485 Validity: 28-08-2027		
192.	M/s Anwar & Sons Apartment No 10, Safari Villas-2 Commercial Complex, Bahria Town Phase-7 Rawalpindi Pakistan ELI- 00017	Legal Manufacturer: M/s Ningbo Advan Electrical Co. Limited Industrial Development Zone, Fuhai Town, 315332 Cixi City, Ningbo, Zhejiang Province, People's Republic of China TEL: +86-574-58961012 Email: customerservice@advan-china.com Website: www.advan-china.com LOA issuance: 11 May 2022 valid till 10 May 2027 FSC Validity: 06-01-2022 ISO Validity: 09-04-2027	Advan-Remover for Skin Stapler Class A Shelf Life 5 years Codes as per FSC C-W C-WC	Approved subject to submission of valid FSC
193.	M/s Anwar & Sons Apartment No 10, Safari Villas-2 Commercial Complex, Bahria Town Phase-7 Rawalpindi Pakistan ELI-00017	Legal Manufacturer: M/s SMI AG Steinerberg 8 4780-St. Vith. Belgium TEL: +32 80 227 292 Email: info@sutures.be Website: www.sutures.be LOA Issuance: 17-04-27 valid till 31-12-2029 FSC Validity not mentioned ISO Validity: 01-03-2027	SMI-Skin Stapler Class B Shelf Life 5 years Codes as per FSC ZS-35W	Approved subject to submission of valid FSC
194.	M/s Anwar & Sons Apartment No 10, Safari Villas-2 Commercial Complex, Bahria Town Phase-7 Rawalpindi Pakistan ELI-00017	Legal Manufacturer: M/s MBK Group Tekstil Sanayi Ic Ve Dis Tic. Ltd. Sti Ikitelli OSB Mah. ISDOK SOSYAL TESIS 2 Sok. A Block No:9 KAT:2, Basaksehir/Istanbul, 34490, Turkey TEL: +90 545 472 1602 Email: info@mbkgroup.com.tr Website: www.mbkgroup.com.tr LOA Issuance: 13.03.24 FSC Validity: 22.07.2029 ISO Validity: 12.04.2025	Midikal - Anti Embolism Stockings Class A Codes as per FSC KHMA31S, KHMA31M KHMA31L, KHMA31XL THMA31S, THMA31M THMA31L, THMA31XL	Approved subject to submission of valid FSC
195.	MTM Associates Suite#F2, First Floor, Zainab Square. 9-10 Block-B. Architects Housing Scheme Lahore-54770 Pakistan.	Legal Manufacturer: FITONE LATEX PRODUCTSCO., LTD GUANGDONG with address at NO.5 TONGYI ROAD, LINGBEI INDUSTRIAL ZONE, SUIXI, 524338 ZHANJIANG, GUANGDONG, CHINA	FITONE Powdered Surgical Gloves Sizes: Codes and sizes as per FSC Single-use Sterile Latex Smooth/Textured, Straight/Curved, 5.5/6.0/6.5/7.0/7.5/8.0/8.5/9.0	Approved

	<p>Mob# +92 3214028833</p> <p>ELI No.: ELI-01112 R&I DATE.20/2/2025 DEPOSITED SLIP NO,2790630534. FEE;31000/=</p>	<p>FSC Valid till: 24-04-2025</p> <p>EC Validity: Expired in 11-03-2024, CE confirmation letter is attached for further validity.</p> <p>ISO Valid till: 11-03-2026</p> <p>LOA Valid till: 15 DEC 2029</p>	<p>Class-B</p> <p>Shelf life: 3 Years</p>	
196.	<p>MTM Associates Suite#F2, First Floor, Zainab Square.</p> <p>9-10 Block-B. Architects Housing Scheme</p> <p>Lahore-54770 Pakistan.</p> <p>Mob# +92 3214028833 ELI No.: ELI-01112R&I DATE.20/2/2025DEPOSITE D SLIP NO,982628407 FEE;31000/=</p>	<p>Legal Manufacturer: FITONE LATEX PRODUCTSCO., LTD GUANGDONG with address at NO.5 TONGYI ROAD, LINGBEI INDUSTRIAL ZONE, SUIXI, 524338 ZHANJIANG, GUANGDONG, CHINA</p> <p>FSC Valid till: 24-04-2025</p> <p>EC Validity: Expired in 11-03-2024, CE confirmation letter is attached for further validity.</p> <p>ISO Valid till: 11-03-2026</p> <p>LOA Valid till: 15 DEC 2029</p>	<p>FITONE Powder-Free Surgical Gloves</p> <p><u>Sizes:</u> Codes and sizes as per FSC Single-use Sterile Latex Smooth/Textured, Straight/Curved, 5.5/6.0/6.5/7.0/7.5/8.0/8.5/9.0</p> <p>Class-B</p> <p>Shelf life: 3 Years</p>	Approved
197.	<p>SUDAIS ASSOCIATES</p> <p>Sudais House, House No: 01 Street No.: 07 Khan bahadar Colony Duran Peshawar KPK Pakistan.</p> <p>(ELI- 00031)</p> <p>Date of submission: 13th Feb 2024</p> <p>Fee submitted: PKR 5000/-</p> <p>Tracking Id: 4DP-PNY- WMD8</p>	<p>Legal Manufacture Zhejiang Ailebao Medical Technology Co., LTD.</p> <p>No.599, Haijing Rd., Longgang City, Wenzhou, Zhejiang, China 325802</p> <p>LOA Expiry Date: January 2029</p> <p>FSC Country of Origin: China Validity: 23rd-Oct-2024</p> <p>ISO 13485 Expiry: 26-11-2024</p>	<p>ILIFE CARE Colostomy Bag</p> <p>Class A</p> <p>Shelf Life: 5 Years</p> <p>Codes: 5010、 5013、 5015、 5020、 5023、 5025、 5030、 5040、 5050、 5053、 5055、 5060、 5063 、 5065、 5070</p> <p>One-Piece Closed Colostomy System : Type 5010/5013/5015</p> <p>One-Piece Open Colostomy System: Type 5020/5023/5025</p> <p>Two-Piece Closed Colostomy Bag: Type 5030</p> <p>Two-Piece Open Colostomy Bag: Type 5040</p> <p>One-Piece Urostomy System: Type 5060/5063/5065</p>	Approved

			Two-Piece Urostomy Bag: Type 5070 Max Cut: 15-90mm Closure: Clip closure/Twist Tie closure/Velcro closure	
198.	<p>SUDAIS ASSOCIATES</p> <p>Sudais House, House No: 01 Street No.: 07 Khan bahadar Colony Duran Peshawar KPK Pakistan.</p> <p>(ELI- 00031)</p> <p>Date of submission: 13th Feb 2024</p> <p>Fee submitted: PKR 5000/-</p> <p>Tracking id: Y3N-S5R- 2R1X</p>	<p>Legal Manufacture</p> <p>Zhejiang Ailebao Medical Technology Co., LTD.</p> <p>No.599, Haijing Rd., Longgang City, Wenzhou, Zhejiang, China 325802</p> <p>LOA Expiry Date: January 2029</p> <p>FSC Country of Origin: China Validity: 23rd-Oct-2024</p> <p>ISO 13485 Expiry: 26-11-2024</p>	<p>ILIFE CARE Ostomy Bag</p> <p>Class A</p> <p>Shelf Life: 5 Years</p> <p>Codes: 5050、5053、5055</p> <p>Two-Piece Ostomy Barrier: Type 5050/5053/5055</p>	Approved
199.	<p>M/s Uniplan Trade International (Pvt) Ltd.</p> <p>Address: 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan</p> <p>ELI-00132</p>	<p>Legal manufacturer _M/s.Fresenius Kabi AG</p> <p>Address: Else-Kroner-Str. 1 61346, Bad Homburg Germany Tel : +49 6172 686-0 Email: communication@fresenius- kabi.com Website <a href="http://www.fresenius-
kabi.com">www.fresenius- kabi.com</p> <p>LOA issue date: 01-05-2023 Validity 31-12-2024</p> <p>FSC Czech Republic issue date: 27-07-2023 validity not mentioned</p>	<p>ACD-A</p> <p>Acid Citrate Dextrose Solution A</p> <p>Class -B</p> <p>Shelf life: 24 months</p> <p>Codes as per FSC TC14024 TC14025 TS14015</p>	Approved subject to submission of CE or FSC of RRA
200.	<p>M/s Uniplan Trade International (Pvt) Ltd.</p> <p>Address: 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan</p> <p>ELI-00132</p>	<p>Legal manufacturer M/s.Fresenius Kabi AG</p> <p>Address: Else-Kroner-Str. 1 61346, Bad Homburg Germany Tel : +49 6172 686-0 Email: communication@fresenius- kabi.com Website <a href="http://www.fresenius-
kabi.com">www.fresenius- kabi.com</p> <p>LOA issue date: 01-05-2023 Validity 31-12-2024</p>	<p>Catsmart Disposables</p> <p>I. ATF 120 fast start kit II. ATF 120 fast start kit with AT3 III. ATV-180 vacuum line</p> <p>Class-B</p> <p>Shelf life: 36 months</p> <p>Codes as per FSC 9308501 9308503</p>	Approved subject to submission of CE or FSC of RRA

		FSC Dominican republic issue date : 02-11-2023 validity not mentioned	9308553	
201.	M/s Uniplan Trade International (Pvt) Ltd. Address: 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan ELI-00132	Legal manufacturer M/s.Fresenius Kabi AG Address: Else-Kroner-Str. 1 61352, Bad Homburg Germany Tel : +49 6172 686-0 Email: communication@fresenius-kabi.com Website www.fresenius-kabi.com LOA issue date: 01-05-2023 Validity 31-12-2026 FSC dominican Republic issue date: 23-1-2024 validity not mentioned	Amicus Apheresis Kit Single Needle (X7R2301) Apheresis Platelet collection kit Class - C Shelf life: 24 months Code as per FSC: X7R2301	Approved subject to submission of CE or FSC of RRA
202.	M/s Uniplan Trade International (Pvt) Ltd. Address: 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore-Pakistan ELI-00132	Legal manufacturer M/s.Fresenius Kabi AG Address: Else-Kroner-Str. 1 61346, Bad Homburg Germany Tel : +49 6172 686-0 Email: communication@fresenius-kabi.com Website www.fresenius-kabi.com LOA issue date: 01-05-2023 Validity 31-12-2024 FSC Dominican Republic issue date: 16-04-2024 validity not mentioned	Catsmart machine Class-B Shelf life: N/A Codes as per FSC 9005751	Approved subject to submission of CE or FSC of RRA
203.	Applicant: M/s. Ontech Corporation Address: B-154 Block 13-D/2 Gulshan-e-Iqbal, Karachi. ELI-00289 R&I details 28-11-2022 Track ID: PY2-RP8-51SV Fee: PKR 25000/- Slip: 21930124501 Dated: 16-11-2022 R&I 28.11.22	Legal Manufacturer: PLASTI-MED Plastik Medikal Ürünler San. ve Tic. Ltd. Şti. Address: Deri Osb Mahallesi Yan Sanayi Cad. No:13 TUZLA / ISTANBUL - TÜRKİYE Post Code: 34956 LOA Validity: 6-May-2022 FSC: Country of Origin: Turkey Validity: 16-01-2027 FSC: FSC of Reference Country - MHRA approval letter dated	PLASTI-MED GUIDE WIRE (Urology Guidewires, PTFE, Hydrophilic, super stiff) Class B Shelf Life: 05 years Codes/Sizes: S # Product Name and sizes Cat No. 1 HYDROPHILIC GUIDE WIRE 0.025" x 150 CM (STRAIGHT TIP) 536002 2 HYDROPHILIC GUIDE WIRE 0.028" x 150 CM (STRAIGHT TIP) 536003 3 HYDROPHILIC	Approved Hydrophilic guide wire. Firm will pay remaining fee PTFE, super stiff guided wires as per S.R.O 1324(1)/2024.

