



No. 4-7/2022-MD (M-51)
Government of Pakistan
Ministry of National Health services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the, 30th November, 2022

Subject: DECISIONS OF MEDICAL DEVICE BOARD-ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT/LOCAL

The applications of following applicants were placed before Medical Device Board (MDB) in its 51st meeting held on 10th November, 2022 and Board deferred these applications being deficient of information/documents as specified in last column (V) of the Table below;

Sr.No.	Name & Address of Establishment	Manufacturer Details	Name of Medical Devices With Size	Decision
(I)	(II)	(III)	(IV)	(V)
1.	M/s Medica, House No. 188-1-B (First Floor) near Nursery area, Block 2, PECHS Karachi. (ELI-00237) 1259 Evaluator: AD-III	Legal Manufacturer: SaSan Saglik Malzemeleri uretim ve Pazarlama a.s. (Dagyaka Mah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye. (FSC Turkey issued on 09-03-2017 valid for 36 Months)	Sasan Neonatal Tubing Set Class-B Shelf Life: 3 Years. Codes: SD920302/A SD920302/B SD921302/A SD921302/B	Defferred Firm shall submit valid LOA
2.	Roche Pakistan Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi (ELI-00009) Evaluator: AD-VI	Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany FSC Germany Issuance Date (19-06-2016)	COBAS Elecsys HSV-2 IgG Test Kits Class-C Shelf Life: 02-years. Codes & Sizes as per FSC: 05572193190, 07027508190	Defferred. Firm shall submit differential fee of class C and original & valid FSC.
3.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi (ELI-00084) Evaluator: AD-VI -4394-	Legal Manufacturer & mfg. site: Ortho- Legal Manufacturer & mfg. site: Clinical Diagnostics, Inc. Felindre Meadows, Pencoed, Bridgend, CF35 5PZ, United Kingdom FSC: UK Valid Till: 08-07-2023.	ORTHO-CLINICAL Diagnostics, Inc. 1. ABD Confirmation (100 Pack) 2. ABD Confirmation RUMI (100 Pack) 3. BioVue A/B/A+B/D/CDE/CTL (400 Pack) 4. BioVue A/B/D/CTL/REV DIL (100 Pack) 5. BioVue C/E/SMC/SME/K/CTL (400 Pack) 6. BioVue C/E/SMC/SME/K/CTL (100 Pack) 7. BioVue Reverse Diluent (400 Pack) 8. BioVue SYS ABODD GRP Cassette (100 Pack) 9. BioVue SYS Newborn Cassette (100 Pack) Class-D Shelf life:08-months.	Defferred. Firm shall submit valid ISO 13485 and valid Agency Agreement.

4.	M/s Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e- Faisal, Karachi. (ELI-00347) Evaluator: AD-VI -1692-	Legal Manufacturer & mfg. site: Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Bershire, RG6 4UT, United Kingdom. (FSC Valid 07-03-2023)	LORNE Grouping Reagents for Group Reagents for rare blood Class C Shelf Life: 24 Months Sizes & Codes as Per FSC	Defferred. Firm shall submit valid ISO 13485 and valid Agency Agreement.
5.	UDL Distribution Pvt Ltd. I-D-13, Sector 30, Korangi Industrial Area Karachi (ELI-00073) Evaluator: AD-VI -2703-	Legal Manufacturer: Arrow International, Inc. Subsidiary of Teleflex Incorporated 2400 Bernville Road, Reading PA 19605 USA.	AUTOCAT2 Series Intra- Aortic Balloon Pump (IABP) Class-C. Shelf Life: N/A (Single -USE) Codes & Sizes as per FSC.	Deferred for provision of following documents: a) Firm shall submit original and valid Letter of Authorization, FSC, FQA, DoC and ISO 13485. b) Mention the shelf life or service life.
6.	Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi (ELI-00240) (Duplicate Dossier) Evaluator: AD-VI	Legal Manufacturer and mfg. site: Scientillence Sdn. Bhd. No. 65, Persiaran Selangor, Section 15, 40200, Shah Alam, Selangor Darul Ehsan, Malaysia.	IBP Hemodialyzer Class-C. Shelf Life: -----, Codes & Sizes as per FSC	Deferred for provision of original & valid FSC, ISO, LOA & Shelf life/ validation studies.
7.	M/s A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190. Evaluator: AD-VI -1536-	Legal Manufacturer C-4&5 Floor, 16, Deogyong- daero 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea FSC: Korea	STANDARD Q HIV /Syphilis Combo Test (Rapid Test Kit for HIV and Syphilis) Code: As per FSC Class-D Shelf Life: 24 months	Defferred. Firm shall submit differential fee for approval of subject device for identification of two different diseases that is HIV & Syphilis. The firm shall also submit valid ISO 13485, FQA and Design Examination Certificate.
8.	Sohail Corporation, Plot No. 7 Serai Quarters, WH-42, Techno City Mall Karachi (ELI-00676) Evaluator: AD-VI -1810-	Shandong Caremed Medical Products Co., Ltd. Yan Tai Industrial Park, DIngTao County (The East of Zhanqian Road Heze 274100 Shandong PR China FSC: China (copy) Valid Till: 17-02-2024.	ROYAL Auto disable Syringe Codes & Sizes: As per FSC. Class-B Shelf life: 05-years.	Deferred for provision of following documents: <ul style="list-style-type: none">• Original agency agreement.• Original and valid FSC of country of origin.• Full quality assurance system.• Production quality assurance.• Product quality assurance.
9.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi (ELI-00051) Evaluator: AD-VI -1702-	Legal Manufacturer: Huaian Helen Medical Instruments Co., Ltd. Group 3, Zhengtai Village, matou Town, Huaiyin Dostrect, Huain City, Jiangsu China. (FSC Issue 25-07-2020)	Disposable Blood Lancets, Sterile Class B Shelf Life: 5 Years Sizes & Codes as Per FSC	Deferred for provision of original and valid FSC of country of origin and any RRA.
10.	M/s Ahmad Care International, 2nd Flor, 7 Shahrah-e-Tajbagh, Main Market, Phase 1, Tajbagh	Legal Manufacaturer: M/s Shenzhen Antmed Co., Ltd, 18 Jinhui Avenue, Pingshan New District,	ANTMED (Contrast Media Injectors) Codes & Sizes: As per FSC.	Deferred The firm shall submit valid and original FSC of RRA or CE mark document or

	Housing Scheme, Lahore, Pakistan Evaluator: AD-VI -2734-	Shenzhen 518122 FSC: China Valid till: 13.03.2022	Class-C Shelf Life: 10-years	WHO PQ
11.	M/a Anwar & Sons, Apartment-10, Safari Villas-2 Commercial Complex, Bahria Town, Phase-7, Rawalpindi ELI:00017 Evaluator: AD-VI -2924-	Legal Manufacturer: M/s SUMI, SUMI sp. o z ograniczona odpowiedzialoscia sp. k. 05- 070 Sulejowek, No. 35 Drobiarska, str, Poland FSC: Poland Valid Till: 2020-04-02.	Tracheostomy tube Codes & Sizes: As per FSC Class-C Shelf Life: 05-years. Codes & Sizes: As per FSC.	Deferred for provision of brand name, FSC of country of origin and FSC of any SRA country.
12.	M/s Medicamp Internatinal, Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi ELI: 00200. Evaluator: AD-VI -1598-	Legal Manufacturer MMD Sp. ZO.O Grudizaazka 159A, 87-100, Torun Poland. FSC: Poland Date of Issue: 2020.06.05	MEDITAMP EXTRA (Absorbable Hemostat Oxidized Cellulose) Codes & Sizes: As per FSC Class-C Shelf Life: 2 years.	Deferred for provision of FSC of any reference country or CE marked documents/WHO PQ.
13.	M/s. Mian Scientific Corporation (Pvt) Ltd 534- Jinnah Colony Faisalabad ELI: 00442. Evaluator: AD-VI	Legal Manufacturer i-SENS Inc, 94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do 26365, Korea FSC: Korea Date of Issue: 29.05.2020	NIPRO premier Blood Glucose Test Strips. (Blood Glucose Test Strips) Class-C. Shelf Life: 24 month	Deferred for provision of FSC of any reference country or CE marked documents/WHO PQ.
14.	M/s. MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI: not issued. Evaluator: AD-VI -3294-	Legal Manufacturer: M/s Shenzhen Mindray Bio- Medical Electronics Co., Ltd, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. FSC: China Valid till: 12/04/2022	MINDRAY (Automated External Defibrillator)-DI Codes & Sizes: As per FSC Class-C Shelf Life: 10-years	Deferred. The firm shall submit original & valid FSC of RRA or CE document or WHO PQ.
15.	M/s Medicamp International Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah Rawalpindi, Pakistan ELI: 00200. Evaluator: AD-VI -1934-	Legal Manufacturer: •Kollsut International Inc. 1763 NE 162nd Street, North Miami Beach, FL 33162, USA •FOOSIN MEDICAL SUPPLIES Inc Ltd No. 20 Xingshan rd, Weihai Torch Hi-Tech Science Park, Shandong P.R China, 264210 FSC: FDA. U.S FOOD & DRUG Valid till: 09.03.2022.	RADIK TM (Sterilized Absorbable Polyglactin Acid 910 Suture) Codes & Sizes: As per FSC Class-D Shelf Life: 5 years	Deferred. Firm shall submit valid FSC, LOA and ISO 13485.
16.	Usmanco International 220, Block 3, DMCHS, S.Abdul Tawwab road	Bicakcilar Tibbi OsmanGazi Mahallesi Gazi Cad. 34522 Istanbul / Turkiye.	BCAT LV Cannula G-14, G-16, G-18, G-20, G-22 & G-24	Deferred. Firm shall submit valid FSC, LOA and ISO 13485.

	karachi Pakistan (ELI-00121) Evaluator: AD-VI	FSC Turkey Issued: 20-5-2020 Valid Till: 36 Months from date of Issue	Class B Shelf Life: 5 Years. Codes & Sizes as per FSC	
17.	Usmanco International 220, Block 3, DMCHS, S.Abdul Tawwab road karachi Pakistan (ELI-00121) Evaluator: AD-VI	Bicakcilar Global Tibbi Chazlarsanayi Gazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC Turkey valid 11-08- 2017)	BCAT2 I.V Cannula with injection port with stopper G-14, G-16, G-18, G-20, G-22 & G-24 Class B Shelf Life: 5 Years	Deferred. Firm shall submit valid FSC, LOA and ISO 13485.
18.	Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi (ELI-00170) Evaluator: AD-VI	Legal Manufacturer: Zibo Eastmed Healthcare Products Co. Ltd. No. 118 Huaguang Road, Zhangdian District Zibo 255000 Shandong, China.	New Golden Sterile Oxygen Mask Codes & Sizes as per FSC Class B Shelf Life: 5-Years	Deferred. Firm shall submit valid FSC, LOA and ISO 13485.
19.	Interex Company, 195, Block # 7/8, 2nd Floor, KMCHS, Justice Inamullah Road, near Hill Park Karachi 74800 (ELI-00249) Evaluator: AD-VI	Balton Sp. Z O.O. ul. Nowy Swiat 7/14, 00-696 Warszawa, Poland FSC: Poland Issued: 26-8-2020	"FLEBOGRIF" Set for Venous Insufficiency Treatment. Class B Shelf Life: 5 Years. Codes & Sizes as per FSC	Deferred. Firm shall submit valid FSC, LOA and ISO 13485.
20.	Sapphire International Room No. 901 & 903 9th Floor Uni center LI Chundrigar Road Karachi (ELI-00430) Evaluator: AD-VI	Legal Manufacturer: Beijing Demax Medical Technology Co. Ltd. A13-7 Jingshengnansi Street Tongzhou District 101102 Beijing Peoples Republic China, PRC. FSC China	INTRODUCER Sheath Kit Hydrphilic Vascular Catheter Introduction set, nonimplantable (en) Class: C Shelf Life: 2-Years Codes & Sizes as per FSC	Deferred for provision of valid FSC and FSC of any reference country or CE mark documents.
21.	JF International 4th Floor, 10-C, 6th sunset commercial Lane Phase 2 EXT DHA Karachi Pakistan (ELI-00246) Evaluator: AD-VI	CONTEC MEDICAL Systems., Ltd. No. 112 Qinhuang West Street, Economic & Technical Devolpment Zone, Qinhuangdao, 066004, Hebei Province China FSC: China Valid Till: 26-8-2020	CONTEC Dynamic ECG System. Class: C Shelf Life: 2-Years Codes & Sizes as per FSC	Deferred for provision of valid FSC, LOA, shef life studies, ISO 13485 and FSC of any reference country or CE mark documents.
22.	JF International 4th Floor, 10-C, 6th sunset commercial Lane Phase 2 EXT DHA Karachi Pakistan (ELI-00246) Evaluator: AD-VI	CONTEC MEDICAL Systems., Ltd. No. 112 Qinhuang West Street, Economic & Technical Devolpment Zone, Qinhuangdao, 066004, Hebei Province China FSC: China Valid Till: 26-8-2020	CONTEC Electrocardiograph ECG 1200G. Class: C Shelf Life: N/A Codes & Sizes as per FSC	Deferred for provision of valid FSC, LOA, shef life studies, ISO 13485 and FSC of any reference country or CE mark documents/WHO PQ.
23.	Sultansons 133, Kutchi Gali No. 1 Marriot road karachi ELI-00051 Evaluator: AD-VI	Legal Manufacturer: Fujian Bestway Medical Polymer Cooperation China 138 Guanpu Road, Fuzhou China.	CLASSIC IV Cannula Codes & Sizes as per FSC Class: B Shelf Life: 63929/7-5-2020	Deferred for provision of valid FSC, LOA, shef life studies, ISO 13485 and FSC of any reference country or CE mark documents/WHO PQ.
24.	Hospital supply Cooperation 42 Darul Aman Housing Society, Block 7 & 8 Karachi (ELI-00005)	Legal Manufacturer: Shanghai Kindly Enterprise Devolpment Group Co. Ltd. No. 658 GaoChao Road Shinaghai China	YMS Disposable Infusion Set. Class: B Shelf Life: 2-years Codes & Sizes as per FSC	Deferred for provision of valid FSC, LOA, shef life studies, ISO 13485 and FSC of any reference country or CE mark documents/WHO PQ.

	Evaluator: AD-VI			
25.	New Pakistan Traders., Office # 306/1, Trade Tower, New Challi Road Karachi (ELI-00161) Evaluator: AD-VI	Legal Manufacturer: Bonree Medical Co. Ltd. No. 4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, China	K & K Tracheal Tube Class: B Shelf Life: 2-years Codes & Sizes as per FSC	Deferred for provision of valid FSC, LOA, shelf life studies, ISO 13485 and FSC of any reference country or CE mark documents/WHO PQ.
26.	New Pakistan Traders., Office # 306/1, Trade Tower, New Challi Road Karachi (ELI-00161) Evaluator: AD-VI	Legal Manufacturer: Bonree Medical Co. Ltd. No. 4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, China	COMFORT Care Aerosol Masks. Tube Class: B Shelf Life: 2-years. Codes & Sizes as per FSC	Deferred for provision of valid FSC, LOA, shelf life studies, ISO 13485 and FSC of any reference country or CE mark documents /WHO PQ.
27.	Coral Pharmaceuticals, A- 85 SMCHS, Karachi (ELI-00065) Evaluator: AD-VI	Legal Manufacturer: Dynek Pty Ltd. 9 Circuit Drive, Hendon, SA 5014 Australia FSC: Australia Issued: 27-8-2018	BIOVEK Suture. Class: D Shelf Life: 03-Years 044805 / 21-11-2021	Deferred. Firm shall submit valid FSC, LOA, justifiable Shelf Life and ISO 13485.
28.	Ghani Brothers, 2nd Floor karimjee Building, Opposite Habib Bank Building, North Napier Road, Karachi (ELI-00870) Evaluator: AD-VI	Legal Manufacturer: Huaiyin Medical Instruments Co., Ltd Huaian China	VITAL SILK SUTURE 080466 / 19-4-2021 Class: C Shelf Life: 5-Years	Deferred for provision of valid FSC, LOA, justifiable shelf life studies, ISO 13485 and FSC of any reference country or CE mark documents.
29.	BAIN Medical SMC-Pvt) Ltd Shop No. 2, Ground Floor, Plot 58-C, Street No. 24, Touheed Commercial Area, phase 5 DHA Karachi (ELI-00614) Evaluator: AD-VI	Legal Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10 Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China. FSC: China Valid till: 17-03-2023	BAIN Hollow Fiber Dialyzer Codes & Sizes as per FSC Class: C Shelf Life: 03-Years.	Deferred. The firm shall submit FSC of RRA/CE mark/WHO PQ.
30.	Ghani Brothers, 2nd Floor karimjee Building, Opposite Habib Bank Building, North Napier Road, Karachi (ELI-00870) Evaluator: AD-VI	Legal Manufacturer: Huaiyin Medical Instruments Co., Ltd Huaian China	POLY PINE surgical suture. Codes & Sizes as per FSC: 080465 / 20-4-2021 Class: C Shelf Life: 5 Years	Deferred for provision of valid FSC, LOA, justifiable shelf life studies, ISO 13485 and FSC of any reference country or CE mark documents.
31.	Ghani Brothers, 2nd Floor karimjee Building, Opposite Habib Bank Building, North Napier Road, Karachi (ELI-00870) Evaluator: AD-VI	Legal Manufacturer: Huaiyin Medical Instruments Co., Ltd Huaian China	VITAL Polyglactin Suture 080468 / 19-4-2021 Class: C Shelf Life: 5 Years. Codes & Sizes as per FSC:	Deferred for provision of valid FSC, LOA, justifiable shelf life studies, ISO 13485 and FSC of any reference country or CE mark documents.
32.	Ghani Brothers, 2nd Floor karimjee Building, Opposite Habib Bank Building, North Napier Road, Karachi	Legal Manufacturer: Huaiyin Medical Instruments Co., Ltd Huaian China	VITAL Polypropylene Suture 080467 / 19-4-2021 Class: C Shelf Life: 05-Years	Deferred for provision of valid FSC, LOA, justifiable shelf life studies, ISO 13485 and FSC of any reference country or CE mark

	(ELI-00870) Evaluator: AD-VI		Codes & Sizes as per FSC:	documents.
33.	M/s Claris Medical Unit No. 27, Twin City Plaza, 1-8 Markez, Islamabad. ELI: 00269 Evaluator: AD-VI -1855-	Legal Manufacturer & mfg. site: M/s MEDISTIM ASA Okernveien 94 No-0579 Oslo, Norway. Manufacturing Site: Bromsveien 17 3183 Horten, Norway. FSC (copy): Norway Date of issue: 02.03.2020.	MEDISTIM Doppler Probe. (Doppler Probes to Measure Blood Flow Velocity) Class-B Shelf Life: ——— Codes and Sizes as per FSC.	Deferred for provision of following documents: <ul style="list-style-type: none">Differential fee as the product fall in class-C, while firm applied in class-B.Original and Valid FSC of country of origin & any RRA and Letter of authorization.valid ISO-13485 Certificate of all manufacturing sites; Justifiable stability study data with protocols.
34.	M/s Medisurg Innovatives Health Care, 1/6-N, Block-6, PECHS, Main Nursery, Shahrah e Faisal, Karachi. ELI: 00242. Evaluator: AD-VI -1388-K	Legal Manufacturer & mfg. site: The Legal MFG: Contract Medical International GmbH Lauensteiner Strasse 37 01277 Dresden, Germany The actual MFG: Contract Medical International spol S.r.o Vazni 848 500 03 Haradec Kralove Czech Republic 2. Merit Medical Systems, Inc, 1600 West Merit Parkway, South Jordan, Utah, 84095, USA Manufacturer of critical component Steris AST CZ s.t.o Proumyslova zona, Kosikov 80, 59 501 Velka Bites Czech, Republic sterilization. FSC: Germany Date of issue: 14.05.2019.	FORTRESS Introducer Sheath System. Codes and Sizes as per FSC. Class: D Shelf Life: 3 years.	Deferred for provision of original and valid Agency Agreement, ISO 13485 and undertaking on stamp paer.
35.	M/s Treu-Dynamic International (Pvt), Ltd Office No. C-206, 2 nd Floor, City Towers, Main Boulevard Gulberg, Lahore. ELI: 00175 Evaluator: AD-VI	Legal Manufacturer & mfg. site: ANTON HIPPI GmbH Annastrasse 25/1 78567 Frindingen/ Germany. FSC: Germany (copy) Date of issue: 01 st Dec.2017	MAXILLOFACIAL Osteosynthesis System. GMDN 16056. Class C Shelf Life: ——— Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none">Original FSC, ISO-13485 and DoC.Justifiable validation and quality details.Provide brand name as 'MAXILLOFACIAL' While on fee slip it is mentioned as CRANIOFACIAL, clarification required in this regard.
36.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) Evaluator:	Legal Manufacturer: M/s Diatron MI Plc. H-1097, Budapest, Tablas u 39, Hungary. FSC Hungary Issuance Date (22-11-2019)	H 380 Hemo Control Low H 380 Hemo Control Medium H 380 Hemo Control High H 380 Hemo Control Kit H Hemo Calibrator Class B Shelf Life:	Deferred for provision of FSC of any reference country or CE mark documents.