		<p><u>Validity: 27-05-2024</u> OR EC Certificate Validity: 27-05-2024 Ext date: 31-12-2028 ISO 13485 Validity: 11-06-2026</p>	<p>GUIDE WIRE 0.032" x 150 CM (STRAIGHT TIP) 536004 4 HYDROPHILIC GUIDE WIRE 0.035" x 150 CM (STRAIGHT TIP) 536005 5 HYDROPHILIC GUIDE WIRE 0.038" x 150 CM (STRAIGHT TIP) 536006 6 HYDROPHILIC GUIDE WIRE 0.032" x 150 CM (ANGLED) 536010 7 HYDROPHILIC GUIDE WIRE 0.035" x 150 CM (ANGLED) 536011 8 HYDROPHILIC GUIDE WIRE 0.038" x 150 CM (ANGLED) 536012 9 GUIDE WIRE 0.032" x 150 CM ZEBRA 536016 10 GUIDE WIRE 0.035" x 150 CM ZEBRA 536017</p> <p>11 GUIDE WIRE 0.038" x 150 CM ZEBRA 536018 12 PTFE GUIDE WIRE 0.018" x 150 CM (STRAIGHT TIP) 536025 13 PTFE GUIDE WIRE 0.025" x 150 CM (STRAIGHT TIP) 536026 14 PTFE GUIDE WIRE 0.028" x 150 CM (STRAIGHT TIP) 536027 15 PTFE GUIDE WIRE</p>	
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			0.032" x 150 CM (STRAIGHT TIP) 536028 16 PTFE GUIDE WIRE 0.035" x 150 CM (STRAIGHT TIP) 536029 17 PTFE GUIDE WIRE 0.038" x 150 CM (STRAIGHT TIP) 536030 18 PTFE GUIDE WIRE 0.032" x 150 CM (J TYPE) 536034 19 PTFE GUIDE WIRE 0.035" x 150 CM (J TYPE) 536035 20 PTFE GUIDE WIRE 0.038" x 150 CM (J TYPE) 536036 21 SUPER STIFF GUIDE WIRE 0,035" 150 cm 536037 22 SUPER STIFF GUIDE WIRE 0.035, 80CM, J-Tip 536037 -J 23 Angel- Ii Two Edge Flexible Nitinol Guide Wire 0.035" X 150cm 536038 24 HYDROPHILIC SLIPPY GUIDE WIRE 0,035"x150 CM 536042 25 HYDROPHILIC SLIPPY GUIDE WIRE 0,038"x150 CM 53604	
204.	Applicant: M/s. Ontech Corporation Address: B-154 Block 13-D/2 Gulshan-e-Iqbal, Karachi.	Legal Manufacturer: PLASTI-MED Plastik Medikal Ürünler San. ve Tic. Ltd. Şti. Address: Deri Osb Mahallesi Yan Sanayi Cad. No:13 TUZLA /	PLASTI-MED DILATORS (URETERAL DILATOR, AMPLATZ RENAL DILATOR, FASCIAL DILATORS, RENAL KLIF, HYDROPHILIC	Approved URETERAL DILATOR. Firm will pay remaining fee for amplatz renal dilator, fascial dilators, renal klif, hydrophilic

<p>ELI-00289 R&I details 28-11-2022</p> <p>Track ID: Q6U-USB-7NE2 Fee: PKR 25000/- Slip: <u>21930124501</u> Dated: 16-11-2022 R&I 28.11.22</p>	<p>ISTANBUL - TÜRKİYE Post Code: 34956 LOA <u>Validity: 6-May-2022</u> FSC: <u>Country of Origin:</u> <u>Turkey</u> <u>Validity: 16-01-2027</u> FSC: <u>FSC of Reference</u> <u>Country - MHRA</u> <u>approval letter dated</u> <u>Validity: 27-05-2024</u> OR EC Certificate Validity: 27-05-2024 Ext date: 31-12-2028 ISO 13485 Validity: 11-06-2026</p>	<p>URETERAL DILATORS, MINI RENAL DILATOR, Ureteral Balloon Dilator, NEPHROSTOMY BALLOON DILATOR SET, TRANSDUCER DILATOR) Class B Shelf Life: 05 years Codes/Sizes: S # Product Name Cat No. 1 URETERAL DILATOR (ECONOMY) 8-22 FR X 70 CM SET 533001 2 AMPLATZ RENAL DILATOR AND SHEATH SET 6-30 FR 542003 3 FASCIAL DILATOR 6 FR 22 CM 542008 4 FASCIAL DILATOR 8 FR 22 CM 542009 5 FASCIAL DILATOR 10 FR 22 CM 542010 6 FASCIAL DILATOR 12 FR 22 CM 542011 7 FASCIAL DILATOR 14 FR 22 CM 542012 8 FASCIAL DILATOR 16 FR 22 CM 542013 9 FASCIAL DILATOR SET 6-16 FR 542014 10 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 38CM 542015 11 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 54CM 542016 12 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 25CM 542021 13 HYDROPHILIC</p>	<p>ureteral dilators, mini renal dilator, ureteral balloon dilator, nephrostomy balloon dilator set, transducer dilator) as per S.R.O 1324(1)/2024.</p>
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			<p>URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 45CM 542026 14 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 11,5 FR I.D. 9,5 FR/ 39CM 542027 15 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 11,5 FR I.D. 9,5 FR/ 45CM 542028 16 MINI RENAL DILATOR AND SHEATH SET 542029 17 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 13 FR I.D. 11 FR/ 45CM 542033 18 AMPLATZ RENAL DILATOR &SHEATH SET PEDIATRIC 542034 19 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 11,5 FR I.D. 9,5 FR/ 20 CM 542036 20 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 11,5 FR I.D. 9,5 FR/ 35 CM 542037 21 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 14 FR I.D. 12 FR/ 35 CM 542038 22 HYDROPHILIC URETERAL</p>	
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			<p>ACCESS SHEATH & DILATOR SET O.D. 12 FR I.D. 10 FR/ 20 CM 542040 23 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 12 FR I.D. 10 FR/ 35 CM 542041 24 HYDROPHILIC URETERAL ACCESS SHEATH & DILATOR SET O.D. 12 FR I.D. 10 FR/ 45 CM 542042 25 URETERAL BALLOON DILATOR 4 MM X 4 CM X 75CM 533002 26 URETERAL BALLOON DILATOR 5 MM X 4 CM X 75CM 533005 27 URETERAL BALLOON DILATOR 6 MM X 4 CM X 75CM 533008 28 NEPHROSTOMY BALLOON DILATOR CATHETER SET 30FR 12CM 533013 29 TRANSURETERO SCOPIC BALLOON DILATOR 533014 30 TRANSURETERO SCOPIC BALLOON DILATOR AND INFLATION DEVICE 533022 31 URETERAL BALLOON DILATOR SET WITH</p>	
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			<p>HYDROPHILIC TIP 5 MM X 4 CM X 75CM 533025 32 URETERAL BALLOON DILATOR SET WITH HYDROPHILIC TIP 6 MM X 4 CM X 75CM 533026 33 URETERAL BALLOON DILATOR SET WITH HYDROPHILIC TIP 4 MM X 4 CM X 75CM 53302</p>	
205.	<p>Applicant: M/s Nisa Impex Private Limited, Office 1, First Floor, Maxim Arcade, Plot 13 14, Usman Block, Jeddah Town Ph1, GT road, Islamabad. (ELI-00128) Track ID: MVU-WEE-6V57 Fee: PKR 25000/- Slip: <u>80724194556</u> Dated: <u>25-10-2023</u> R&I : <u>22.05.24</u></p>	<p>Legal Manufacturer: Foshan Nanhai KJT Rehabilitation Equipment Co., Ltd Manufacturing Site: Qixing Precinct, Xiqiao town, Nanhai District, 528204 Foshan City, Guangdong Province, People's Republic of China</p> <p>FSC Validity: 03-08-2025</p> <p><u>LOA Validity:</u> <u>31-07-2028</u></p> <p>EC Certificate: 26-05-2024</p> <p>ISO 13485: 11-02-2026</p>	<p>Brand Name KJT (Generic name) Commode Chair</p> <p>Class A</p> <p>Shelf Life: N.A.</p> <p>Codes/Sizes: KJT717,KJTSS715,KJT715, KJTSS716,KJT716,KJT718 ,KJT713,KJT710C,KJ T710B KJT710BU,KJT725U, KJT729,KJT726,KJT7 09,KJT709B,KJT709C, KJT709D,KJT709D U,KJT705,KJT708,KJ T707C,KJT708L,KJT7 20,KJT707,KJT707B, KJT727,KJT727B,KJ T703,KJT706,KJT706 B,KJT721,KJT730,KJ T731,KJT732,KJT733, KJT734,KJT735,KJT 736,KJT737,KJT738,K JT739,KJT739S,KJT74 0,KJT740C,KJT740CS ,KJT740CK,KJT7 41,KJT742,KJT743,KJ T744,KJT745,KJT746, KJT747,KJT748,KJT7 49,KJT75</p>	<p>Deferred for brand name as already approved.</p>
206.	<p>Applicant: M/s MOON ENTERPRISES 5/6 Rabani Road , Old</p>	<p>(LEGAL MANUFACTURER) M/s Jianguo Jichun Medical</p>	<p>Brand Name: JJMD® (Scalp Vein Set)</p>	<p>Approved subject to submission of CE or FSC of RRA</p>

	<p>Anarkali Lahore Pakistan (ELI-000356) Track ID:</p> <p><u>R3T-1YV-BW7J</u> Fee: PKR 25000/- Slip: 6212341659 Dated: 09-07-2024 R&I : 12-Oct-2023</p>	<p>Devices Co., Ltd., China. Manufacturing Site: Zhenglu Town,Changzhou Gity,Jiangsu Province,China.</p> <p>FSC: Country of Origin: China Validity: 24-02-2025</p> <p>LOA Validity: 04-06-2028</p> <p>ISO 13485 Validity: 16-06-2026</p>	<p>Class B</p> <p>Shelf Life: 5 years</p> <p>Codes/Sizes: 1/Pc Pack</p>	
207.	<p>Applicant: M/s MOON ENTERPRISES 5/6 Rabani Road , Old Anarkali Lahore Pakistan (ELI-000356) Track ID:</p> <p><u>PR5-JVE-V39R</u> Fee: PKR 25000/- Slip: 6212341659 Dated: 09-07-2024 R&I : 12-Oct-2023</p>	<p>(LEGAL MANUFACTURER) M/s Jiangsu Jichun Medical Devices Co., Ltd., China. Manufacturing Site: Zhenglu Town,Changzhou Gity,Jiangsu Province,China.</p> <p>FSC: Country of Origin: China Validity: 24-02-2025</p> <p>LOA Validity: 04-06-2028</p> <p>ISO 13485 Validity: 16-06-2026</p>	<p>Brand Name: JJMD® (Disposable Infusion Set)</p> <p>Class B</p> <p>Shelf Life: 5 years</p> <p>Codes/Sizes: 1/Pc Pack</p>	<p>Approved subject to submission of CE or FSC of RRA</p>
208.	<p>Applicant: M/s : Biologic Medical Systems 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road (ELI- 000346) Track ID:</p> <p><u>MRH-V35-L9GX</u></p>	<p>(LEGAL MANUFACTURER) Legal Manufacturer: Name: M/s Euroclinic Medicare Solutions S.r.l, Italy Manufacturer Address: Italy.</p> <p>LOA Validity: 30-12-2025</p> <p>ISO 13485 Certificate validity: 15-11-2026</p>	<p>OTOCOMPACT PROFESSIONAL TYPE 11 Class B</p> <p>Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2-8</p>	<p>Deferred for provision of Fsc or CE and Fee along with evidence of submission of application</p>
209.	<p>Applicant: M/s : Biologic Medical</p>	<p>(LEGAL MANUFACTURER)</p>	<p>OTOCOMPACT Steel TYPE 11</p>	<p>Deferred for provision of Fsc or CE and Fee</p>