	AD-VI -2453-		11-Months 12-Months Codes & Sizes as per FSC	
37.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00238) -2121-	Legal Manufacturer: M/s Wayson Medical Co. Ltd., No.81, Junfeng Road, Huangpu District, Guangzhou, China. FSC China Valid Till (08-01-2021)	OXYMAX Surgi-Site Incise Drape. Class-B Shelf Life: Not mentioned. Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • Original AND Valid free sale certificate, • Original agency agreement, • justifiable stability study data • certificate of ISO-13485. • FSC of any reference country of CE mark documents.
38.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00238)	Legal Manufacturer & mfg. site: Careglove Global Sdn Bhd, Lot, 17479, Lorong Senawang 3/2, Off Jalan Senawang 3, Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan, Malaysia.	OR-CARE latex surgical gloves powder-free. Class-B Shelf Life: Not mentioned. Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • original free sale certificate, • original agency agreement, • justifiable stability study data • certificate of ISO-13485 • FSC of zany reference country or CE mark documents.
39.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00238)	Legal Manufacturer & mfg. site: Careglove Global Sdn Bhd, Lot, 17479, Lorong Senawang 3/2, Off Jalan Senawang 3, Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan, Malaysia.	OR-CARE. latex surgical gloves powdered. Class-B Shelf Life: Not mentioned. Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • original free sale certificate, • original agency agreement, • justifiable stability study data • certificate of ISO-13485 • FSC of zany reference country or CE mark documents.
40.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00238)	Legal Manufacturer & mfg. site: Adventa Health SDN BHD 1, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu Kelantan Darul Naim Malaysia	COMFEEL Plus sterile surgical gloves. (POWDER free) Class-B Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • original free sale certificate, • original agency agreement, • justifiable stability study data • certificate of ISO-13485 • FSC of zany reference country or CE mark documents.
41.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00238)	Legal Manufacturer & mfg. site: Adventa Health SDN BHD 1, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu Kelantan Darul Naim Malaysia	COMFEEL Plus sterile surgical gloves. (Powdered) Class-B Codes & Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • original free sale certificate, • original agency agreement, • justifiable stability study data • certificate of ISO-13485 • FSC of zany reference country or CE mark

				documents.
42.	M/s Mehran International 498/C Feroz Shah Mehta Road Karachi ELI-00351	M/s. Suzhou Laishi Transfusion Equipment Co., Ltd Company Changsheng Road, Tongli Town 215217 Wujiang city Jinangsu China. FSC China valid till 22-04- 2024.	M.I. Blood Bag. Class-D Shelf Life: 05-YEARS. Codes and sizes as per FSC or RRA documentation.	Deferred for provision of following documents: <ul style="list-style-type: none"> original free sale certificate of country of origin, original agency agreement, justifiable stability study data certificate of ISO-13485 FSC of any reference country or CE mark documents.
43.	KAF Surgical & Disposable Equipment, HM Disposable Office No.24-25, Mezzanine Floor, Medicine Corner, Kachi Gali No.2, Marriot Road, Karachi. (ELI-00398) Evaluator AD-III 1925	Legal Manufacturer: M/s Plasti Lab S.A.R.L, Roumieh, Industrial Area, Main Road 70407, Beirut, Lebanon FSC Lebanon Valid Till (31-01-2024)	JRZ IV Cannula Cannula Plain with Stopper Class-B Shelf life: 3 years Codes & Sizes as per FSC G-14, G-16, G-18, G-20, G-22, G-24, G-26	Deferred for provision of following documents: <ul style="list-style-type: none"> Provided FSC of country of origin is not issued by any Regulatory Authority, justify. Provided FSC of reference country i.e Netherland is issued for Egypt, submit original FSC of reference country to be issued for Pakistan, duly attested. Provide valid QMS certificate issued by NANDO data based notified body, duly notarized. Provide Essential Principle checklist.
44.	KAF Surgical & Disposable Equipment, HM Disposable Office No.24-25, Mezzanine Floor, Medicine Corner, Kachi Gali No.2, Marriot Road, Karachi. (ELI-00398) Evaluator AD-III 1926	Legal Manufacturer: M/s Plasti Lab S.A.R.L, Roumieh, Industrial Area, Main Road 70407, Beirut, Lebanon FSC Lebanon Valid Till (31-01-2024)	JRZ IV Cannula Cannula Pen Type Class-B Shelf life: 3 years Codes & Sizes as per FSC G-14, G-16, G-18, G-20, G-22, G-24, G-26	Deferred for provision of following documents: <ul style="list-style-type: none"> Provided FSC of country of origin is not issued by any Regulatory Authority, justify. Provided FSC of reference country i.e Netherland is issued for Egypt, submit original FSC of reference country to be issued for Pakistan, duly attested. Provide valid QMS certificate issued by NANDO based notified body, duly notarized. Provide Essential Principle checklist.
45.	M/s Cabbot Surgicals CB- 6060 Rose Lane 3A New	Legal Manufacturing: ShenZhen Sangun	Sanguan KN 95 (Disposable mask Non	Deferred for provision of following documents:

	<p>Lalazar Rawalpindi.</p> <p>ELI: 00415 Evaluator AD-III 434-P</p>	<p>Technology Co., Ltd Jialingyu Industrial Building 802, No. 59 Dapu North Rod, Houting Community, Shajing Town, Bao'an District, Shenzhen Guangdong, China</p> <p>FSC not provided</p>	<p>sterile)</p> <p>Class-A</p> <p>Shelf Life: 5 years</p>	<ul style="list-style-type: none"> • Apply on Form-6A as the applied device falls in Class-A • Credentials of the manufacturer abroad duly notarized in the country of origin. • Product details. • Original Agency agreement from Market Authorization Holder duly notarized from the country of origin. • FREE SALE CERTIFICATE in the country of origin duly attested by Embassy of Pakistan. • FSC of reference country as given in Rule 67, duly attested. • Full Quality assurance certificate duly notarized in the country of origin. • Specimen of Label as approved in country of origin. • Essential principle of safety and performance Declaration of conformity (DoC): —Please attach the complete, signed and attested DoC. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
46.	<p>M/s A.S Enterprises, 03-Mozang Lahore, Pakistan.</p> <p>ELI: 00190 Evaluator AD-III 1718-P</p>	<p>Legal Manufacturer: M/s SD Biosensor Inc. C-4&5 Floor, 16, Deogyong-daero 1556 beon-gil, Yeongton-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea</p> <p>FSC: Korea Date of issue: 09.06.2020</p>	<p>SD Check GOLD GLUCO-METER Blood Glucose Monitoring System</p> <p>Class-C</p> <p>Shelf Life: 9 years</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Provide original and valid FSC of the country of origin, duly attested. The attached FSC in the reference file missing the applied device. • Provide valid and attested FSC of reference country as the device is from non-reference country, duly attested. The provided FSC of Germany missing the applied device. • Provide updated ISO 13485 and FQA certificates.

47.	<p>Nasir Brothers Suit#22, 2nd Floor Zeenat Medicine Market North Napier Road Karachi.</p> <p>(ELI-00036) Evaluator AD-III 3006</p>	<p>Legal Manufacturer: Shanxian Runte Medical Instruments Co. Ltd Nanduan Wenhua Road, Shan County, Heze City Shandong, China 274300.</p> <p>FSC China validity 27-02- 2022 FSC MHRA issuance 18-04- 2019</p>	<p>SUICON SURGICAL SUTURES SUILENE Polypropylene monofilament Surgical Suture with Needle</p> <p>Class-D</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Provided FSC of reference country is the copy without attestation, submit original and Embassy attested FSC of MHRA. • Provide Real-time stability studies of claimed shelf life. • Provide MRP of the device. • Provide valid FQA certificate, duly notarized mentioning the applied device. • Provide valid and notarized Design Examination certificate as the device falls in Class-D. <p>Provide labels of all applied codes approved in the country of origin.</p>
48.	<p>M/s Sky Traders, A-11, Ground Floor, Al- Hail Co-operative Housing Society, Block No. IV & V, Scheme No. 7 Karachi.</p> <p>(ELI- 00047) Evaluator AD-III 1497</p>	<p>Legal Manufacturer: Shangdong Yiguang Medical Instruments Co., Ltd Sanjiu Science-Technology Industrial Park, Chiping county, Shandong Province, China.</p> <p>(FSC China validity 25-08- 2019)</p>	<p>Sky Plus Sterile Hypodermic Syringes for single use (Disposable Syringes)</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC 1ml, 10ml, 20ml, 50ml.</p>	<p>Deferred for provision of following documents: Provide credentials of manufacturer with original notarization.</p> <p>FSC of reference country, duly attested.</p> <p>Name of qualified person/responsible person to be mention at Sr. No. 2(iii) of Form-7A.</p> <p>GMDN number is not provided at Sr. No. 4(iv) of Form-7A.</p> <p>Provide valid FSC as certificate attached is expired on 25/08/2019.</p> <p>Provide original Declaration of conformity (DoC).</p> <p>Provide original agency agreement from market authorization holder duly notarized from the country of origin.</p>

49.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi. (ELI-00077) Evaluator AD-III 3608	Legal Manufacturer: KNGMED Medikal Ltd STI 29 Ekim Mah. 10007 Sk. No:26/B Ulukent/ Menemen/Izmir/ Turkey. FSC Turkey issuance 29-07-2022 valid for 36 months	KNGMED Anesthesia Face Masks (Reusable Silicon Anesthesia Face) Class-B Shelf life: 5 years Codes and sizes as per FSC	Deferred for provision of following documents: Differential fee of Rs. 20,000/-. MRP of the device. FSC of reference country. Labels of applied codes.
50.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi. (ELI-00077) Evaluator AD-III 3607	Legal Manufacturer: KNGMED Medikal Ltd STI 29 Ekim Mah. 10007 Sk. No:26/B Ulukent/ Menemen/Izmir/ Turkey. FSC Turkey issuance 29-07-2022 valid for 36 months	KNGMED Anesthesia Face Masks (Full face breathing masks) Class-B Shelf life: 5 years Codes and sizes as per FSC	Deferred for provision of following documents: Differential fee of Rs. 20,000/-. MRP of the device. FSC of reference country. Labels of applied codes.
51.	Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi. (ELI-00170) Evaluator AD-III 88-R 89-R	Legal Manufacturer: Jiangxi Yikang Medical Instrument Group Co., Ltd, No. 23. Lidu road Jiangxian County, Nanchang City, Jiangxi Province, China. FSC China validity 02-04-2022	Crystal Disposable syringe with needle Class-B Shelf life: 5 years Sizes: 1ml, 10ml, 20ml, 30ml, 50ml, 60ml	Deferred for provision of following documents: <ul style="list-style-type: none"> • Submit differential fee of Rs. 12500/- as the applied application will be considered as new registration. • Provide Credentials of manufacturer abroad as per format given in 3rd meeting of MDB, duly notarized. • Provided Agency agreement is copy, without notarization and validity is also not mentioned in the letter, submit original and notarized Agency agreement. • Provide original updated and attested FSC in the country of origin, the given FSC is expired. • Provide FSC of SRA country as the device is from non-reference country, duly attested. • Provided Production Quality assurance certificate is copy without notarization. • Provide valid ISO 13485 certificate, duly notarized. • Provide stability studies of claimed shelf life. • Provide complete

				<p>description of the device with intended purpose.</p> <ul style="list-style-type: none"> • Provide original Declaration of Conformity, duly notarized of the applied device. • Provide labels as per codes/ reference number/ models/ sizes as per FSC approved in the country of origin. • Provide manufacturing and QC processes in detail. • Provide validation information and warnings and contraindications. <p>Provide essential principle checklist of the applied device.</p>
52.	<p>Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi.</p> <p>(ELI-00170) Evaluator AD-III 90-R</p>	<p>Legal Manufacturer: Jiangxi Yikang Medical Instrument Group Co., Ltd, Aihua Ave. Jiangxian Lidu County, Nanchang City, Jiangxi Province, China.</p>	<p>Golden+ Disposable Scalp vein set (Scalp vein set)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes: not provided</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Submit differential fee of Rs. 12500/- as the applied application will be considered as new registration. • Provide Credentials of manufacturer abroad as per format given in 3rd meeting of MDB, duly notarized. • Provided Agency agreement is copy, without notarization and validity is also not mentioned in the letter, submit original and notarized Agency agreement. • Provide original updated and attested FSC in the country of origin, the given FSC is expired. • Provide FSC of SRA country as the device is from non-reference country, duly attested. • Provided Production Quality assurance certificate is copy without notarization.