	Systems 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road (ELI- 000346) Track ID: <u>NSS-VZ6-E7MZ</u>	Legal Manufacturer: Name: M/s Euroclinic Medicare Solutions S.r.l, Italy Manufacturer Address: Italy. <u>LOA Validity:</u> <u>30-12-2025</u> <u>ISO 13485</u> <u>Certificate validity:</u> <u>15-11-2026</u>	Class B Shelf life: For assay: 18 months For controls: 18 months Storage condition: 2 8	along with evidence of submission of application
210.	M/s. Alfa Scientific Store, Lahore ELI:00148 R&I Details: 01-June-2021 Track ID: REN-82H-AE9L Fee: PKR <u>25000/-</u> Slip: <u>9143976188</u> <u>27.05.21</u>	M/s Weiner Laboratoris S.A.I.C Manufacturing Site: Maipu 2571 street (2000) - Rosario city, Santa Fe, Argentina. LOA Validity: 31-Dec-2026 <i>FSC:</i> <i>Country of Origin:</i> <i>Argentina</i> <i>Validity: 27-Feb-2026</i> EC Certificate: Validity: 14-Dec-2026 <u>ISO 13485</u> <u>Validity: 26-April-2027</u>	Brand Name: WEINER LAB Generic Name: METABOLITES Cluster Name: METABOLITES PART 2 Class B Product Name: Colestat Enzimatico AA Liquida (Cholesterol) Shelf Life: -- 18 Months Codes / Sizes (if any) GMDN: 53359 Product Registration No FSC: PM-1102-152 Product Catalogue Codes: 1009253, 1009308, 1009610, 1220114, 1220222 Product Name: Colestat enzimatico (Cholestrol) Shelf Life: -- 21 Months Codes / Sizes (if any) GMDN: 53460 Product Registration No FSC: C-2086/97 Product Catalogue Codes:1220110 Product Name:	Approved Colestat Enzimatico AA Liquida (Cholesterol) The following are approved subject to submission of separate fee for each as per revised SRO Product Name: Colestat enzimatico (Cholestrol) Shelf Life: -- 21 Months Codes / Sizes (if any) GMDN: 53460 Product Registration No FSC: C-2086/97 Product Catalogue Codes:1220110 Product Name: Glicemia enzimatica AA liquida: Glucose Shelf Life: -- 18 Months Codes / Sizes (if any) GMDN: 53301 Product Registration No FSC: PM-1102-153

			<p>Glicemia enzimatica AA liquida: Glucose Shelf Life: -- 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53301 . Status Pending. Product Registration No FSC: PM-1102-153</p> <p>Product Catalogue Codes:1009260, 1009617, 1009313, 1400060</p> <p>Product Name: TG Color GPO/PAP AA liquida: TRIGLYCERIDES Shelf Life: -- 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53460 Product Registration No FSC: PM-1102-155 Product Catalogue Codes:1009274, 1009632, 1009318, 1780111, 1780112</p> <p>Product Name: Uricostat enzimatica AA liquida : URIC ACID Shelf Life: -- 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53583 Product Registration No FSC: PM-1102-157 Product Catalogue Codes:1009277, 1009635, 1009320, 1840107, 1840110</p>	<p>Product Catalogue Codes:1009260, 1009617, 1009313, 1400060</p> <p>Product Name: TG Color GPO/PAP AA liquida: TRIGLYCERIDES Shelf Life: -- 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53460 Product Registration No FSC: PM-1102-155 Product Catalogue Codes:1009274, 1009632, 1009318, 1780111, 1780112</p> <p>Product Name: Uricostat enzimatica AA liquida : URIC ACID Shelf Life: -- 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53583 Product Registration No FSC: PM-1102-157 Product Catalogue Codes:1009277, 1009635, 1009320, 1840107, 1840110</p>
211.	<p>M/s. Alfa Scientific Store, Lahore</p> <p>ELI:00148</p> <p>R&I Details: 01-June-2021</p>	<p>M/s Weiner Laboratoris S.A.I.C</p> <p>Manufacturing Site: Maipu 2571 street (2000) - Rosario city, Santa Fe, Argentina.</p>	<p>Brand Name: WEINER LAB Generic Name: METABOLITES Cluster Name: METABOLITES PART 01</p>	<p>Approved ALBUMINA AA (ALBUMIN) The following are approved subject to the submission of seperate fee for each as per revised S.R.O.</p>

<p>Track ID: REN-82H-AE9L</p> <p>Fee: PKR <u>25000/-</u> Slip: <u>9143976188</u> <u>27.05.21</u></p>	<p>LOA Validity: 31-Dec-2026</p> <p><i>FSC:</i> <i>Country of Origin:</i> <i>Argentina</i> <i>Validity: 27-Feb-2026</i></p> <p>EC Certificate: Validity: 14-Dec-2026</p> <p><u>ISO 13485</u> <u>Validity: 26-April-2027</u></p>	<p>Class B</p> <p>Product Name: ALBUMINA AA (ALBUMIN) Shelf Life: 36 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53597 Product Registration No FSC: PM-1102-150 Product Catalogue Codes: 1009240, 1009601, 1009300, 1690008</p> <p>Product Name: BILIRRUBINA DIRECTA AA LIQUIDA (DIRECT BILIRUBIN) Shelf Life: 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53233 Product Registration No FSC: PM-1102-197 Product Catalogue Codes:1009246, 1009604, 1009335, 1120007</p> <p>Product Name: BILIRRUBINA TOTAL AA LIQUIDA (TOTAL BILIRUBIN) Shelf Life: 18 Months</p> <p>GMDN: 53229 Product Registration No FSC: PM-1102-12</p> <p>Product Catalogue Codes:1009244, 1009605, 1009334, 1120008</p> <p>Product Name: PROTEINAS TOTALES AA (TOTAL PROTEINS) Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 61900</p>	<p>Product Name: BILIRRUBINA DIRECTA AA LIQUIDA (DIRECT BILIRUBIN Shelf Life: 18 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53233 Product Registration No FSC: PM-1102-197 Product Catalogue Codes:1009246, 1009604, 1009335, 1120007</p> <p>Product Name: BILIRRUBINA TOTAL AA LIQUIDA (TOTAL BILIRUBIN Shelf Life: 18 Months</p> <p>GMDN: 53229 Product Registration No FSC: PM-1102-12</p> <p>Product Catalogue Codes:1009244, 1009605, 1009334, 1120008</p> <p>Product Name: PROTEINAS TOTALES AA (TOTAL PROTEINS Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 61900 Product Registration No FSC: PM-1102-154 Product Catalogue Codes:1009273, 1009605, 1009334, 1690009</p> <p>Product Name: PROTI</p>
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			<p>Product Registration No FSC: PM-1102-154 Product Catalogue Codes:1009273, 1009605, 1009334, 1690009</p> <p>Product Name: PROTI U/LCR (URINARY/ CSF PROYEINS) Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 61900 Product Registration No FSC: PM-1102-1128 Product Catalogue Codes:1009282, 1009631, 1009317, 1690007</p> <p>Product Name: LDL CHOLESTROL MONOFASE (LDL CHOLESTROL) Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53395 Product Registration No FSC: C-3135/99 Product Catalogue Codes: 1009283, 1009627, 1009348, 1220220</p> <p>Product Name: HDL CHOLESTROL FAST Shelf Life: -- 22 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53391 Product Registration No FSC: PM-1102-115 Product Catalogue Codes: 1220229, 1220233</p> <p>Product Name: HDL CHOLESTROL MONOFASE Shelf Life: -- 22 Months</p> <p>Codes / Sizes (if any)</p>	<p>U/LCR (URINARY/ CSF PROYEINS Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 61900 Product Registration No FSC: PM-1102-1128 Product Catalogue Codes:1009282, 1009631, 1009317, 1690007</p> <p>Product Name: LDL CHOLESTROL MONOFASE (LDL CHOLESTROL) Shelf Life: 24 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53395 Product Registration No FSC: C-3135/99 Product Catalogue Codes: 1009283, 1009627, 1009348, 1220220</p> <p>Product Name: HDL CHOLESTROL FAST Shelf Life: -- 22 Months</p> <p>Codes / Sizes (if any)</p> <p>GMDN: 53391 Product Registration No FSC: PM-1102-115 Product Catalogue Codes: 1220229, 1220233</p> <p>Product Name: HDL CHOLESTROL MONOFASE Shelf Life: -- 22 Months</p> <p>Codes / Sizes (if any)</p>
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			Codes / Sizes (if any) GMDN: 53391 Product Registration No FSC: PM-1102-147 Product Catalogue Codes: 1009264, 1009622, 1009328, 1220231, 1220239	GMDN: 53391 Product Registration No FSC: PM-1102-147 Product Catalogue Codes: 1009264, 1009622, 1009328, 1220231, 1220239
212.	M/s. Alfa Scientific Store, Lahore ELI:00148 Track ID: N2T-GMQ-YDLH Fee: PKR 25000/- dated 27.05.21 Slip: 407652984190 <u>(R&I Receiving): 01-June-2021</u>	M/s Weiner Laboratoris S.A.I.C Manufacturing Site: Maipu 2571 street (2000) - Rosario city, Santa Fe, Argentina. <u>LOA</u> <u>Validity: 31-Dec-2026</u> FSC: Country of Origin: Argentina Validity: 27-Feb-2026 <u>ISO 13485</u> <u>Validity: 26-April-2027</u>	Brand Name: Wiener Lab Generic Name: Lipase Product Names: LIPASA AA LIQUIDA (LIPASE) Class B Shelf Life: 18 Months Codes / Sizes (if any) GMDN: 53108 Product Registration No FSC: PM-1102-26 Product Catalogue Codes: 1009284, 1009628, 1009339	Approved subject to submission of valid CE
213.	M/s Global Clinical Cura (Pvt) Ltd 18, Mian Iqbal Road, Westridge 1, Rawalpindi, Pakistan Tel: +92-51- 8357282 Fax: +92-51- 8357283 info@gcc- health.com ELI-00196 <u>R&I details 05/06/2024</u> Fee: PKR 25000/- dated 27.05.21 Slip: 839249290 <u>Tracking ID</u> <u>PUZ-QY2-21VT</u>	Legal Manufacturer: Protia Inc. (Formerly ProteomeTech Inc.) Manufacturing Site: A-702 & 813 & 1103 & 1104, Yangcheon- ro, Gangseo- gu, Seoul, 07528, Republic of Korea Website: www.proteometech.com LOA: 06.07.23 to Open FSC: <i>Country of Origin Validity:</i> 10.05.2023 TO 09.05.28 ISO 13485: Validity : 08.01.26	Brand Name: Protia Allergy Q Generic Name: Model name: PROTIA Allergy-Q Immunoglobulin E.Screen PROTIA Allergy-Q 64 Food panel PROTIA Allergy-Q 64 Inhalant panel PROTIA Allergy-Q 64S panel PROTIA Allergy-Q Atopy panel Class: B Shelf Life: 24 months Code/sizes:	Approved Subject to facility of Storage 2-8 ⁰
214.	Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326)	Legal Manufacturer: CHEMELEX, S.A. Address: Pol. Ind. Can Castells, C/ Industria 113, nave J 08420 CANOVELLES (BARCELONA) – SPAIN FSC Spain:	Brand Name: GLUCOSE LS (Product Code: 30234). Class-B Shelf life: 24 Months. Storage Conditions: Room temperature	Approved

	<p>Track ID: N68-WRP-H4GY Fee: PKR 25000/- Slip: 964034087638 Dated: 30-05-2022 Date of R&I 31 may 2022</p>	<p>DOI : 15-10-2021 LOA Notarized LOA Valid till 31-12-2027</p> <p>ISO 13485 Validity: 13-05-2021 Expired at submission</p>		
215.	<p>Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326) Track ID: N68-WRP-H4GY Fee: PKR 25000/- Slip: 77353911881 Dated: 30-05-2022 Date of R&I 31 may 2022</p>	<p>Legal Manufacturer: CHEMELEX, S.A. Address: Pol. Ind. Can Castells, C/ Industria 113, nave J 08420 CANOVELLES (BARCELONA) – SPAIN FSC Spain: DOI : 15-10-2021 LOA Notarized LOA Valid till 31-12-2027</p> <p>ISO 13485 Validity: 13-05-2021 Expired at submission</p>	<p>Brand Name: Generic Name: BIOCHEMISTRY KITS; LIVER FUNTION TESTS:</p> <ul style="list-style-type: none"> • GPT/ALT-LQ (Product Codes: 30253, 30254) • GOT/AST-LQ (Product Code: 30243, 30244) Product Names: BIOCHEMISTRY KITS; LIVER FUNTION TESTS: • GPT/ALT-LQ (Product Codes: 30253, 30254) • GOT/AST-LQ (Product Code: 30243, 30244) <p>Class-B</p> <p>Shelf life: 18 Months. Storage Conditions: Room temperature</p>	Approved
216.	<p>Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326) Track ID: MN5-HZQ-VA41 Fee: PKR 5000/- Slip: 95180375493 Dated: 11-10-2022 Date of R&I 12 10 2022</p>	<p>Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China.. Jiangxi Exquisite Technology Co.,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024</p> <p>ISO 13485 Validity: 25-12-2027</p>	<p>Brand Name: Generic Name: 3.2% Sodium Citrate Tube. Product Names: 3.2% Sodium Citrate Tube. Class-A</p> <p>Shelf life: 24 Months. Storage Conditions: Room temperature</p>	Deferred for the submission of valid valid LOA

217.	<p>Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326)</p> <p>Track ID: R9X-NTT-SVLE</p> <p>Fee: PKR 5000/-</p> <p>Slip: 5597059583</p> <p>Dated: 12-10-2022</p> <p>Date of R&I 12 10 2022</p>	<p>Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China..</p> <p>Jiangxi Exquisite Technology Co.,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China</p> <p>FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024</p> <p>ISO 13485 Validity: 25-12-2027</p>	<p>Brand Name: Generic Name: Glucose, Fluoride Tube. Class-A</p> <p>Shelf life: 24 Months. Storage Conditions: Room temperature</p>	Deferred for the submission of valid valid LOA
218.	<p>Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326)</p> <p>Track ID: NNP-A2G-4PZ8</p> <p>Fee: PKR 5000/-</p> <p>Slip: 239350145</p> <p>Dated: 12-10-2022</p> <p>Date of R&I 12 10 2022</p>	<p>Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China..</p> <p>Jiangxi Exquisite Technology Co.,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China</p> <p>FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024</p> <p>ISO 13485 Validity: 25-12-2027</p>	<p>Brand Name: Generic Name: K3 EDTA Tube. Class-A</p> <p>Shelf life: 24 Months. Storage Conditions: Room temperature</p>	Deferred for the submission of valid valid LOA
219.	<p>Radiant Medical Private Limited Address of Importer 06-Sher Shah Block New Garden Town Lahore, Pakistan. ELI- 00135 R.s. 25,000/ through slip no: 697617226, date: 01.09. 2023</p> <p>Date of R& I 21-Feb-2024</p>	<p>LEGAL MANUFACTURER Livetec Ingenieurbüro GmbH</p> <p>(Manufacturing site) Marie-Curie-Strasse 8, 79539 Lörrach Germany</p> <p>LOA validity 31-12-2026</p> <p>ISO 13485 Validity: 14-04-2025</p>	<p>kECG ECG Recorder</p> <p>Class-A</p> <p>Shelf Life: 5 Years Storage temperature: Temperature: - 25 °C -> + 70 °</p>	Approved

		FSC Germany issuance 16-10-2023		
220.	<p>Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326) Track ID: R3P-AEX-VU2W Fee: PKR 25000/- Slip: 6277749824 Dated: 30-05-2022 Date of R&I 31 may 2022</p>	<p>Legal Manufacturer: CHEMELEX, S.A. Address: Pol. Ind. Can Castells, C/ Industria 113, nave J 08420 CANOVELLES (BARCELONA) – SPAIN FSC Spain: DOI : 15-10-2021 LOA Notarized LOA Valid till 31-12-2027 ISO 13485 Validity: 13-05-2021 Expired at submission</p>	<p>Brand Name: Amylase-LQ, LabKit. Class-B Letter of authorization: Validity date: 21-02-2028 Shelf life: 24 Months. Storage Conditions: Room temperature</p>	Approved
221.	<p>FUTURE SCIENTIFIC Address of Importer Shaheen Town, Rawalpindi. ELI- 00209 R.s. 25,000/ through slip no: 2105256, date: 11.03. 2021 Track ID: QLS-SH9-Y9E8 Date of R& I : 16.03. 2021</p>	<p>LEGAL MANUFACTURER Immunodiagnostic Systems Limited 10 Didcot Way, Boldon Business Park, Tyne & Wear, NE35 9PD, United Kingdom LOA validity 31-12-2026 ISO 13485 Validity: 14-04-2025 FSC Germany issuance 16-10-2023</p>	<p>IDS ANA Screen IDS ENA Screen IDS ANA Screen Control Set IDS dsDNA IgG IDS Centromere B IDS ANA Control Set IDS CCP IDS CCP Control Set IDS Deamidated Gliadin IgA IDS Deamidated Gliadin IgG IDS CELIAC Control Set IDS Cardioliplin IgG IDS B2-Glycoprotein I IgG IDS APS IgG Control Set IDS Cardioliplin IgM IDS B2-Glycoprotein I IgM IDS APS IgM Control Set IDS GBM IDS ANCA/GBM Control Set IDS AMA (M2) Class-B Shelf Life IDS ANA Screen – 12 months IDS ENA Screen – 12 months IDS ANA Screen Control Set – 24 months IDS dsDNA IgG – 12 months IDS Centromere B – 12 months IDS ANA Control Set – 24 months IDS CCP – 12 months IDS CCP Control Set – 24 months IDS Deamidated Gliadin IgA – 12 months IDS Deamidated Gliadin IgG – 12 months</p>	Approved

			<p>IDS CELIAC Control Set – 24 months IDS Cardiolipin IgG – 12 months IDS B2-Glycoprotein I IgG – 12 months IDS APS IgG Control Set – 24 months IDS Cardiolipin IgM – 12 months IDS B2-Glycoprotein I IgM – 12 months IDS APS IgM Control Set – 24 months IDS GBM – 12 months IDS ANCA/GBM Control Set – 24 months IDS AMA (M2) – 12 months</p> <p>2°C-8°C</p>	
222.	<p>Applicant: M/s HEALTH TEC House No 10-B,Street 24,Valley road Westridge 1 (ELI- 00046) Track ID: QDT-BZR-W6VZ</p>	<p>Legal Manufacturer: SCW Medicath, LTD, No:4, Baolong 6 road baolong Industrial town, Longang District Shenzhen, Guangdong China.</p> <p>FSC China: DOI : 22-10-2026 LOA Notarized LOA Valid till 26-08-2029</p> <p>ISO 13485 Validity: 08-07-2027</p>	<p>Brand Name: Manifold Class-B</p> <p>Shelf life: 24 Months. Storage Conditions: Room temperature</p>	<p>Deferred for DRAP R&I evidence for application submission, fee and CE certificate</p>
223.	<p>Applicant: M/s HEALTH TEC House No 10-B,Street 24,Valley road Westridge 1 (ELI- 00046) Track ID: QDT-BZR-W6VZ</p>	<p>Legal Manufacturer: SCW Medicath, LTD, No:4, Baolong 6 road baolong Industrial town, Longang District Shenzhen, Guangdong China.</p> <p>FSC China: DOI : 22-10-2026 LOA Notarized LOA Valid till 26-08-2029</p> <p>ISO 13485 Validity: 08-07-2027</p>	<p>Brand Name: pressure bandage Class-A</p> <p>Shelf life: 24 Months. Storage Conditions: Room temperature</p>	<p>Deferred for DRAP R&I evidence for application submission, fee</p>
224.	<p>M/s Meher Enterprises, Pakistan</p> <p>1st Floor Az Zainab Court, Campbell Street,</p>	<p>Legal Manufacturer: Bonree Medical Co., Ltd. No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, China Phone: 0086 760 8520 7588</p>	<p>Brand Name: Greatcare Nasal Oxygen Cannula</p> <p>Generic Name: Nasal Oxygen Cannula</p>	<p>Approved subject to submission of valid CE certificate</p>

	<p>Karachi-Pakistan. (ELI-00241)</p> <p>R&I Dated: 06-09-2021 Fee Challan No.: 06459033628 dated 27.8.21 PKR: 25,000/- Track ID: Q93-EW1-7HP2</p>	<p>LOA: Validity: 11-05-2025</p> <p>FSC: China Validity: 09-05-2023</p> <p>EC Certificate: Validity: 26-05-2024</p> <p>ISO: Validity Date: 31-07-2022</p>	<p>Class: B</p> <p>Shelf life: 5 years</p> <p>Size & Model: Neonate, infant, pediatric, adult</p>	
225.	<p>Sure Bio-Diagnostics & Pharmaceuticals Address of Importer EE-10, Defence View Phase-II, Near Iqra University Shaheed e-Millat Express Way, Karachi. (ELI 00084)</p> <p>R&I Dated: 03-10-2024 Fee Challan No.: 20296865324 PKR: 6000/-</p>	<p>M/s.Nalge Nunc International Corporation Company Address: 75 Panorama Creek Drive, Rochester, New York, USA, 14625,</p> <p>FSC country of origin: Date of expiry: 29-01-2026 FSC RRA : 29-01 2026 LOA Validity: Valid until notification to DRAP LOA Issuance date : 05-11-2024</p> <p>ISO 13485: 20-12-2024</p>	<p>Nunc CryoTube Internally Threaded, Nunc Cryotube 1.8mL. Sterile, internal thread, Nunc Cryotube 4.5mL. Sterile, internal thread Nunc Cryotube 3.6mL. Sterile, internal thread Nunc Cryotube 1.0mL. Sterile, internal thread Nunc Cryotube 1.8mL. Sterile, internal thread round. Nunc Cryotube 1.0mL. Sterile, internal thread, starfoot, conical Nunc Cryotube 1.8mL. Sterile, internal thread, starfoot, round Nunc Cryotube 4.5mL. Sterile, internal thread,starfoot, round Nunc Cryotube 3.6mL. Sterile, internal thread,starfoot, round</p> <p>Class: A MD group: family Shelf Life: 5 years Codes/Sizes: 363401 363452 366524 366656 368632 377224 377267 379146 379189</p>	<p>Approved subject to the clarification of site of manufacturing either USA or Denmark, Differential Fee as per S.R.O 1324/2024</p>
226.	<p>SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400,</p>	<p>M/s. DiaSorin Inc., 1951 Northwestern Avenue, Stillwater, MN 55082 USA.</p> <p>LOA Validity: 20-01-2024</p>	<p>BONE AND MINERAL METABOLISM ASSAYS (Cluster):</p> <p>Class A: - LIAISON N-TACT</p>	<p>Deferred for the submission of clarification of cluster formation as per MDR 2017</p>

	<p>PAKISTAN</p> <p>Lic. No.: ELI-00010 Date of issue: 03-08-2018 Date of Renewal: 20-06-2023</p> <p>R&I Date: 25-01-2023 Fee Challan No.:6161812283 Rs.: 25,000/- Dated: 13-01-2023</p>	<p>FSC Country of origin: USA Validity: 03-05-2024</p> <p>ISO 13485 Validity: 15-08-2024</p>	<p>PTH GEN II SPECIMEN DILUENT – REF. NO. 317912 - LIAISON BAP OSTASE SPECIMEN DILUENT – REF. NO. 310972</p> <p>Class B: - LIAISON N- TACT PTH GEN II – REF. NO. 317910 - LIAISON N-TACT PTH GEN II CONTROL SET– REF. NO. 317911 - LIAISON BAP OSTASE - REF. NO. 310970 - LIAISON BAP OSTASE CONTROL - REF. NO. 310971</p> <p>Shelf Life: 540 Days</p> <p>365 Days for LIAISON BAP OSTASE SPECIMEN DILUENT (REF NO. 310972)</p> <p>Storage Condition: 2-8 0 C</p>	
227.	<p>M/s BIOSORIN (PRIVATE) LIMITED 19-USMAN BLOCK, MAIN BOULEVARD NEW GARDEN TOWN LAHORE-PAKISTAN (ELI-00186)</p> <p>Track ID: RLQ-U87-ZBN9</p>	<p>Legal Manufacturer: Cook Vandergrift USA</p> <p>LOA: Validity: till 12th February 2024 FSC USFDA valid till date of issue 01.03.2024</p> <p>ISO: Validity Date: 14-05-2023</p>	<p>Brand Name; denuding pipette</p> <p>Class: B</p> <p>Shelf life: 3 years</p> <p>Size & Model:</p>	Deferred for provision of valid LOA, fee and R&I details
228.	<p>M/s BIOSORIN (PRIVATE) LIMITED 19-USMAN BLOCK, MAIN BOULEVARD NEW GARDEN TOWN LAHORE-PAKISTAN (ELI-00186)</p> <p>Track ID: RLQ-U87-ZBN9</p>	<p>Legal Manufacturer: William A cook australia pvt ltd</p> <p>LOA: Validity: valid till 12th February 2024 FSC Australia date of issue 16.12.2021</p> <p>ISO: Validity Date: 21-11-2024</p>	<p>Brand Name; test tube heater</p> <p>Class: B</p> <p>Shelf life: 7 years</p> <p>Size & Model:</p>	Deferred for provision of valid LOA, fee and R&I details
229.	<p>Applicant: M/s G MED (PVT.) LIMITED. House No 218 B2 Block Johar Town Lahore</p> <p>(ELI- 00914)</p>	<p>(Legal Manufacturer) Name: M/s Famed Żywiec Sp. z o.o. Manufacturer Address: ul. Fabryczna 1 34-300 Żywiec</p>	<p>Brand Name Electric ICU Bed. Models:</p> <p>Class: A</p>	Approved