				<ul style="list-style-type: none"> • Provide valid ISO 13485 certificate, duly notarized. • Provide stability studies of claimed shelf life. • Provide complete description of the device with intended purpose. • Provide original Declaration of Conformity, duly notarized of the applied device. • Provide labels as per codes/ reference number/ models/ sizes as per FSC approved in the country of origin. • Provide manufacturing and QC processes in detail. • Provide validation information and warnings and contraindications. <p>Provide essential principle checklist of the applied device.</p>
53.	<p>Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi.</p> <p>(ELI-00170) Evaluator AD-III 949</p>	<p>Legal Manufacturer: M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China.</p> <p>FSC China issuance (03-09-2019) valid for 5 years</p>	<p>Golden+ Latex Surgical gloves (Latex Surgical gloves)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes as per FSC: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Applied on Form-7A as the device falls in Class-B and submit differential fee of Rs. 20,000/. • The device applied is from non-reference country, submit FSC of reference country duly attested. • Provide updated and notarized Full Quality Assurance certificate as the provided document is expired before the submission of file. • Provide MRP of the device. <p>Provide the label for applied sizes as per FSC, approved in the country of origin.</p>
54.	<p>Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 &</p>	<p>Legal Manufacturer: M/s Human Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21,</p>	<p>Humalyte Plus Analyzer Clinical Chemistry Analyzer</p> <p>Class-A</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Provided LOA and FSC

	8 KMCHS Near Hill Park, Karachi. (ELI-00091) Evaluator AD-III 265	65205 Wiesbaden, Germany FSC Germany issuance (27-05-2017)	Shelf life: N/A Codes & Sizes as per FSC: 17470/10 17470/20	are not original, submit the original LOA and FSC. Provide notarized ISO 13485 and FQA certificate, duly notarized.
55.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) Evaluator AD-III 266	Legal Manufacturer: M/s Human Gesellschaft fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany FSC Germany issuance (27-05-2017)	HumaStar Analyzer Clinical Chemistry Analyzer Class-A Shelf life: N/A Codes & Sizes as per FSC: 17470/10 17470/20	Deferred for provision of following documents: <ul style="list-style-type: none"> • Provided LOA and FSC are not original, submit the original LOA and FSC. Provide notarized ISO 13485 and FQA certificate, duly notarized.
56.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 Evaluator AD-III 1442-P	Legal manufacturer Inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen Germany. FSC: Germany Date of issue: 09.05.2019	Inomed Biopsy Probes Biopsy Probes Class- D Shelf Life: 3 Years Code & Sizes: As per FSC: 805601 805602 805603	Deferred for provision of following documents: <ul style="list-style-type: none"> • Provide Stability studies for the claimed shelf life to be signed by authorized person. • Clarify the difference between 3 types of Biopsy probes mentioned in FSC. Also justify as the device in FSC differs from the device mentioned in Design Examination certificate and submit updated design examination certificate of the applied product/ codes. Provide updated ISO 13485 certificate.
57.	M/s Greenz Pharmaceuticals, 568, J, Johar Town, Lahore ELI: 00643 Evaluator AD-III 2577-P	Legal Manufacturer: M/s CY Medical Co. Ltd, Coex Trade Plaza 2F, 513, Yeongdong-Daero, Gangnam-Gu, SWOUL, Korea FSC: Korea Date of Issue: 12.11.2020	Green Life Blood Bags (Blood Bags) Class-D Shelf Life: Not provided Codes & Sizes: As per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • Provide GMDN code of the applied device. • Provide FSC of Reference country as the device is from non-reference country, duly attested by Embassy of Pakistan. • Provide valid Full Quality assurance certificate/ CE marked document of the applied device, duly notarized. • Provide original and valid Design Examination certificate, duly notarized as the device falls in Class-D

				<ul style="list-style-type: none"> • Provide labels of applied codes/ sizes approved in the country of origin. <p>Also specify the type of device applied i.e single, double or triple, all the types would be applied in separate application.</p> <p>Mention your priority related to type of blood bag in this application.</p>
58.	<p>M/s Medinostic Healthcare (Pvt) Limited, B-18, SITE, Karachi</p> <p>(ELI-00012) Evaluator AD-III 1535</p>	<p>Legal Manufacturer: HdryaChem Limited, Gillmans Industrial Estate, Billingshurst, West Sussex, RH14 9EZ, UK.</p> <p>(FSC UK issuance 21-08-2018)</p>	<p>Oasis Water Purification Tablets 67 mg Water purification tablets</p> <p>Class C</p> <p>Shelf Life: 5 Years</p> <p>Sizes & Codes as Per FSC 10 Tablets per strip x 2500 strips 10 Tablets per strip x 1000 strips 10 Tablets per strip x 500 strips 10 Tablets per strip x 100 strips</p>	<p>The device applied conforms to the requirements of the EU Biocides Regulation 528/2012 (EU BPR) and are manufactured under the scope of QMS Standard ISO 9001:2015.</p> <p>Following are the shortcomings:</p> <ul style="list-style-type: none"> • The product is not included in Agency agreement and FSC • The provided FSC is not issued by any regulatory body in the country of origin. • QMS & FQA certificates are missing. <p>Justify and give reference of reliable regulatory authorities whether the subject device falls under medical devices or otherwise.</p>
59.	<p>M/s A.J. Mirza Pharma (Pvt) Ltd. 1st Floor, Shafi Court, Merewether Road, Civil Lines Karachi.</p> <p>(ELI-00321) Evaluator AD-III 119</p>	<p>Legal Manufacturer: Biohit Oyj, laippatie 1 FI-00880 Helsinki Finland.</p> <p>(FSC Issuance 23-5-2016)</p>	<p>BIOHIT Colon View Fecal Immunochemical test for fecal (Test Cassette)</p> <p>Class A</p> <p>Shelf Life: 18 Months</p> <p>Code: (602 250.02)</p>	<p>Deferred for provision of following documents: The applied device refers to kit for testing of fecal material which falls in Class-B. Apply on relevant form i.e. Form 7(A) with all requisite documents.</p>
60.	<p>M/s Pak Punjab Cardex Medical Systems, Ground Floor, 210-J/2 Block, Johar Town, Lahore</p> <p>ELI-00174 Evaluator AD-III</p>	<p>Legal Manufacturer: M/s MHK Medikal Tekstil San. Ve tic Ltd Sti Korkun MAH, Hidayet Cd, No. 23 oguzeli Gaziantep Turkey</p> <p>FSC Turkey issuance 24-12-2018 valid for 36 months</p>	<p>MHK MEDIKAL DISPOSABLE STERILE SURGICAL DRAPE SETS (Disposable Sterile Surgical Drape Sets)</p> <p>Class-B</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Provide FSC of Reference country as the device is not from reference country, duly attested.

	1848-P		Shelf Life: 5 years Codes/ models as per FSC	Provide the codes required.
61.	Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi. (ELI-00240) Evaluator AD-III 115-Renewal	Legal Manufacturer: M/s. Shandong Qiaopai Group Co. Ltd. Zibo Shandong Province, China.	Xtra Fine Disposable Syringe (Disposable sterile syringe with disposable sterile needle). Class-B Shelf life: 5 years Sizes: 1ml, 3ml, 5ml, 10ml, 20ml	Deferred for provision of following documents: The firm has submitted the renewal application with half of the registration fee and undertaking on stamp paper. The firm has to submit all the required information and documents as per Form-7A with differential fee of Rs-12500/-.
62.	M/s Otsuka Pakistan Limited, 30-B, SMCHS, Karachi (ELI-00243) Evaluator AD-III 1502	Legal Manufacturer: Microport Orthopedics Inc. 5677 Airline Rd Arlington, tn USA 38002. (FSC valid 10-05-2019)	Evolution® MP Knee System Implants Knee System Implants Class-D Shelf Life: not provided Codes as per FSC	Deferred for provision of following documents: • Provide all documents as per checklist of Form-7A, also provide all original and valid legal documents. Original FSC is provided but it was expired at the time of submission
63.	Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00238) Evaluator AD-III 2531	Legal Manufacturer: Terang Nusa (Malaysia) SDN BHD 2 Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100, Kota Bharu, Kelantan Malaysia. FSC Malaysia validity 11-08-2022 to 10-08-2027	Comfeel Plus Latex Surgical gloves (Surgical gloves Powdered) Class-B Shelf life: 5 years	Deferred for provision of following documents: Applied on CE marked basis.
64.	Medichem Enterprises, 331/C Block 3, Alamgir Road, DMCHS, Karachi. (ELI-00252) Evaluator AD-III 883	Legal Manufacture: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC: UK Issued: 1-4-2019	Promed Oxygen Mask Class: A Shelf Life: 5 Years Codes as per FSC	Deferred for provision of following info/documents: • Apply on Form-7A as the device applied falls in Class-B with differential fee of Rs. 20,000/-. The form must be signed and stamped by the authorized persons mentioned on Establishment license. The name mentioned is Mr. Zeeshan, clarify. • Provide credentials of manufacturer abroad, duly notarized. • Provide stability studies of claimed shelf life. • Provide original and updated Agency agreement from the legal manufacturer,

				<p>duly notarized.</p> <ul style="list-style-type: none"> • Provide original FSC of MHRA as the provided FSC is copy. • Provide valid and notarized ISO 13485 and FQA certificate, duly notarized. • Provide Declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person. • Provided labels are of Endotracheal tube, provide labels of applied device approved in the country of origin.
65.	<p>Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi.</p> <p>(ELI-00170)</p> <p>Evaluator AD-III 93 (Renewal)</p>	<p>Legal Manufacturer: Changzhou Huichun Medical Instrument Co. Ltd Sanhekou, Zhenglu Town Changzhou City, Jiangsu Province China.</p> <p>FSC China validity 02-04-2022</p>	<p>Golden + I.V. Cannula Disposable I.V. Cannula all types</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide Credentials of manufacturer abroad as per format given in 3rd meeting of MDB, duly notarized. • Provided Agency agreement is copy, without notarization and validity is also not mentioned in the letter, submit original and notarized Agency agreement. • Provide original and attested FSC in the country of origin. • Provided FSC of SRA country i.e Germany is issued for Republic of Argentine, submit the FSC of any reference country issued for Pakistan, duly attested. • Provided Production Quality assurance certificate is copy without notarization. • Provide the ISO 13485, duly notarized. • Provide stability studies of claimed shelf life, as the provided data is for

				<p>Scalp vein set.</p> <ul style="list-style-type: none"> • Provide complete description of the device with intended purpose. • Provide original Declaration of Conformity, duly notarized of the applied device. The given DoC is of Scalp vein set. <p>Provide labels of applied strength approved in the country of origin. also give your priority of type of Cannula in this application and apply separately for other types of IV Cannula.</p>
66.	<p>Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi.</p> <p>(ELI-00170) Evaluator AD-III 87(Renewal)</p>	<p>Legal Manufacturer: Jiangxi Yikang Medical Instrument Group Co. Ltd. No. 23, Lidu Road Jiangxi county, Nanchang, Jiangxi Province China.</p> <p>FSC China 17-11-2020 valid for 2 years</p>	<p>Golden + Disposable Infusion Set.</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide Credentials of manufacturer abroad as per format given in 3rd meeting of MDB, duly notarized. • Provided Agency agreement is copy, without notarization and validity is also not mentioned in the letter, submit original and notarized Agency agreement. • Provide original updated and attested FSC in the country of origin, the given FSC is expired. • Provide FSC of SRA country as the device is from non-reference country, duly attested. • Provided Production Quality assurance certificate is copy without notarization. • Provide valid ISO 13485 certificate, duly notarized. • Provide stability studies of claimed shelf life. • Provide complete description of the device with intended purpose. • Provide original Declaration of