	<p>Track ID: M3U-62R-WMYW Dated: <u>25-02-2023</u> Fee Challan No.: <u>479748939</u> PKR: 5000/- Dated: <u>7-03-2023</u></p>	<p>Poland.</p> <p>LOA Validity: 30-06-2026</p> <p>FSC Validity (country of origin) Poland: Date of issue 2.10.21</p> <p>ISO 13485 Certificate validity: 07-11-2025</p>	<p>Shelf life: 05 years</p>	
230.	<p>Applicant: M/s G MED (PVT.) LIMITED. House No 218 B2 Block Johar Town Lahore</p> <p>(ELI- 00914)</p> <p>Track ID: Q6A-UQ9-GG74 Dated: <u>25-02-2023</u> Fee Challan No.: <u>02166154221</u> PKR: 5000/- Dated: <u>7-03-2023</u></p>	<p>(Legal Manufacturer) Name De Soutter Medical UK. Manufacturer Address: Halton Brook Business Park, Weston Road, Aston Clinton, HP22 5WF, United Kingdom.</p> <p>LOA Validity: 5-09-2027</p> <p>ISO 13485 Certificate validity: 11-08-2026</p>	<p>Brand Name Plaster Cutter. Models: Plaster Cutter with Accessories & Kits Model: CC7 CleanCast with Extraction, CC8 CleanCast with Extraction, CC4 CleanCast with Extractor, CSB-100 CleanCast, CSP-201</p> <p>Class: A</p> <p>Shelf life: 05 years</p>	<p>Approved subject to submission of valid FSC of country of origin</p>
231.	<p>Name: Fresenius Medical Care Pakistan Pvt. Ltd</p> <p>Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore</p> <p>Warehouse Address: 1. Al-Madina Warehouse, 28-Km, Multan Road, Lahore</p> <p>2. Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi</p>	<p>Legal Manufacturer: Name: Nipro Corporation</p> <p>Address: 3-26, Senriokashinmachi, Settsu, Osaka, 566-8510, JAPAN</p> <p>Manufacturing Site: Name: Nipro (Thailand) Corporation Limited Address: 10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayutthaya 13110 THAILAND</p>	<p>Brand Name: Fistula Needle</p> <p>Class B</p> <p>Shelf Life: 05 Years after the date of sterilization</p> <p>Codes/Sizes: 14GA-R25L-R (F00012655) 15GA-R25L-R (F00012656) 16GA-R25L-R (F00012657) 17GA-R25L-R (F00012658) 14GV-R25L-R (F00012665) 15GV-R25L-R (F00012666) 16GV-R25L-R (F00012667) 17GV-R25L-R (F00012668)</p>	<p>Deferred for the submission of DRAP R&I evidence of application, fee, FSC of country of origion and CE or FSC of RRA</p>
232.	<p>Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247</p>	<p>Legal Manufacturer: Magnamed Tenologia Médica S/A. Rua Santa Monica 801/831, Cotia - São Paulo Brazil</p>	<p>ICU Ventilator FLEXIMAG MAX 300 LUNG VENTILATOR NEONATE TO ADULT</p> <p>Class – C</p> <p>Shelf Life: Three Years</p>	<p>Deferred for the submission of valid CE (FQA) and Design qualification or FSC of RRA or WHO PQ</p> <p>The firm will also submit clarification</p>

	R & I submission Date: 03.06.2024	FSC Validity (11.11.2029) Brazil ISO Valid Till (27.12.2025) EC Valid Till (29.11.2022) LOA Valid Till (03.02.2028)	Codes/Sizes (mention as pet FSC)	for submitting multiple models and submit brand name
233.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I submission Date: 03.06.2024	<u>Legal Manufacturer:</u> Magnamed Tenologia Médica S/A. Rua Santa Monica 801/831, Cotia - São Paulo Brazil FSC Validity (11.11.2029) Brazil ISO Valid Till (27.12.2025) EC Valid Till (29.11.2022) LOA Valid Till (03.02.2028)	Lungs Ventilator OXYMAG EMERGENCY AND TRANSPORT VENTILATOR Class – C Shelf Life: Five years Codes/Sizes (mention as pet FSC)	Deferred for the submission of valid CE (FQA) and Design qualification or FSC of RRA or WHO PQ The firm will also submit clarification for submitting multiple models and submit brand name
234.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I submission Date: 03.06.2024	MEDIANA.CO.LTD 132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea FSC Validity (14.09.2023) Korea ISO Valid Till (29.10.2025) EC Valid Till (05.11.2023) LOA Valid Till (12.09.2028)	AUTOMATED EXTERNAL DEFIBRILLATOR HEART ON A-16-DS Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	Deferred for the submission of FSC of country of origin, valid CE (FQA) and Design qualification or FSC of RRA or WHO PQ The firm will also submit brand name
235.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I submission Date: 03.06.2024	MEDIANA.CO.LTD 132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea FSC Validity (14.09.2023) Korea ISO Valid Till (29.10.2025) EC Valid Till (05.11.2023) LOA Valid Till (12.09.2028)	DEFIBILLATOR / MONITOR D100 Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	Deferred for the submission of FSC of country of origin, valid CE (FQA) and Design qualification or FSC of RRA or WHO PQ The firm will also submit brand name
236.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I submission Date: 03.06.2024	ELLTEC JAPAN Shirakawa No. 6 Bldg., 18-5, Nishiki 2-chome, Naka-ku Nagoya, Japan FSC Validity Japan ISO Valid Till (14.12.2021)	BLOOD/INFUSION WARMER ANIMEC AM 301-4AF AM 301-5AF Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	Approved both models subject to submission of valid CE (Full Quality Assurance certificate). For BLOOD/INFUSION WARMER ANIMEC AM 301-5AF The firm will submit separate fee as per

		EC Valid Till (18.12.2020) LOA Valid Till (28.06.2025)		revised SRO.
237.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I Submission Date: 27.01.2023	XUZHOU YONGKANG ELECTRONIC SCIENCE TECHNOLOGY CO. LTD China FSC Validity (13.03.2023) China ISO Valid Till (29.04.2022) EC Valid Till LOA Valid Till (05.07.2025)	MULTIPARAMETER PATIENT MONITER YK 8000C Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	
238.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI-00247 R & I Submission Date: 24.11.2022	MA. EL “SIEM. SRI” Via Veggioletta, 16/C – IT29121 – Piacenza – Italy FSC Validity (13.05.2022) Italy ISO Valid Till (11.03.2024) EC Valid Till (06.05.2023) LOA Valid Till (15.03.2022)	EMERGENCY AND TRANSPORT LUNG VENTILTOR BA -2001 Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	Deferred for the submission of valid LoA, FSC of country of origion or CE (FQA)
239.	M/s. Uniprom Healthcare ELI-00286 Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi	M/s. Anhui Putian Plastic Industry Co., Ltd Address : East Batian Street, Datong Town,Tianchang, Anhui Province, China Contact : +865507090878 Fax: +865507314458 CFS Validity: 10 th April 2025 LOA Validity: 23 rd February 2025 Valid ISO Fee 6000/-	Brand Name: UniSheet Generic Name: Sterilization Crepe Paper Class A Shelf Life: 5 years Sizes: 30 x 30 cm 50 x 50 cm 60 x 60 cm 75 x 75 cm 90 x 90 cm 100 x 100 cm 120 x 120 cm	Approved
240.	M/s. Uniprom Healthcare ELI-00286 Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi	M/s. Wuhan Huawei Technology Co., Ltd. Office: Address : Room 808-810, 8 th Floor, Unite I,C1 Building, The Eastern Shopping Park, Spaceflight Star Town, Two, Jiang’an District, 430012, Wuhan, Hubei, China	Brand Name: HUAWEI PU INCISE DRAPE Generic Name: Medical Surgical Incision Dressing Class A Shelf Life: 3 years	Approved

		<p>Factory B-F-11-3, Huazhong International Industrial Park, Yangluo Port, 430415, Wuhan Hubei China</p> <p>Tel: +86-27-88868926 Fax: +86-27-88876095</p> <p>FSC issue date 29.03.2024 LOA Validity: 13th July 2026</p> <p>Fee 6000/-</p>	<p>Sizes: 10cm x 14cm 15cm x 28cm 30cm x 28cm 28cm x 45cm 45cm x 55cm 84 cm x 56cm</p>	
241.	<p>M/s. Uniprom Healthcare ELI-00286 Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi</p>	<p>M/s. Planet (Anhui) Medical Products Co., Ltd. Address : No.2066 West Jianshe Road, Hi-tech Zone 239300 Chuzhou City, Anhui China] Tel:0086 180 1989 8800 Fax:0086-550-7715866 COFS Validity:8th April 2026 LOA Validity: 31st March 2029 Fee 6000/-</p>	<p>Brand Name: Nichi Tape Generic Name: Medical Tapes Class A Shelf Life: 3 years Sizes: 12.5 mm x 4.5 m 25 mm x 4.5 m 50 mm x 4.5 m 75 mm x 4.5 m</p>	Approved
242.	<p>M/s. Uniprom Healthcare ELI-00286 Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi</p>	<p>M/s. Nurel Medikal Sanayi ve Ticaret A.S. Address : Demirtaş Sakarya Mahallesi, Karanfil Sok. 4/B, 16245 Osmangazi / Bursa, Turkey FSC Validity:29th March 2025 LOA Validity: 30th June 2025 Fee 5000/-</p>	<p>Brand Name: EUROSET Generic Name: (Disposable Surgical Drape Pack Sterile). Class A Shelf Life: 5 years</p>	Approved
243.	<p>M/s. Uniprom Healthcare ELI-00286 Address: L-151, 2nd Floor, 13-G, Sehba Akhtar Road, Gulshan e Iqbal, Karachi</p>	<p>M/s. Nurel Medikal Sanayi ve Ticaret A.S. Address : Demirtaş Sakarya Mahallesi, Karanfil Sok. 4/B, 16245 Osmangazi / Bursa, Turkey FSC Validity: 29th March 2025 LOA Validity: 30th June 2025 Fee 5000</p>	<p>Brand Name: EUROSET Generic Name : Disposable Surgical Gown Shelf Life : 5 years Class : Class A Sizes : Disposable Surgical Gown (Sterile) Sizes: S, M, L,XL, XXL, Disposable Standard Surgical Gown Sizes: S, M, L,XL, XXL, XL+10 cm long Codes 0600,0601,0602,0603 0604,0605</p>	Approved

			0200,0201,0202,0203, 0204,0205,0206,0207	
244.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA Validity: 14/07/2026 LOA Validity: 12.05.2029	Brand Name; COMFORT CARE FIRST AID BANDAGE Generic Name; FIRST AID BANDAGE SCHEDULE-E Class A Shelf Life: 05 years	Approved
245.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA Validity: 14/07/2026 LOA Validity: 12.05.2029	Brand Name; COMFORT CARE WOUND DRESSING Generic Name; WOUND DRESSING SCHEDULE-E Class A Shelf Life: 05 years Sizes: 9*15/9*25/9*30 10*10	Approved
246.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA Validity: 14/07/2026 LOA Validity: 12.05.2029 Fee 5000/-	Brand Name; COMFORT CARE SURGICAL TAPE Generic Name; SURGICAL TAPE Class A Shelf Life: 05 years Sizes: 1.25cm/2.5cm/ 5cm/7.5cm/10cm	Approved
247.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA Validity: 14/07/2026 LOA Validity: 12.05.2029	Brand Name; COMFORT CARE ZINC OXIDE PLASTER Generic Name; ZINC OXIDE PLASTER Class A Shelf Life: 05 years Sizes: 2.5cm/5.0cm/7.5cm/ 10cm	Approved
248.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA	Brand Name; COMFORT CARE CORN PLASTER Generic Name; CORN PLASTER Class A Shelf Life: 05 years	Approved

		Validity: 14/07/2026 LOA Validity: 16/11/2027	Fee 5000/-	
249.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 Submission 19/12/2022 Fee 5000/-	Legal Manufacturer: M/S. Zhejiang Bangli Medical Products Co., Ltd. ADD: No.118 Yuegui South Road, New Western Area, Yongkang City, Zhejiang Province, China. FSC: CHINA Validity: 14/07/2026 LOA Validity: 16/11/2027	Brand Name; COMFORT CARE COOLING GEL PATCH Generic Name; COOLING GEL PATCH Class A Shelf Life: 05 years	Approved
250.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 19/12/2022	Legal Manufacturer: JIANGSU SHUANGSHENG MEDICAL APPLIANCE CO., LTD No. 12, Dandong industrial zone, Lingkou town, Danyang city, Jiangsu province, China FSC: CHINA Validity: 26.05.2025 LOA: Validity: issued in 2022 and validity not mentioned written until cancellation by al madina ISO 13485: ISSUANCE DATE: 28/06/2023 EXPIRY DATE: 27/06/2026 EC Certificate: ISSUANCE DATE: 01/07/2021 EXPIRY DATE: RENEWAL PENDING	Brand Name; COMFORT CARE NEBULIZER Generic Name; NEBULIZER Class B Shelf Life: 05 years Fee 25000/-	Approved
251.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 19/12/2022	Legal Manufacturer: JIANGSU SHUANGSHENG MEDICAL APPLIANCE CO., LTD No. 12, Dandong industrial zone, Lingkou town, Danyang city, Jiangsu province, China FSC: CHINA Validity: 26.05.2025 LOA: Validity: issued in 2022 and validity not mentioned written until cancellation by al madina ISO 13485: ISSUANCE DATE: 28/06/2023 EXPIRY DATE: 27/06/2026	Brand Name; COMFORT CARE OXYGEN CONCENTRATOR Generic Name; OXYGEN CONCENTRATOR Class B Shelf Life: 05 years Fee 25000/-	Approved subject to submission of valid CE
252.	M/s. AL-MADINA INTERNATIONAL CO.	Legal Manufacturer: JIANGSU SHUANGSHENG	Brand Name; COMFORT CARE ANTI DECUBITUS	Approved

	Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 28/02/2020	MEDICAL APPLIANCE CO., LTD No. 12, Dandong industrial zone, Lingkou town, Danyang city, Jiangsu province, China FSC: CHINA Validity: 26/05/2025 LOA: Validity: not mentioned ISO 13485: ISSUANCE DATE: 28/06/2023 EXPIRY DATE: 27/06/2026	MATTRESS Generic Name; ANTI DECUBITUS MATTRESS Class A Shelf Life: 05 years Sizes: SF-TA18、 SF-TA22、 SFB01、 SF-C01	
253.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 19/12/2022	Legal Manufacturer: JIANGSU SHUANGSHENG MEDICAL APPLIANCE CO., LTD No. 12, Dandong industrial zone, Lingkou town, Danyang city, Jiangsu province, China FSC: CHINA Validity: 26.05.2025 Validity: issued in 2022 and validity not mentioned written until cancellation by al madina ISO 13485: ISSUANCE DATE: 28/06/2023 EXPIRY DATE: 27/06/2026	Brand Name; COMFORT CARE PORTABLE PHLEGM SUCTION UNIT Generic Name; PORTABLE PHLEGM SUCTION UNIT Class B Shelf Life: 05 years Fee 25000/-	Approved subject to submission of the CE certificate
254.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 08/01/2025	Legal Manufacturer: Shanghai Zhichen Medical Technology Co., Ltd Floor 1, Building 16, No. 686, Nanfeng Road, Fengxian District, Shanghai, China FSC: CHINA Validity: 12.12.02025 LOA Validity: 2.10.2029	Brand Name; *GREEN* ECG Electrode Generic Name; ECG Electrode Class A Shelf Life: 05 years SIZE: ADULT/PAEDS Fee 5000/-	Approved
255.	M/s. AL-MADINA INTERNATIONAL CO. Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI:00661 R&I: 08/01/2025 Fee 31000/-	M/S. SHANGHAI KINMED IMPORT & EXPORT CO., LTD ADD: SUIT L, 12TH FLOOR, NO.588 YINGKOU ROAD, SHANGHAI, CHINA Tel:+86 21 61172171 Fax:+86 21 61172173 LOA: Validity: 31/12/2030 FSC: CHINA 20/12/2025 Issued by the ISO 13485: ISSUANCE	COMFORT CARE SUCTION CONNECTING TUBE WITH YANKUER HANDLE CLASS: B Shelf life 5 years	Approved subject to the submission of CE certificate
256.	Aftab Life Care Impex 1st floor Al-Falah Chambers	Legal Manufacturer: M/s Galemed Corporation	Brand Name: GaleMed HME	Approved subject to clarification of Two

	<p>Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024</p> <p>Fee Slip No: 883369835526 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p>87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 15-08-2025</p> <p>FSC:FSC of Reference Country</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>GaleMed Filter</p> <p>Generic Name: HME& Filter / Bacterial Filter</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AH0041/39012 -HMEF w/Luer, 22F/15M, 22/15mm</p> <p>AF0020/39016 -Filter, 22F/15M, 22M/15F w/Luer</p>	<p>different codes in Taiwan and Netherlands</p>
257.	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024</p> <p>Fee Slip No:509711691818 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p><u>Legal Manufacturer:</u> <u>Galemed Corporation</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 18-10-2025</p> <p>FSC:FSC of Reference Country</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>Brand Name: GaleMed *EVA Circuit *Breathing Bag</p> <p>Generic Name: Ventilator Circuit and accessories</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AB0264-EVA Circuit, Adult, 150cm</p> <p>AB0200-EVA Catheter mount, 15cm w/Luer, 15M</p> <p>AB0119-Breathing Bag, 0.5L, Latex Free</p> <p>AB0120-Breathing Bag, 1L, Latex Free</p> <p>AB0121-Breathing Bag, 2L, Latex Free</p>	<p>Deferred for Clarification of the brand name as per FSC. Clarify the family / system as per the MDR 2017 and clarify that AB0200-EVA Catheter mount, 15cm w/Luer, 15M not in reference country FSC</p>
258.	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad</p>	<p><u>Legal Manufacturer:</u> <u>Galemed Corporation</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan</p>	<p>Brand Name: GaleMed Bubble CPAP System</p> <p>Generic Name:</p>	<p>Approved</p>

	<p>Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024</p> <p>Fee Slip No: 28087388 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p>FSC:Country of Origin Taiwan Validity: 18-01-2027</p> <p>FSC:FSC of Reference Country Netherlands</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>nCPAP Cannula circuit and accessory</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AN0074-nCPAP Circuit Set</p> <p>AN0020-nCannula, #0 w/nBonnet</p> <p>AN0021-nCannula, #1 w/nBonnet</p> <p>AN0022-nCannula, #2 w/nBonnet</p> <p>AN0023-nCannula, #3 w/nBonnet</p> <p>AN0018/BC01-Bubble PAP Valve</p> <p>AN0066/BC21-Adj PLS Valve, 2-10cmH2O, 22F</p> <p>AN0019/ BC22-PLS Valve, 10cmH2O, 22F</p>	
259.	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024</p> <p>Fee Slip No: 4394670834 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p>Legal Manufacturer: <u>M/s Galemed Corporation</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 11-08-2025</p> <p>FSC:FSC of Reference Country</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>Brand Name: GaleMed Bubble Humidifier</p> <p>Generic Name: Oxygen Therapy / Humidifier</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AH0027/3402-BH-3 Bubble Humidifier</p> <p>AH0030/3404 -BH-1 Bubble Humidifier, 4PSI</p>	<p>Approved subject to clarification of the two different codes in Taiwan and Netherlands</p>
260.		<p>Legal Manufacturer:</p>	<p>Brand Name: GaleMed</p>	<p>Approved</p>

	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024 Fee Slip No: 45336418073 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p><u>M/s Galemed Corporation</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 12-10-2025</p> <p>FSC:FSC of Reference Country Netherlands</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>DispoBag (Disposable Manual Resuscitator)</p> <p>Generic Name: Resuscitator kit and Accessory</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AR0022/2318 - Child w/Pop-Off, Mask</p> <p>AR0079/2328-Infant w/Pop-Off, Mask</p> <p>AR0081 Adult w/Pop-Off, Mask</p>	
261.	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024 Fee Slip No: 97688510463 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p><u>Legal Manufacturer:</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 17-05-2025 /12-09-2026</p> <p>FSC:FSC of Reference Country</p> <p>Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>Brand Name: GaleMed *nAPV Circuit *Hyperinflation Kit</p> <p>Generic Name: Emergency Care/Breathing Circuit</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any)</p> <p>AN0028-nAPV Circuit</p> <p>AN0029-nAPV Circuit w/Pressure Port</p> <p>AB0157-Hyperinflation circuit w/latex</p>	Approved
262.	<p>Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024 Fee Slip</p>	<p><u>Legal Manufacturer:</u> <u>M/s Galemed Corporation</u> 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan</p> <p>FSC:Country of Origin Taiwan Validity: 11-08-2025</p> <p>FSC:FSC of Reference Country Netherlands</p>	<p>Brand Name: GaleMed Nebulizer kit and Accessory</p> <p>Generic Name: Aerosol Therapy</p> <p>Class: B</p> <p>Shelf Life: Three years</p>	Approved

	No: 6738499737 PKR: 25000/- Fee submitted Dated: 16-05-2024	Validity: 08-05-2028 LOA Validity: 17-01-2027 ISO 13485 Validity: 05-09-2026 EC Certificate Validity: 08-05-2028	Codes / Sizes (if any) AH0031/3405-LVN Nebulizer, K Resin AD0044/3558-Neb.Easy Nebulizer Kit AD0049/3564-Neb.Easy AM-1 Mask, Adult w/Tube AD0051/3565-Neb.Easy AM-1 Mask, Child w/Tube AD0053/3566-Neb.Easy AM-1 Mask, Infant w/Tube	
263.	Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344 ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024 (R&I)Dated:29-05-2024 Fee Slip No: 9425394025 PKR: 25000/- Fee submitted Dated: 16-05-2024	Legal Manufacturer: M/s Galemed Corporation 87, Li-gong 2nd Road, Wu-Jia, I- Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618 FSC:Country of Origin Taiwan Validity: 25-05-2025 FSC:FSC of Reference Country Validity: 08-05-2028 LOA Validity: 17-01-2027 ISO 13485 Validity: 05-09-2026 EC Certificate Validity: 08-05-2028	Brand Name: GaleMed OM-2 HiO2 Mask Generic Name: Oxygen Therapy/ Non rebreathing mask set (non sterile) Class: B Shelf Life: Three years Codes / Sizes (if any) AO0093-OM-2 HiO2 Mask, Adult AO0094-OM-2 HiO2 Mask, Child w/res	Approved
264.	Aftab Life Care Impex 1st floor Al-Falah ChambersTilakRoad Hyderabad Tel: 022-3642787 Cellno:0321-2422344 ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024 (R&I)Dated:29-05-2024 Fee Slip No: 8262725107 PKR: 25000/-	Legal Manufacturer: M/s Galemed Corporation 87, Li-gong 2nd Road, Wu-Jia, I- Lan 268, Taiwan FSC:Country of Origin Taiwan Validity: 17-07-2025 FSC:FSC of Reference Country Netherlands Validity: 08-05-2028 LOA Validity: 17-01-2027 ISO 13485 Validity: 05-09-2026	Brand Name: GaleMed Oxygen Mask Generic Name: Oxygen therapy/Mask and accessories Class: B Shelf Life: Three years Codes / Sizes (if any) AO0085-OM-2 Mask, Child w/Tubing AO0086-OM-2 Mask, Adult AO0104-OM-4 Trachea Mask, Child w/Tubing	Approved