				<p>Conformity, duly notarized of the applied device.</p> <ul style="list-style-type: none"> • Provide labels as per codes/ reference number/ models/ sizes as per FSC approved in the country of origin. • Provide manufacturing and QC processes in detail. • Provide validation information and warnings and contraindications. <p>Provide essential principle checklist of the applied device.</p>
67.	<p>Batla Impex, Sh. 40, Namco Centre, Cambell Street, Karachi.</p> <p>(ELI-00170)91 (Renewal) Evaluator AD-III</p>	<p>Legal Manufacturer: Jiangxi Yikang Medical Instrument Group Co. Ltd. No. 23, Lidu Road Jiangxi county, Nanchang, Jiangxi Province China.</p> <p>FSC China 01-04-2008 valid for 2 years</p>	<p>Super Blood Transfusion Set</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide Credentials of manufacturer abroad as per format given in 3rd meeting of MDB, duly notarized. • Provided Agency agreement is copy, without notarization and validity is also not mentioned in the letter, submit original and notarized Agency agreement. • Provide original updated and attested FSC in the country of origin, the given FSC is expired. • Provide FSC of SRA country as the device is from non-reference country, duly attested. • Provided Production Quality assurance certificate is copy without notarization. • Provide valid ISO 13485 certificate, duly notarized. • Provide stability studies of claimed shelf life. • Provide complete description of the device with intended purpose. • Provide original Declaration of

				<p>Conformity, duly notarized of the applied device.</p> <ul style="list-style-type: none"> • Provide labels as per codes/ reference number/ models/ sizes as per FSC approved in the country of origin. • Provide manufacturing and QC processes in detail. • Provide validation information and warnings and contraindications. <p>Provide essential principle checklist of the applied device.</p>
68.	<p>M/s Safeway system Pakistan, Office No. 4, second Floor Amna sh</p> <p>opping centre Misrial Road Chur Choke Rawalpindi</p> <p>ELI:00308 Evaluator AD-III 550-P</p>	<p>Legal Manufacturer: M/s Henan Yoshield Medical Products Co., Ltd, Xinghui Industrial Park, Changyuan County, Xinxiang City, Henan, China</p> <p>FSC: China Valid till: 2020.07.26</p>	<p>Yoshield (Surgical Gown Reinforced)</p> <p>Class-A</p> <p>Shelf Life: 3 year</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide original and notarized LOA, as the provided agreement is the copy only. • Provided FSC is copy without attestation, submit original and attested FSC and also updated FSC as the provided FSC had been expired before the submission of application. • Provide notarized QMS and FQA certificates. • Provide Stability studies for claimed shelf life. • Provide EU Declaration of Conformity on letter head of the manufacturer to be signed and filled by responsible person, duly notarized. <p>Provide labels of applied sized as per FSC, the applied codes on Form-6A are not mentioned in FSC, clarify.</p>
69.	<p>M/s Safeway system Pakistan, Office No. 4, second Floor Amna shopping centre Misrial Road Chur Choke Rawalpindi</p>	<p>Legal Manufacturer: M/s Henan Yoshield Medical Products Co., Ltd, Xinghui Industrial Park, Changyuan County, Xinxiang City, Henan, China</p>	<p>Yoshield (Surgical Drape)</p> <p>Class-A</p> <p>Shelf Life: 3 year</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide original and notarized LOA, as the provided agreement is the copy only.

	ELI:00308 Evaluator AD-III 551-P	FSC: China Valid till: 2020.07.26	Codes & Sizes: As per FSC	<ul style="list-style-type: none"> • Provided FSC is copy without attestation, submit original and attested FSC and also updated FSC as the provided FSC had been expired before the submission of application. • Provide notarized QMS and FQA certificates. • Provide Stability studies for claimed shelf life. • Provided Declaration of Conformity is without signatures of responsible person. <p>Provide labels of applied sized as per FSC, the applied codes on Form-6A differ from the codes mentioned in FSC, clarify.</p>
70.	M/s TEK Enterprises Office No. MZ-9 Al-Hafeez Heights Sir Syed road, Gulberg Lahore. Evaluator AD-III 890-P	<p>Legal Manufacturer: Bluejay Diagnostics 360 Massachusetts Ave Suite 203 Acton, MA 01720 USA. Manufacturing sites: Maxim Biomedical, Inc 1500 East Gude Drive, Suite A Rockville Maryland 20850 USA.</p> <p>FSC USFDA valid from 04-12-2019 to 03-12-2021</p>	<p>Cambridge Biotech HIV-1 Urine Western Blot kit HIV Western Blot kit</p> <p>Class-D</p> <p>Shelf life: 5 years</p> <p>Codes:</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide original fee challan of Rupees 50,000/- endorsed by Statistical officer, DRAP. • Provide shelf life studies of claimed shelf life. • Provide MRP of the device. • Provide details of manufacturing and QC control processes. • Provide updated LOA, duly notarized. • Provide ISO 13485 of Legal Manufacture, duly notarized. • Provide valid FQA certificate of Legal manufacturer and manufacturing site, duly notarized. • Provide valid Design Examination certificate duly notarized. <p>Provide label of applied device, approved in the country of origin.</p>
71.	M/s TEK Enterprises Office No. MZ-9	Legal Manufacturer:	Maxim Biomedical Urine kit EIA HIV-I Urine kit EIA	Deferred for provision of following info/documents:

	<p>Al-Hafeez Heights Sir Syed road, Gulberg Lahore.</p> <p>Evaluator AD-III 891-P</p>	<p>Bluejay Diagnostics 360 Massachusetts Ave Suite 203 Acton, MA 01720 USA. Manufacturing sites: Maxim Biomedical, Inc 1500 East Gude Drive, Suite A Rockville Maryland 20850 USA.</p> <p>FSC USFDA valid from 04-12-2019 to 03-12-2021</p>	<p>Class-D</p> <p>Shelf life: 3 years</p> <p>Codes:</p>	<ul style="list-style-type: none"> • Provide original fee challan of Rupees 50,000/- endorsed by Statistical officer, DRAP. • Provide shelf life studies of claimed shelf life. • Provide MRP of the device. • Provide details of manufacturing and QC control processes. • Provide updated LOA, duly notarized. • Provide ISO 13485 of Legal Manufacture, duly notarized. • Provide valid FQA certificate of Legal manufacturer and manufacturing site, duly notarized. <p>Provide valid Design Examination certificate and Pre-market approval, duly notarized.</p>
72.	<p>M/s. Tech Zone, 764 Askari 9, Zarar Shaheed Road Cantt Lahore.</p> <p>ELI-00040</p> <p>Evaluator AD-III 895-P</p>	<p>Legal Manufacturer: International Company for Medical Zone, Block No. 19&67 ABU TIG, ASSIUT Egypt</p> <p>FSC Egypt Date of issue 27th August, 2019 Valid till 15th March 2021</p>	<p>I.C.O Disposable Syringes</p> <p>Class: B</p> <p>Shelf Life: 5 years</p> <p>Sizes: (10ml, 20ml, 50ml)</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide original LOA with applied devices list, duly notarized. • Provide original FSC in the country of origin, duly attested, the provided FSC is copy. • Provide FSC of Reference country as the device is not from reference country, duly attested. • Provide valid FQA certificate, duly notarized. • Provide MRP of the device. <p>Provide Labels of applied device approved in the country of origin.</p>
73.	<p>M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B-17, Islamabad.</p> <p>ELI: 00228</p> <p>Evaluator:</p>	<p>Legal Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain.</p> <p>FSC Spain issued on 3-9-2018</p>	<p>Spinreact Salmonella Paratyphi AO (Bacterial Antigen Serology Test Kit</p> <p>Class-C</p> <p>Shelf Life: 30 months</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide Brand name of the device. • Provide the file reference where original documents are

	AD-III 2880-P		Code: 1205021 (100 tests)	<p>attached.</p> <ul style="list-style-type: none"> • Provided IFU is in Spanish language, submit the document with English translation. • Provided ISO 13485 is expired before the file submission, submit valid and notarized certificate. • Provide valid and notarized FQA certificate. <p>Provide Essential principle checklist.</p>
74.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi.</p> <p>(ELI-00078)</p> <p>Evaluator AD-III 2527</p>	<p>Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany.</p> <p>FSC (scanned copy): Germany Date of issue: 29-04-2019</p>	<p>Dade Actin FSL Activated PTT Reagent kit (Activated PTT Reagent)</p> <p>Class-C</p> <p>Shelf life: 24 Months</p> <p>Codes as per FSC: B4219-1 B4219-2</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Only the reagent kit will be considered on this application, apply separately for the Controls and Diluents/ buffer solution. • Provide original and updated Letter of Authorization, duly notarized. • Provided FSC is scanned copy, provide original and attested document or provide the reference file where original document is attached. • Provide valid ISO 13485 certificate. • Provide FQA certificate, duly notarized. <p>Provide undertaking on Stamp paper.</p>
75.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi.</p> <p>(ELI-00078)</p> <p>Evaluator AD-III 2606</p>	<p>Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany.</p> <p>FSC (scanned copy): Germany Date of issue: 29-04-2019</p>	<p>Thromboclotin Reagent kit</p> <p>Class-C</p> <p>Shelf life: 24 Months</p> <p>Code as per FSC: 281007</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Justify the grouping of applied device in kit whether the reagent and the controls come under single unit or separate packing. Otherwise apply separately for the controls. • Provide updated Letter of Authorization, duly notarized.