	Fee submitted Dated: 16-05-2024	EC Certificate Validity: 08-05-2028	AO0105-OM-4 Trachea Mask, Adult w/Tubing	
265.	Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344 ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024 (R&I)Dated:29-05-2024 Fee Slip No: 08791646 PKR: 25000/- Fee submitted Dated: 16-05-2024	Legal Manufacturer: 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618 FSC:Country of Origin Taiwan Validity: 27-07-2025 FSC:FSC of Reference Country Validity: 08-05-2028 LOA Validity: 17-01-2027 ISO 13485 Validity: 05-09-2026 EC Certificate Validity: 08-05-2028	Brand Name: GaleMed Single Limb Circuit, Adult and PEEP Valves Generic Name: Ventilation Circuit,/ Valves Class: B Shelf Life: Three years Codes / Sizes (if any) AV0038/2421 -PEEP Valve, 5~20cmH2O, 22F AB0128/71058 -Single Limb Circuit, Adult, 150cm	Approved subject to the clarification of the two different codes in Taiwan and Netherlands FSC
266.	Aftab Life Care Impex 1st floor Al-Falah Chambers Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344 ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024 (R&I)Dated:29-05-2024 Fee Slip No: 22017843 PKR: 25000/- Fee submitted Dated: 16-05-2024	Legal Manufacturer: M/s Galemed Corporation 87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618 FSC:Country of Origin Taiwan Validity: 24-04-2025 FSC:FSC of Reference Country Validity: 08-05-2028 LOA Validity: 17-01-2027 ISO 13485 Validity: 05-09-2026 EC Certificate Validity: 08-05-2028	Brand Name: GaleMed Air-Soft Mask Generic Name: Mask / Anesthetic gas mask (non sterile) Class: B Shelf Life: Three years Codes / Sizes (if any) XYZ: AM0026- Airsoft Mask, #0 w/Valve AM0027-Airsoft Mask, #1 w/Valve AM0028-Airsoft Mask, #2 w/Valve AM0029-Airsoft Mask, #3 w/Valve AM0030-Airsoft Mask, #4 w/Valve AM0031-Airsoft Mask, #5 w/Valve	Approved
267.	Aftab Life Care Impex 1st floor Al-Falah Chambers	Legal Manufacturer: M/s Galemed Corporation	Brand Name: GaleMed CPAP Full Face	Approved

	<p>Tilak Road Hyderabad Tel: 022-3642787 Cellno:0321-2422344</p> <p>ELI-000357 IssueDate:27th Feb,2019 26th Feb,2024</p> <p>(R&I)Dated:29-05-2024</p> <p>Fee Slip No: 23737185461 PKR: 25000/-</p> <p>Fee submitted Dated: 16-05-2024</p>	<p>87, Li-gong 2nd Road, Wu-Jia, I-Lan 268, Taiwan www.galemed.com Tel: + +886 (0)3 9908-618</p> <p>FSC:Country of Origin Taiwan Validity: 08-03-2029</p> <p>FSC:FSC of Reference Country Validity:08-05-2028</p> <p>LOA Validity: 17-01-2027</p> <p>ISO 13485 Validity:05-09-2026</p> <p>EC Certificate Validity:08-05-2028</p>	<p>Mask & Circuit NIV Mask</p> <p>Generic Name: Non invasive ventilation (NIV) Mask/CPAP Mask and accessory</p> <p>Class: B</p> <p>Shelf Life: Three years</p> <p>Codes / Sizes (if any) AM0120-CPAP Face Mask Set w/Hose,L</p> <p>AM0121-CPAP Face Mask Set w/Hose M</p> <p>AM0122-CPAP Face Mask Set w/HoseS</p> <p>AM0076-NIV Mask w/port, L</p> <p>AM0077-NIV Mask w/port, M</p> <p>AM0078-NIV Mask w/port,S</p> <p>AM0057-CPAP-SL Mask, L</p> <p>AM0058-CPAP-SL Mask,M</p>	
268.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p>	<p>Brand Name: BH-40P Automated Hematology Analyzer (Generic name): Automated Hematology Analyzer</p> <p>Class: A</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes: BH-40P</p>	Approved

		<p>ISO 13485 Validity: 19-07-2024</p>		
269.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Brand Name: BH-70P Automated Hematology Analyzer (Generic name): Automated Hematology Analyzer</p> <p>Class: A</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes: BH-70P</p>	Approved
270.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Brand Name: URIT Control Material for Hematology Analyzer (Generic name): Control Material for URIT Automated Hematology Analyzer.</p> <p>Class: A</p> <p>Shelf Life:</p> <p>Codes/Sizes: URIT QC 11</p>	Approved

271.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Brand Name: URIT Detergent (Generic name): Detergent for URIT Automated Hematology Analyzer.</p> <p>Class: A</p> <p>Shelf Life: 24 months</p> <p>Codes/Sizes: URIT D46</p>	Approved
272.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Brand Name: URIT Diluent (Generic name): Diluent for URIT Automated Hematology Analyzer.</p> <p>Class: A</p> <p>Shelf Life: 24 months</p> <p>Codes/Sizes: URIT D31</p>	Approved
273.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B,</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd.</p>	<p>Brand Name: URIT Lytic Reagent (Generic name): Lytic</p>	Approved

	<p>Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Reagent for URIT Automated Hematology Analyzer.</p> <p>Class: A</p> <p>Shelf Life: 24 months</p> <p>Codes/Sizes: URIT L21</p>	
274.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p> <p>R&I Dated: 23-11-202.</p>	<p>Legal Manufacturer M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>Manufacturing Site M/s. URIT Medical Electronic Co., Ltd. No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.</p> <p>LOA Validity: 20.02.2028</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Germany Validity: 24.04.2028</p> <p>ISO 13485 Validity: 19-07-2024</p>	<p>Brand Name: URIT Probe Cleaner</p> <p>(Generic name): Cleaner for URIT Automated Hematology Analyzer.</p> <p>Class: A</p> <p>Shelf Life: 24 months</p> <p>Codes/Sizes: URIT D43</p>	Approved
275.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228)</p>	<p>Legal Manufacturer M/s. HORIBA ABX SAS. Parc Euromedecine, Rue du Caducee, BP 7290, 34184 Montpellier Cedex 4,</p>	<p>Brand Name: Hematology Reagents</p> <p>(Generic name): Reagents for Hematology Analyzer</p> <p>Class: A</p>	Approved

	<p>R&I Dated: 02-07-2021.</p>	<p>France.</p> <p>Manufacturing Site M/s. HORIBA ABX SAS. Parc Euromedecine, Rue du Caducee, BP 7290, 34184 Montpellier Cedex 4, France.</p> <p>LOA Validity: 13.11.2025</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: France Validity: 04.11.2025</p> <p>ISO 13485 Validity: 10-09-2027</p>	<p>Shelf Life:</p> <p>ABX Basolyse 5L = 12 months ABX Basolyse II 1L = 12 months ABX Cleaner 1L = 12 months ABX Diluent 10L = 12 months ABX Diluent 20L = 12 months ABX Eosinofix 1L = 9 months ABX Fluocyte 0.5L = 6 months ABX Lysebio 0.4L = 12 months ABX Lysebio 1L = 12 months ABX Miniclean 1L = 12 months ABX Minidil LMG 10L = 18 months ABX Minidil LMG 20L = 18 months ABX Minilyse LMG 1L = 18 months ABX Minoclair 0.5L = 12 months Minilysebio 0.4L = 12 months Nucediff 1L = 9 months Whitediff 1L = 12 months</p> <p>Codes/Sizes:</p> <p>ABX Basolyse 5L = 0204050 ABX Basolyse II 1L = 0906003 ABX Cleaner 1L = 0903010 ABX Diluent 10L = 0901010 ABX Diluent 20L = 0901020 ABX Eosinofix 1L = 0206010 ABX Fluocyte 0.5L = 0904011 ABX Lysebio 0.4L = 0906013 ABX Lysebio 1L = 0906012 ABX Miniclean 1L = 0403010 ABX Minidil LMG 10L = 0802010 ABX Minidil LMG 20L = 0802020 ABX Minilyse LMG 1L = 0702010 ABX Minoclair 0.5L = 0401005 Minilysebio 0.4L = 0906020</p>	
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276.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 06-02-2025.	Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China. Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China. LOA Validity: 30.06.2029 FSC: Country of Origin: Validity: N/A FSC: Reference country: Spain Validity: 21.06.2028 ISO 13485 Validity: 04-12-2026	Brand Name: Electrolyte Analyzer (Generic name): Ion-Selective Electrode (ISE) technology analyzer Class: A Shelf Life: 5 years Codes/Sizes: IMS-972	Approved
277.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 06-02-2025.	Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China. Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China. LOA	Brand Name: Calibration Solution (Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method) Class: A Shelf Life: 2 years Codes/Sizes: Calibration Solution A: 350ml Bottle/Bag Calibration Solution B: 350ml Bottle/Bag	Approved

		<p>Validity: 30.06.2029</p> <p><u>FSC:</u> Country of Origin: Validity: N/A</p> <p><u>FSC:</u> Reference country: Spain Validity: 21.06.2028</p> <p><u>ISO 13485</u> Validity: 04-12-2026</p>		
278.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p><u>LOA</u> Validity: 30.06.2029</p> <p><u>FSC:</u> Country of Origin: Validity: N/A</p> <p><u>FSC:</u> Reference country: Spain Validity: 21.06.2028</p> <p><u>ISO 13485</u> Validity: 04-12-2026</p>	<p>Brand Name: Cleaning Solution</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: 110ml/bottle.</p>	Approved
279.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site</p>	<p>Brand Name: Electrode Internal Solution</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p>	Approved

		<p>M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>LOA Validity: 30.06.2029</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Spain Validity: 21.06.2028</p> <p>ISO 13485 Validity: 04-12-2026</p>	<p>Shelf Life: 2 years</p> <p>Codes/Sizes: 3ml/bottle.</p>	
280.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>LOA Validity: 30.06.2029</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Spain Validity: 21.06.2028</p> <p>ISO 13485 Validity: 04-12-2026</p>	<p>Brand Name: Electrode Washing Solution (Enzyme)</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: Protein Enzyme 25mg/bottle*5, Diluent 5ml/bottle*1, Dropper*1.</p>	Approved
281.	<p>M/s Reaction Scientific Private Limited.</p>	<p>Legal Manufacturer</p>	<p>Brand Name: Electrolyte Multiple</p>	Approved

	<p>337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 06-02-2025.</p>	<p>M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>LOA Validity: 30.06.2029</p> <p>FSC: Country of Origin: Validity: N/A</p> <p>FSC: Reference country: Spain Validity: 21.06.2028</p> <p>ISO 13485 Validity: 04-12-2026</p>	<p>Quality Control</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: Specification 1: R1: 5mL/bottlex1, R2: 5mL/bottlex1, R3: 5mL/bottlex1. Specification 2: R1: 5mL/bottlex2, R2: 5mL/bottlex2, R3: 5mL/bottlex2.</p>	
282.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>LOA Validity: 30.06.2029</p> <p>FSC: Country of Origin: Validity: N/A</p>	<p>Brand Name: QC Solution</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: QC Solution 1: 110ml/bottle, 5ml/bottle, 3ml/bottle, 1.7ml/bottle. QC Solution 2: 110ml/bottle, 5ml/bottle, 3ml/bottle, 1.7ml/bottle. QC Solution 3: 110ml/bottle, 5ml/bottle, 3ml/bottle.</p>	Approved

		<p><u>FSC:</u> Reference country: Spain Validity: 21.06.2028</p> <p><u>ISO 13485</u> Validity: 04-12-2026</p>		
283.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p><u>LOA</u> Validity: 30.06.2029</p> <p><u>FSC:</u> Country of Origin: Validity: N/A</p> <p><u>FSC:</u> Reference country: Spain Validity: 21.06.2028</p> <p><u>ISO 13485</u> Validity: 04-12-2026</p>	<p>Brand Name: Reference Electrode Internal Solution</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: 10ml/bottle.</p>	Approved
284.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 06-02-2025.</p>	<p>Legal Manufacturer M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p>Manufacturing Site M/s. Shenzhen Xilaiheng Medical Electronics Co., Ltd. (HORRON) 10/F, YiFangBuilding, No.315, ShuangMing Road, DongZhou</p>	<p>Brand Name: Activating Solution</p> <p>(Generic name): Reagents for Electrolyte Analyzer (Ion-Selective Electrode Method)</p> <p>Class: A</p> <p>Shelf Life: 2 years</p> <p>Codes/Sizes: 110ml/bottle.</p>	Approved