				<ul style="list-style-type: none"> Provide FQA certificate, duly notarized. Provide EU type Declaration of Conformity.
76.	S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi. (ELI-00078) Evaluator AD-III 2608	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany. FSC (scanned copy): Germany Date of issue: 29-04-2019	Factor VIII Chromogenic Assay kit Class-C Shelf life: 24 Months Code as per FSC: B4238-40	Deferred for provision of following info/documents: <ul style="list-style-type: none"> Only the reagent kit will be considered on this application, apply separately for the Controls and Diluents/ buffer solution. Provide original and updated Letter of Authorization, duly notarized. Provided FSC is scanned copy, provide original and attested document or provide the reference file where original document is attached. Provide valid ISO 13485 certificate. Provide FQA certificate, duly notarized. Provide undertaking on Stamp paper.
77.	M/s Zedco, 203 Skymark tower, Plot A-13 Block 7/8, KCHSU Shahrah e Faisal Karachi. ELI-00347 Evaluator AD-III 2525	Legal Manufacturer: Terumo BCT Inc 10811 West Collins Avenue Lakewood Colorado 80215, USA. Manufacturing site: Terumo BCT Inc 10811 West Collins Avenue Lakewood Colorado 80215, USA. and M/s Terumo BCT Vietnam Co. Ltd. Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam. FSC US FDA validity 12-12-2018 to 11-12-2020 FSC Vietnam issuance 02-06-2019 valid for 3 years	Trima Accel LRS Disposable Tubing Set (kits). Class-C Shelf life: 24 Month Codes as per FSC: 80330 (Single Platelet) 80300 (Double Platelet)	Deferred for provision of following info/documents: <ul style="list-style-type: none"> Justify the grouping of applied device in kit or give clarification whether both the type the short-term storage and long term both come under single packing or both kits are in separate packing. The LOA and FSC submitted are copies, submit the original documents or give the reference of file where original documents are attached and submitted updated FSC. The FSC of US FDA provided, missing the product code 80330 (long term storage of 5 days). Copy of US FDA export only certificate is

				<p>provided for code 80330.</p> <ul style="list-style-type: none"> • Provide updated ISO 13485 certificate. <p>Provide undertaking on stamp paper.</p>
78.	<p>Excel Corporation, 435 BYJ Society, Bahadurabad, Karachi.</p> <p>(ELI-00110) Evaluator AD-III 4227</p>	<p>Legal Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd. No. 39 South Shengli Road, Jinxian Country, 331700 Nanchang, Jiangxi Province, P.R.China.</p> <p>FSC China validity 05-11-2022</p>	<p>Star One Infusion Set for Single Use</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide Stability studies for the claimed shelf life to be signed by authorized person. • Provide all the legal documents in original, the provided documents are not original. • As the product is not on Free Sale in country of origin, so provide free sale certificate from reference countries as provided in Rule 67 duly attested by Embassy of Pakistan. • The codes/ specifications mentioned in FSC are different from those mentioned on DoC <p>Provide labels of all applied codes as per FSC approved in the country of origin.</p>
79.	<p>M/s Hamza Trading Co., office No. 302, 3rd floor, Makkah Market, Katchigali No.1, Marriot road, Densohall, Karachi</p> <p>Evaluator AD-III [1700]</p>	<p>Legal Manufacturer: Changzhou Chuangja Medical appliance Co., Ltd., Sanhekou development zone, zhenglu town, Changzhou 213115, China.</p> <p>(FSC Issue 29-07-2020)</p>	<p>National Sterile Surgical Mask</p> <p>Class: B</p> <p>Shelf Life: N/A</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents: Provide Manufacturing and QC processes in detail.</p> <p>Provide valid FSC in the country or origin (valid at the time of submission) mentioning the subject device with applied sizes / codes</p> <p>Provide original and valid FSC of any reference country as per rule 71 of MDR, 2017 duly attested.</p> <p>Provide valid ISO 13485 certificate, duly notarized</p>

				Apply separately for oxygen mask.
80.	<p>M/s United Healthcare, Plot No.330, 2nd Floor, DMCH, Bahadurabad, Karachi</p> <p>Evaluator AD-III [2062]</p>	<p>Legal Manufacturer: M/s Joytech Healthcare Co. Ltd., No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, China</p> <p>FSC China Valid Till (17-09-2021)</p>	<p>Senior Wrist type blood pressure monitor</p> <p>Class: B</p> <p>Shelf Life: N/A</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents: Provide original LOA on manufacturer's letter head, duly notarized.</p> <p>Credentials given are without notarization, submit as per approved format in MDB-03.</p> <p>Provide valid FSC in the country of origin, duly attested by the embassy of Pakistan.</p> <p>Provide valid FSC of reference country as the device is not on free sale in reference country, duly attested.</p> <p>Provide ISO 13485 and Full QA certificate</p> <p>Provide manufacturing and QC processes in detail.</p> <p>Provide labels of applied codes, approved in the country of origin.</p> <p>Clearly state the models need to be registered.</p>
81.	<p>M/s Muslim Medical Services, 1st Floor of sky star travers, 3-syed moj darya road, Lahore basement of building, R34 – Mozang Road, Opp. Total petrol pump, Lahore</p> <p>Evaluator AD-III [2036]</p>	<p>Legal Manufacturer: M/s Guangdong Biolight Meditech Co., Ltd., No.2, Innovation First Road, Technical Innovation Coast Hi-Tech Zone, Zhuhai, PR China</p> <p>FSC China Valid Till (27-07-2019)</p>	<p>Patient Monitor</p> <p>Class: C</p> <p>Shelf Life: 05 Years</p> <p>Codes & sizes as per FSC</p>	<p>Deferred for provision of following info/documents: Provide updated LOA, as the provided LOA has been expired, duly notarized.</p> <p>Provide valid FSC in the country of origin, duly attested.</p> <p>Provide FSC of any</p>

				<p>reference country as per rule 71 or MDR, 2017.</p> <p>Provide valid ISO 13485 certificate, duly notarized.</p> <p>Provide valid FQA/CE marked documents of subject device, duly notarized</p>
82.	<p>M/s United International, GNB-F 18/A Ground Floor, F-Block, Mehar Sons Estate, Karachi</p> <p>Evaluator AD-III [125 (6A)]</p>	<p>Legal Manufacturer: Shandong Kanglilai Medical Apparatus Co., Ltd. No. 8 Xinchang Road Changyi Weifang City China</p>	<p>Jazz Plus Urine Bag Class A</p> <p>Shelf Life: 05 Years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide original agency agreement as the provided document is the copy of original.</p> <p>Provide original and valid FSC in the country of origin, duly attested by the embassy of Pakistan</p> <p>Provide FSC of any reference country, duly attested as per Rule 71 of MDR, 2017</p> <p>Provide labels of all applied codes, approved in the country of origin</p>
83.	<p>M/s K.S Agencies, Office No.210, 2nd Floor Business Arcade, Main university road, Karachi.</p> <p>Evaluator AD-III [2684]</p>	<p>Legal Manufacturer: Shandong Haidike Medical Products Company Limited Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China.</p>	<p>Cura Blood Bags Class: C</p> <p>Shelf Life: 03 Years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents: As multiple devices are applied in single application. Apply separately for double and triple blood bags.</p> <p>Provide credentials of manufacturer abroad as per format approved in 3rd meeting of MDB.</p> <p>Provided legal documents are copies without notarization and / or attestation. Submit all the documents in original and updated i.e LOA and FSC</p> <p>As the device is from non-</p>

				<p>reference country, submit the FSC of reference country as per rule 67 of MDR, 2017.</p> <p>Provide manufacturing and QC tests in details.</p> <p>Provide stability studies for the claimed shelf life.</p> <p>Provide valid and notarized ISO- 13485, production and full QA certificates.</p> <p>The device falls in Class-D, so provide Design examination certificate, duly notarized.</p> <p>Provide Essential Principle checklist of the applied devices not the general principle.</p> <p>Provide labes approved in the country of origin, (Codes/model as per FSC)</p> <p>Provided Doc is without notarization, submit notarized DoC.</p>
84.	<p>M/s Ethos Healthcare (Pvt) Ltd., Woodcraft House, 1st Floor, Plot No. 18, Sector 47, Survey 86, Off main Korangi, Creek Road, Karachi</p> <p>Evaluator AD-III [901]</p>	<p>Manufacturer: M/s Shandong Yuncheng Shangpin Med Co. Ltd., DingLiZhang Tow, YunCheng County, ShanDong Province, China</p> <p>(FSC China Valid Till 07-10-2020)</p>	<p>Non-Absorbable Suture (Polypropylene)</p> <p>Class B</p> <p>Shelf Life: 48 Months</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide copy of valid establishment license</p> <p>Provide credential of manufacturer aboard.</p> <p>Provide the stability studies for claimed shelf life & storage.</p> <p>Provide original agency agreement duly notarized in the country of origin with clearly mention the validity</p> <p>Provide original and valid</p>

				<p>free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan</p> <p>Provide the production quality management system certificate (ISO-13485)</p> <p>Provide full quality assurance certificate, duly notarized</p> <p>Provide the essential principle of safety and performance</p> <p>Provide brochure of the device.</p>
85.	<p>M/s Ethos Healthcare (Pvt) Ltd., Woodcraft House, 1st Floor, Plot No. 18, Sector 47, Survey 86, Off main Korangi, Creek Road, Karachi</p> <p>Evaluator AD-III [900]</p>	<p>Manufacturer: M/s Shandong Yuncheng Shangpin Med Co. Ltd., DingLiZhang Tow, YunCheng County, ShanDong Province, China</p> <p>(FSC China Valid Till 07-10-2020)</p>	<p>Absorbable Surgical Suture (with Needle) Polyglycolic Acid</p> <p>Class B</p> <p>Shelf Life: 48 Months</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide copy of valid establishment license</p> <p>Provide credential of manufacturer aboard.</p> <p>Provide the stability studies for claimed shelf life & storage.</p> <p>Provide original agency agreement duly notarized in the country of origin with clearly mention the validity</p> <p>Provide original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan</p> <p>Provide the production quality management system certificate (ISO-13485)</p> <p>Provide full quality assurance certificate, duly notarized</p>

				<p>Provide the essential principle of safety and performance</p> <p>Provide Declaration of Conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed.</p> <p>Provide label and its packaging, promotion material and brochure.</p>
86.	<p>M/s Ethos Healthcare (Pvt) Ltd., Woodcraft House, 1st Floor, Plot No. 18, Sector 47, Survey 86, Off main Korangi, Creek Road, Karachi</p> <p>Evaluator AD-III [898]</p>	<p>Manufacturer: M/s Shandong Yuncheng Shangpin Med Co. Ltd., DingLiZhang Tow, YunCheng County, ShanDong Province, China</p> <p>(FSC China Valid Till 07-10-2020)</p>	<p>Non-Absorbable Surgical Suture (with Needle) Silk</p> <p>Class C</p> <p>Shelf Life: 48 Months</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide copy of valid establishment license</p> <p>Provide credential of manufacturer aboard.</p> <p>Provide the stability studies for claimed shelf life & storage.</p> <p>Provide original agency agreement duly notarized in the country of origin with clearly mention the validity</p> <p>Provide original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan</p> <p>Provide the production quality management system certificate (ISO-13485)</p> <p>Provide full quality assurance certificate, duly notarized</p> <p>Provide the essential principle of safety and performance</p> <p>Provide brochure of the</p>


87.	<p>M/s Ethos Healthcare (Pvt) Ltd., Woodcraft House, 1st Floor, Plot No. 18, Sector 47, Survey 86, Off main Korangi, Creek Road, Karachi</p> <p>Evaluator AD-III [899]</p>	<p>Manufacturer: M/s Shandong Yuncheng Shangpin Med Co. Ltd., DingLiZhang Tow, YunCheng County, ShanDong Province, China</p> <p>(FSC China Valid Till 07-10-2020)</p>	<p>Absorbable Surgical Suture (with Needle) Catgut Chromic</p> <p>Class C</p> <p>Shelf Life: 48 Months</p> <p>Codes & Sizes as per FSC</p>	<p>device.</p> <p>Deferred for provision of following info/documents:</p> <p>Provide copy of valid establishment license</p> <p>Provide credential of manufacturer aboard.</p> <p>Provide the stability studies for claimed shelf life & storage.</p> <p>Provide original agency agreement duly notarized in the country of origin with clearly mention the validity</p> <p>Provide original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan</p> <p>Provide the production quality management system certificate (ISO-13485)</p> <p>Provide full quality assurance certificate, duly notarized</p> <p>Provide the essential principle of safety and performance</p> <p>Provide brochure of the device.</p>
88.	<p>M/s Bayer Pakistan (Pvt) Ltd., Bahria Complex II, 4th Floor, M.T Road, Karachi</p> <p>Evaluator AD-III [1764]</p>	<p>Legal Manufacturer: M/s H & B Electronic GmbH & Co. KG Siemenstr.8 75392 Deckenpfronn Germany.</p> <p>(FSC Germany issue 02-11-2017)</p>	<p>Betacomfort auto-injector</p> <p>Class B</p> <p>Shelf Life: N/A</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide original agency agreement form market authorization holder mentioning the validity, duly notarized.</p> <p>Provide valid ISO-13485 certificate, duly notarized.</p>

				<p>Provide FQA certificate, duly notarized.</p> <p>Provide shelf life studies with conclusion.</p> <p>Provide label approved in the country of origin.</p>
89.	<p>M/s S.K Surgicals 60 C, Mezzanine Floor, 11th Commercial Street, DHA Phase II Ext. Karachi</p> <p>Evaluator AD-III [2634]</p>	<p>Legal Manufacturer: Canwell Medical Co Ltd No. 466 South Xianhua Street Jinhua 321000 Zhejiang China</p>	<p>Canwell Metal Bone Screw</p> <p>Class C</p> <p>Shelf Life: 05 Years</p> <p>Codes & sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Provide original and updated Letter of Authorization, duly notarized.</p> <p>Provided FSC is expired before the submission of application, provide origin, valid and attested FSC of China.</p> <p>The device is from non-reference country so provide FSC of reference country and if the device is to be registered on CE marked basis than ask the manufacturer to give an undertaking that the same quality of the device would be exported as exporting to other EU states.</p> <p>Provide manufacturing process details of the applied device not the general process of manufacturing.</p> <p>Provide shelf life studies in details for the claimed shelf life.</p> <p>Provide ISO-13485 certificate</p> <p>Provided DoC is without notarization and sign of responsible person, submit the notarized and original document.</p>
90.	M/s Maqsood Brothers,	Legal Manufacture:	Lifecare AD Syringe	Deferred for provision of

	<p>Office No.503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road, Karachi</p> <p>Evaluator AD-III [4495]</p>	<p>Farmasino Pharmaceuticals (Jiangsu) Co., Ltd. Building 5, No. 9 Weidi Road, Najing Jiangsu China</p> <p>FSC: China Issued :16-8-2021</p>	<p>Class B</p> <p>Shelf Life: 03 Years</p> <p>Codes & Sizes as per FSC</p>	<p>following info/documents:</p> <p>Provided LOA is missing the applied device, clarification is required and submit the agreement mentioning the applied device.</p> <p>Provide updated FQA and product quality assurance certificate as per Annex II and VI of the directives duly notarized</p> <p>Provide lables of required strength approved in the country of origin</p> <p>Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person submit notarized documents.</p> <p>The submitted production quality assurance certificate is missing the scope of applied device.</p> <p>Provide report of information on validation of the device with sterile function.</p>
91.	<p>M/s Sy'ah Impex, 1-6/15 Sector No.5, Korangi Industrial Area, Karachi</p> <p>Evaluator AD-III [178]</p>	<p>Legal Manufacture: M/s Changzhou Yuekang Medical Applcance Co., Ltd., Jiaoxi Town, Changzhou, Jiangsu Province, China</p>	<p>Shifa Urine Bag</p> <p>Class A</p> <p>Shelf Life: 05 Years</p> <p>Codes & sizes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Address on LOA and FSC differs, justify.</p> <p>Provide origina FSC from the country of origin, duly attested.</p> <p>Provide valid QMS certificate, duly notarized</p> <p>Provide details of manufacturing and QC testing</p>

				Provide shelf life studies.
92.	Endovision Enterprises, A-173, Block 3 Gulistan-e- Jauhar Karachi-75290. (ELI-00730) Evaluator AD-III 4243	Legal Manufacturer: Changzhou New District Garson Medical Stent Apparatus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China FSC China Valid Till: 27-2-2022	GARSON (FLEXTENT) Esophageal Stent System (Covered) Class-C Shelf life: 1 year Codes as per FSC	Deferred for provision of following info/documents: Clearly state the Brand name of the device. Clearly state the type whether covered or partially covered. Provide complete details of the manufacturing and QC processes. Provide the shelf life studies for the claimed shelf life of 1 year. Valid FSC of China mentioning the subject device. Labels of all applied codes as per FSC, approved in the country of origin. Complete details of the product. FSC of reference country as the device is from non- reference country. Valid FQA certificate Sterilization/ validation report. MRP of the device.
93.	Endovision Enterprises, A-173, Block 3 Gulistan-e- Jauhar Karachi-75290. (ELI-00730) Evaluator AD-III 4254	Legal Manufacturer: Changzhou New District Garson Medical Stent Apparatus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China FSC China Valid Till: 27-2-2022	GARSON (FLEXTENT) Esophageal Stent System (Partially Covered) Class-C Shelf life: 1 year Codes as per FSC	Deferred for provision of following info/documents: Clearly state the Brand name of the device. Provide complete details of the manufacturing and QC processes. Provide the shelf life studies for the claimed shelf life of 1 year. FSC of China mentioning the subject device. Labels of all applied codes as per FSC, approved in the country of origin. Complete details of the product.


				<p>FSC of reference country as the device is from non-reference country.</p> <p>Valid FQA certificate</p> <p>Sterilization/ validation report.</p> <p>MRP of the device.</p>
94.	<p>Endovision Enterprises, A-173, Block 3 Gulistan-e-Jauhar Karachi-75290.</p> <p>(ELI-00730)</p> <p>Evaluator AD-III 4244</p>	<p>Legal Manufacturer: Changzhou New District Garson Medical Stent Apppartus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China</p> <p>FSC China Valid Till: 27-2-2022</p>	<p>GARSON (FLEXTENT) Duodenum Stent</p> <p>Class-C</p> <p>Shelf life: 1 year</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Clearly state the Brand name of the device.</p> <p>Provide complete details of the manufacturing and QC processes.</p> <p>Provide the shelf life studies for the claimed shelf life of 1 year.</p> <p>FSC of China mentioning the subject device.</p> <p>Labels of all applied codes as per FSC, approved in the country of origin.</p> <p>Complete details of the product.</p> <p>FSC of reference country as the device is from non-reference country.</p> <p>Valid FQA certificate</p> <p>Sterilization/ validation report.</p> <p>MRP of the device.</p>
95.	<p>Endovision Enterprises, A-173, Block 3 Gulistan-e-Jauhar Karachi-75290.</p> <p>(ELI-00730)</p> <p>Evaluator AD-III 4242</p>	<p>Legal Manufacturer: Changzhou New District Garson Medical Stent Apppartus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China</p> <p>FSC China Valid Till: 27-2-2022</p>	<p>GARSON (FLEXTENT) Biliary Stent System (Non-Covered)</p> <p>Class-C</p> <p>Shelf life: 1 year</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Clearly state the Brand name of the device.</p> <p>Clearly state the type whether covered or partially covered.</p> <p>Provide complete details of the manufacturing and QC processes.</p> <p>Provide the shelf life studies for the claimed shelf life of 1 year.</p> <p>FSC of China submitted does not differentiate between the covered and partially covered.</p>

				<p>Labels of all applied codes as per FSC, approved in the country of origin.</p> <p>Complete details of the product.</p> <p>FSC of reference country as the device is from non-reference country.</p> <p>Valid FQA certificate</p> <p>Sterilization/ validation report.</p> <p>MRP of the device.</p>
96.	<p>Endovision Enterprises, A-173, Block 3 Gulistan-e-Jauhar Karachi-75290.</p> <p>(ELI-00730)</p> <p>Evaluator AD-III 4237</p>	<p>Legal Manufacturer: Changzhou New District Garson Medical Stent Apparatus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China</p> <p>FSC China Valid Till: 27-2-2022</p>	<p>GARSON (FLEXTENT) Biliary Stent System (Partially Covered)</p> <p>Class-C</p> <p>Shelf life: 1 year</p> <p>Codes as per FSC</p> 	<p>Deferred for provision of following info/documents:</p> <p>Clearly state the Brand name of the device.</p> <p>Clearly state the type whether covered or partially covered.</p> <p>Provide complete details of the manufacturing and QC processes.</p> <p>Provide the shelf life studies for the claimed shelf life of 1 year.</p> <p>FSC of China submitted does not differentiate between the covered and partially covered.</p> <p>Labels of all applied codes as per FSC, approved in the country of origin.</p> <p>Complete details of the product.</p> <p>FSC of reference country as the device is from non-reference country.</p> <p>Valid FQA certificate</p> <p>Sterilization/ validation report.</p> <p>MRP of the device.</p>
97.	<p>Aliz HealthTech Innovations (Pvt) Limited, Plot No.48-D, Mezzanine Floor, 21st Commercial Street, DHA Phase-II Ext. Karachi.</p>	<p>Legal Manufacturer: TOP DENTAL (Products) Ltd. Unit 12 Ryefield Way Silsden, Keighley West. Yorkshire, BD20 0EF England, UK.</p>	<p>Bosklein Instrument Disinfectant (Concentrated dental and surgical instrument disinfectant)</p> <p>Class-C</p>	<p>Deferred for provision of following info/documents:</p> <p>Form without sign and stamp.</p> <p>Differential fee of 25,000/-</p>

	(ELI-00667) Evaluator AD-III 4259	FSC MHRA UK Valid Till: 22-2-2023	Shelf Life: 3 Years Codes as per FSC	Scanned copy of FSC is attested. Essential Principle checklist. Label of all applied codes. Original DoC is required.
98.	Shirazi Trading Company (Pvt) Ltd., 114-C, Al- Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi (ELI-00263) Evaluator AD-III 2360	Legal Manufacturer: M/s Datex-Ohmeda, Inc. 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707- 7550 USA FSC US FDA Valid Till (10-02-2021)	Tec 820 Isoflurane Vaporizer anesthesia vaporizer Class-C Shelf life: N/A Model: Tec 820	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. • Provide valid FSC in the country of origin, duly attested as the provided FSC has been expired. • Provide valid FQA certificate, duly notarized. • Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan. Provide Reference manual and IFU of the applied device.
99.	M/s Pharmatronics Pvt. Ltd Office # S-11. 2nd Floor Clock Tower, Shamsi Road, Mardan. ELI: 00270 Evaluator AD-III 527-P	Legal Manufacturer: M/s Wuhan Huawei Technology Co., Ltd Head Office: 8/F, Building A, Spaceflight Star Town, Two Seven Road, Jiang'an District 430012, Wuhan, Hubei, China Factory Address: B-F11-3, Huazhong International Industrial Park, Yangluo Port, 430415, Wuhan, Hubei, China FSC: China Valid till: 11.04.2022	Cellotron Transparent Wound Dressing (Wound Dressing) Class-A Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • The address of importer on Form 6(A) differs from the address on the distribution agreement, justify. • Provide MRP of the device. • Provided Production quality assurance certificate is expired, submit valid certificate, duly notarized.
100.	M/s Pharmatronics Pvt. Ltd Office # S-11. 2nd Floor Clock Tower, Shamsi Road, Mardan. ELI: 00270	Legal Manufacturer: M/s Wuhan Huawei Technology Co., Ltd Head Office: 8/F, Building A, Spaceflight Star Town, Two Seven Road, Jiang'an District 430012, Wuhan, Hubei,	Cellotron Nonwoven Wound Dressing (Wound Dressing) Class-A Shelf Life: 3 years	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • The address of importer on Form 6(A) differs from the address on the distribution agreement,