		<p>Community, GuangMing Street, GuangMing District, Shenzhen, China.</p> <p><u>LOA</u> Validity: 30.06.2029</p> <p><u>FSC:</u> Country of Origin: Validity: N/A</p> <p><u>FSC:</u> Reference country: Spain Validity: 21.06.2028</p> <p><u>ISO 13485</u> Validity: 04-12-2026</p>		
285.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p><u>LOA</u> Validity: 31.12.2026</p> <p><u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027</p> <p><u>ISO 13485</u> Validity: 11-03-2025</p>	<p>Brand Name: HumaStar 300SR</p> <p>(Generic name): Automated clinical chemistry system</p> <p>Class: A</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes: 16930</p>	Approved
286.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p>	<p>Brand Name: HumaStar 600</p> <p>(Generic name): Automated clinical chemistry system</p> <p>Class: A</p> <p>Shelf Life: N/A</p> <p>Codes/Sizes: 16660</p>	Approved

		<p><u>LOA</u> Validity: 31.12.2026</p> <p><u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027</p> <p><u>ISO 13485</u> Validity: 11-03-2025</p>		
287.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 25-02-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p><u>LOA</u> Validity: 31.12.2026</p> <p><u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027</p> <p><u>ISO 13485</u> Validity: 11-03-2025</p>	<p>Brand Name: HSRate-Control</p> <p>(Generic name): Erythrocyte Sedimentation Rate (ESR) Control</p> <p>Class: A</p> <p>Shelf Life: 7 months</p> <p>Codes/Sizes: 15024/40</p>	Approved
288.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p><u>LOA</u> Validity: 31.12.2026</p> <p><u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027</p>	<p>Brand Name: Special Wash Solution</p> <p>(Generic name): Reagents for Humastar 600/300SR</p> <p>Class: A</p> <p>Shelf Life: 24 months</p> <p>Codes/Sizes: 18974, 18974/2.</p>	Approved

		<u>ISO 13485</u> Validity: 11-03-2025		
289.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.	Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. <u>LOA</u> Validity: 31.12.2026 <u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027 <u>ISO 13485</u> Validity: 11-03-2025	Brand Name: Tip Cleaning Kit (Generic name): Needle Cleaning Kit for Humastar 600 Class: A Shelf Life: 24 months Codes/Sizes: 16663/25.	Approved
290.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.	Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. <u>LOA</u> Validity: 31.12.2026 <u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027 <u>ISO 13485</u> Validity: 11-03-2025	Brand Name: Wash Additive (Generic name): Washing additive for HumaStar Analyzers Class: A Shelf Life: 24 months Codes/Sizes: 18971	Approved
291.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B,	Legal Manufacturer	Brand Name: Diluent (Generic name): Reagents	Approved

	<p>Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>for Humastar 600/300SR</p> <p>Class: A</p> <p>Shelf Life: 18 months</p> <p>Codes/Sizes: 16663/10, 16663/11.</p>	
292.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>Brand Name: Cuvette Clean</p> <p>(Generic name): Cleaning Solution for Humastar 600/300SR</p> <p>Class: A</p> <p>Shelf Life: 36 months</p> <p>Codes/Sizes: 16663/20.</p>	Approved
293.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p>	<p>Brand Name: Clinical-Chemistry Electrolyte Electrode</p> <p>(Generic name): System Reagent for HumaStar 300SR and 600</p>	Approved

		<p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>FSC: Reference country: N/A</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>Class: A</p> <p>Shelf Life: 10120300 = 18 months 10120600 = 18 months</p> <p>Codes/Sizes: 10120300 = POTASSIUM liquiUV 10120600 = POTASSIUM liquiUV</p>	
294.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>Brand Name: Clinical-Chemistry Electrolyte Reagents</p> <p>(Generic name): System Reagent for HumaStar 300SR and 600</p> <p>Class: A</p> <p>Shelf Life: 10010300 = 24 months 10010600 = 24 months 10011300 = 24 months 10011600 = 24 months 10027300 = 36 months 10027600 = 36 months 10113300 = 18 months 10113600 = 18 months</p> <p>Codes/Sizes: 10010300 = Magnesium Liquicolor 10010600 = Magnesium Liquicolor 10011300 = Calcium Liquicolor 10011600 = Calcium Liquicolor 10027300 = Phosphorus Liquirapid 10027600 = Phosphorus Liquirapid 10113300 = Sodium Liquicolor 10113600 = Sodium Liquicolor</p>	Approved

295.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>Brand Name: Clinical Chemistry – Enzymes</p> <p>(Generic name): System Reagent for HumaStar 300SR and 600</p> <p>Class: A</p> <p>Shelf Life: 10053300 = 18 months 10053600 = 18 months 10660600 = 20 months 12006600 = 18 months 12007300 = 18 months 12009600 = 24 months 12014300 = 18 months 12014600 = 18 months 12015600 = 18 months 12021300 = 18 months 12021600 = 18 months 12022300 = 18 months 12022600 = 18 months 12023300 = 18 months 12023600 = 18 months 12027300 = 18 months 12027600 = 18 months 12028300 = 20 months 12028600 = 20 months 12117300 = 18 months 12117600 = 18 months 12118600 = 18 months 12290300 = 16 months 12290600 = 16 months</p> <p>Codes/Sizes: 10053300 = Creatinine (enzyme) liquicolor 10053600 = Creatinine (enzyme) liquicolor 10660600 = Acid Phosphatase 12006600 = Lipase liquicolor 12007300 = Cholinesterase liquicolor 12009600 = Pancreas-Amylase liquicolor 12014300 = LDH SCE mod. liquiUV 12014600 = LDH SCE mod. liquiUV 12015600 = CK-NAC liquiUV 12021300 = GOT (ASAT) IFCC mod. liquiUV 12021600 = GOT (ASAT) IFCC mod. liquiUV</p>	Approved
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			12022300 = GPT (ALAT) IFCC mod. liquiUV 12022600 = GPT (ALAT) IFCC mod. liquiUV 12023300 = gamma-GT (GGT) liquicolor 12023600 = gamma-GT (GGT) liquicolor 12027300 = Alkaline Phosphatase opt. liquicolor 12027600 = Alkaline Phosphatase opt. liquicolor 12028300 = alpha- AMYLASE liquicolor 12028600 = alpha- AMYLASE liquicolor 12117300 = Alkaline Phosphatase liquicolor, IFCC 12117600 = Alkaline Phosphatase liquicolor, IFCC 12118600 = CK-MB liquiUV 12290300 = IRON TPTZ liquicolor 12290600 = IRON TPTZ liquicolor	
296.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.	Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. LOA Validity: 31.12.2026 FSC: Country of Origin: Germany Validity: 27.02.2027 ISO 13485 Validity: 11-03-2025	Brand Name: Clinical Chemistry – Substrates (Generic name): System Reagent for HumaStar 300SR and 600 Class: A Shelf Life: 10028300 = 20 months 10028600 = 20 months 10052300 = 24 months 10052600 = 24 months 10084300 = 18 months 10084600 = 18 months 10094600 = 18 months 10260300 = 24 months 10260600 = 24 months 10521300 = 18 months 10521600 = 18 months 10560300 = 27 months 10560600 = 27 months 10694300 = 18 months 10694600 = 18 months 10724300 = 22 months 10724600 = 22 months 10741300 = 18 months 10741600 = 18 months 10742300 = 18 months 10742600 = 18 months 11120600 = 60 months	Approved

			<p>Codes/Sizes: 10028300 = CHOLESTEROL liquicolor 10028600 = CHOLESTEROL liquicolor 10052300 = auto- CREATININE liquicolor 10052600 = auto- CREATININE liquicolor 10084300 = HDL CHOLESTEROL liquicolor 10084600 = HDL CHOLESTEROL liquicolor 10094600 = LDL CHOLESTEROL liquicolor 10260300 = GLUCOSE liquicolor 10260600 = GLUCOSE liquicolor 10521300 = UREA liquiUV 10521600 = UREA liquiUV 10560300 = ALBUMIN liquicolor 10560600 = ALBUMIN liquicolor 10694300 = URIC ACID liquicolor plus 10694600 = URIC ACID liquicolor plus 10724300 = TRIGLYCERIDES liquicolor mono 10724600 = TRIGLYCERIDES liquicolor mono 10741300 = auto- BILIRUBIN-D liquicolor 10741600 = auto- BILIRUBIN-D liquicolor 10742300 = auto- BILIRUBIN-T liquicolor 10742600 = auto- BILIRUBIN-T liquicolor 11120600 = MICROALBUMIN</p>	
297.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21,</p>	<p>Brand Name: Immuno-Chemistry Complement Component (Generic name): System Reagent for HumaStar 300SR and 600 Class: A Shelf Life:</p>	Approved

		<p>65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>11110600 = 36 months 11113600 = 60 months</p> <p>Codes/Sizes: 11110600 = Complement C3 11113600 = Complement C4.</p>	
298.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC: Country of Origin: Germany Validity: 27.02.2027</p> <p>ISO 13485 Validity: 11-03-2025</p>	<p>Brand Name: Immuno-Chemistry Diabetes Assay (HbA1c)</p> <p>(Generic name): System Reagent for HumaStar 300SR and 600</p> <p>Class: A</p> <p>Shelf Life: 18 months</p> <p>Codes/Sizes: 10770600 = HbA1c liquidirect</p>	Approved
299.	<p>M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad.</p> <p>(ELI-00228)</p> <p>R&I Dated: 21-09-2022.</p>	<p>Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany.</p> <p>LOA Validity: 31.12.2026</p> <p>FSC:</p>	<p>Brand Name: Immuno-Chemistry Lipoproteins</p> <p>(Generic name): System Reagent for HumaStar 300SR and 600</p> <p>Class: A</p> <p>Shelf Life: 11101600 = 24 months 11102600 = 24 months 11105600 = 24 months</p> <p>Codes/Sizes: 11101600 = Apolipoprotein A1 11102600 = Apolipoprotein B</p>	Approved

		Country of Origin: Germany Validity: 27.02.2027 <u>FSC</u> <u>ISO 13485</u> Validity: 11-03-2025	11105600 = Lipoprotein (a).	
300.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.	Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. <u>LOA</u> Validity: 31.12.2026 <u>FSC:</u> Country of Origin: Germany Validity: 27.02.2027 <u>ISO 13485</u> Validity: 11-03-2025	Brand Name: Immuno-Chemistry Rheumatoid-Inflammatory Diseases Markers (Generic name): System Reagent for HumaStar 300SR and 600 Class: A Shelf Life: 11241300 = 18 months 11241600 = 18 months 11251300 = 24 months 11251600 = 24 months 11261300 = 24 months 11261600 = 24 months Codes/Sizes: 11241300 = CRP 11241600 = CRP 11251300 = anti-Sterptolysin-O 11251600 = anti-Sterptolysin-O 11261300 = Rheumatoid Factors 11261600 = Rheumatoid Factors	Approved
301.	M/s Reaction Scientific Private Limited. 337, Street No.17, Block-B, Sector B-17, Islamabad. (ELI-00228) R&I Dated: 21-09-2022.	Legal Manufacturer M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. Manufacturing Site M/s. HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany. <u>LOA</u> Validity: 31.12.2026 <u>FSC:</u>	Brand Name: Immuno-Chemistry Transport Proteins (Generic name): System Reagent for HumaStar 300SR and 600 Class: A Shelf Life: 10570300 = 24 months 10570600 = 24 months 10590300 = 24 months Codes/Sizes: 10570300 = TOTAL PROTEIN liquicolor 10570600 = TOTAL	Approved

		Country of Origin: Germany Validity: 27.02.2027 <u>ISO 13485</u> Validity: 11-03-2025	PROTEIN liquicolor 10590300 = URINARY TOTAL PROTEIN liquicolor.	
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