	Evaluator AD-III 526-P	China Factory Address: B-F11-3, Huazhong International Industrial Park, Yangluo Port, 430415, Wuhan, Hubei, China FSC: China Valid till: 11.04.2022	Codes & Sizes: As per FSC	justify. <ul style="list-style-type: none"> • Provide MRP of the device. • Provided Production quality assurance certificate is expired, submit valid certificate, duly notarized.
101.	M/s Pharmatronics Pvt. Ltd Office # S-11. 2nd Floor Clock Tower, Shamsi Road, Mardan. ELI: 00270 Evaluator AD-III 528-P	Legal Manufacturer: M/s Wuhan Huawei Technology Co., Ltd Head Office: 8/F, Building A, Spaceflight Star Town, Two Seven Road, Jiang'an District 430012, Wuhan, Hubei, China Factory Address: B-F11-3, Huazhong International Industrial Park, Yangluo Port, 430415, Wuhan, Hubei, China FSC: China Valid till: 11.04.2022	Cellotron IV Fixing Dressing (Wound Dressing) Class-A Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • The address of importer on Form 6(A) differs from the address on the distribution agreement, justify. • Provide MRP of the device. • Provided Production quality assurance certificate is expired, submit valid certificate, duly notarized.
102.	M/s Mian scientific Corporation (Pvt) Ltd 534- Jinnah Colony Faizalabad, 38030 Pakistan ELI: 00442 Evaluator AD-III 1707-P	Legal Manufacture: Wuxi BioHermes Bio & Medical Technology Co., Ltd Address # 1. No. 88 & 136 Mashan Meiliang Road Rinhu, wuxi 214092, Jinnangsu, china, Address # 2, 11th Floor, 530 Mansion # 18 Qingyuan Road, Xinwu District, Wuxi, 214135 Jiangsu, China. Export certificate of China Date of Issue: 17.07.2021	Bio Hermes (Glycohemoglobin Test Kit) Class-C Shelf Life 21 months Codes as per FSC	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • Provide credential of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized. • The addresses provided on Form-7A include three addresses of the manufacturer whereas on the all legal documents, only two addresses are mentioned, clarify. • Provide original and valid FSC of the country of origin, duly attested, the submitted certificate is for export only. • Provide valid and attested FSC of reference country as the device is from non-reference country, duly attested. Provide FQA and Design Examination certificates, duly notarized. • The subject device is not included in the provided FQA certificate, provide the relevant document having the subject

				<p>device mentioned on.</p> <ul style="list-style-type: none"> • Provide instruction for use and complete details of the device including warnings and contraindications. • Provided labels are not clear as the name of legal manufacturer and the model number as per FSC, are not mentioned. Submit revised labels. • Provide Essential principle checklist.
103.	<p>M/s Treu-Dynamic International (Pvt), Ltd Office No. C-206, 2nd Floor, City Towers, Main Boulevard Gulberg, Lahore</p> <p>ELI: 00175</p> <p>Evaluator AD-III 845-P</p>	<p>Legal Manufacturer: M/s Teknimed SAS 8, Rue du Corps France Pommies-65500 Vic en Bigorre-France. Manufacturing site: M/s Teknimed SAS ZI de Montredon Rue d' Apollon-31240 L'Union-France.</p> <p>FSC France issuance 19-02-2019</p>	<p>Euro Screw (Bone Screw)</p> <p>Class-D</p> <p>Shelf Life: 3 years</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide fee challan endorsed by statistical officer, DRAP. • Provide Stability studies of claimed shelf life. • Provide MRP of the device. • ISO 13485 & FQA and Design Examination certificates are expired but valid upon submission. • Provide labels of all applied codes approved in the country of origin. • Apply separately for Euro screw NG.
104.	<p>Ms. JK Traders Suite No. 13, 2nd Floor Majeed Plaza Bank Road Saddar Rawalpindi.</p> <p>ELI-00014</p> <p>Evaluator AD-III 669-P</p>	<p>Legal Manufacturer: XiaMew Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicing Biomedicine Building No.2026, West Wengjiao Road Haicang district, Xiamen, Fujian, China</p> <p>FSC Spain issuance 24-06-2019</p>	<p>NCMT (Manifold Stopcocks))</p> <p>Class B</p> <p>Shelf life 3 years</p> <p>Model: LT-B-03 (30200209)</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • Provide copy of Establishment license. • Provided credential are without notarization. • Provide original and valid agency agreement, duly notarized. • Provide original and valid FSC, duly attested. • Provided FSC of Spain is copy, submit original FSC of Spain. • Provide valid ISO 13485 and Full Quality assurance certificate. • Provide essential principle of safety and performance.

				<ul style="list-style-type: none">• Provide label of all applied model.
105.	M/s. Surgi World 303, Muhammad Plaza, College Road, Rawalpindi. (ELI-00212) Evaluator AD-III 555-P	Legal Manufacturer: Angiomed GmbH & Co. Medizintechnik KG Wachhausstrasse 6 Karlsruhe, Baden- Wurttemberg Germany 76227 FSC Germany Issue date 22.01.2019	E-LUMINEXX Vascular Stent (Vascular Stent) Class-C Codes: ZVL04020- ZVL04030- ZVL04040 ZVL04050- ZVL04060- ZVL04080 ZVL04100- ZVL04120- ZVL05020 ZVL05020- ZVL05030- ZVL05040 ZVL05050- ZVL05060- ZVL05080 ZVL05100- ZVL05120- ZVL06020 ZVL06030- ZVL06040- ZVL06050 ZVL06060- ZVL06080- ZVL06100 ZVL06120- ZVL07020- ZVL07030 ZVL07030- ZVL07040- ZVL07050 ZVL07060- ZVL07080- ZVL07100 ZVL07120- ZVL08020- ZVL08030 ZVL08040- ZVL08050- ZVL08060 ZVL08080- ZVL08100- ZVL08120 ZVL08100- ZVL09020- ZVL09030 ZVL09040- ZVL09050- ZVL09060 ZVL09080- ZVL09100- ZVL09120 ZVL10020- ZVL10030- ZVL10040 ZVL10050- ZVL10060- ZVL10080 ZVL10100- ZVL10120- ZVL12020 ZVL12030- ZVL12040- ZVL12050 ZVL12060- ZVL12080- ZVL12100 ZVL12120- ZVL14020- ZVL14030 ZVL14040- ZVL14050- ZVL14060 ZVL14080- ZVL14100- ZVL14120 ZVM04020- ZVM04030- ZVM04040 ZVM04050- ZVM04060- ZVM04080	<ul style="list-style-type: none">Deferred for provision of following info/documents:• Provide original and valid LOA.• Valid and notarized ISO 13485.• Valid and notarized FQA certificate.• Labels of applied codes. 

			ZVM04100- ZVM05020 ZVM05030- ZVM05060 ZVM05080- ZVM05120 ZVM06020- ZVM06040 ZVM06050- ZVM06080 ZVM06100- ZVM07020 ZVM07030- ZVM07050 ZVM07060- ZVM07100 ZVM07120- ZVM08030 ZVM08040- ZVM08060 ZVM08080- ZVM08120 ZVM09020- ZVM09040 ZVM09050- ZVM09080 ZVM09100- ZVM10020 ZVM10030- ZVM10040 ZVM10050- ZVM10080 ZVM10100- ZVM12020 ZVM12030- ZVM12050 ZVM12060- ZVM12100 ZVM12120- ZVM14030 ZVM14040- ZVM14060 ZVM14080- ZVM14120 Class D Shelf Life: 3 years	ZVM04120- ZVM05040- ZVM05100- ZVM06030- ZVM06060- ZVM06120- ZVM07040- ZVM07080- ZVM08020- ZVM08050- ZVM08100- ZVM09030- ZVM09060- ZVM09120- ZVM10030- ZVM10060- ZVM10120- ZVM12040- ZVM12080- ZVM14020- ZVM14050- ZVM14100-	
106.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi. (ELI-00019) Evaluator AD-III	Legal Manufacturer: Abbott Diagnostics Korea Inc., 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi do 17099, Republic of Korea. Manufacturing sites: Abbott Diagnostics Korea Inc., 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi do 17099, Republic of Korea & Abon Biopharm (Hangzhou) Co., Ltd. #198, 12th Street East, Hangzhou Economic &	Bioline™ Malaria Ag P.f/Pan Bioline™ Malaria Ag P.f/Pan Class-C Shelf life: 24 Months Code: 05FK60	Deferred for provision of following info/documents: ISO 13485 of Abbott Diagnostics Korea expired but valid upon submission. FSC is not provided, the provided FSC is for code 05FK80 i.e Bioline™ Malaria Ag P.f/P.v.	

		Technological Development Area, Hangzhou, Zhejiang, 310018 P.R. China.		
107.	<p>Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00238)</p> <p>Evaluator AD-III 2694</p>	<p>Legal Manufacturer: CAREGLOVE GLOBAL SDN BHD, LOT, 17479, LORONG SENAWANG 3/2, OFF JALAN SENAWANG 3, SENAWANG INDUSTRIAL ESTATE, 70450 SEREMBAN, NEGERI SEMBILAN, MALAYSIA.</p> <p>FSC Malaysia validity 16-12-2024</p>	<p>ORCARE Latex Surgical gloves (Latex gloves, Powdered)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes: not provided</p>	<p>Deferred for provision of following info/documents: Brand name clarification is required, the applied name on application is Orcare whereas on Form it is mentioned as comfeel plus.</p> <p>Real time shelf life studies.</p> <p>FSC of SRA country/ CE marked document.</p> <p>DoC of the applied product.</p> <p>Essential principle checklist.</p> <p>Labels</p>
108.	<p>Allied Surgicals, 1st Floor, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00238)</p> <p>Evaluator AD-III 2695</p>	<p>Legal Manufacturer: CAREGLOVE GLOBAL SDN BHD, LOT, 17479, LORONG SENAWANG 3/2, OFF JALAN SENAWANG 3, SENAWANG INDUSTRIAL ESTATE, 70450 SEREMBAN, NEGERI SEMBILAN, MALAYSIA.</p> <p>FSC Malaysia validity 15-07-2024</p>	<p>ORCARE Latex Surgical gloves (Latex gloves, Powdered)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes & Sizes: not provided</p>	<p>Deferred for provision of following info/documents: Brand name clarification is required, the applied name on application is Orcare whereas on Form it is mentioned as comfeel plus.</p> <p>Real time shelf life studies.</p> <p>FSC of SRA country/ CE marked document.</p> <p>DoC of the applied product.</p> <p>Essential principle checklist.</p> <p>Labels</p>
109.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00049)</p> <p>Evaluator AD-III 489</p>	<p>Legal Manufacturer: Hunan Pingan Medical Device Technology Co. Ltd., Economic Development Zone, LI Country, Hunan Province, China.</p>	<p>ULTIMATE BLOOD TRANSFUSION SET (Transfusion set)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes/ sizes: Not provided</p>	<p>Deferred for provision of following info/documents: The applied device falls in class-b but the firm applied on Form-6A. Submit the relevant Form and information.</p> <p>Incomplete form, form missing the information related to the device applied.</p> <p>Credential, LOA, ISO 13485 and FQA certificate provided are copies, submit original and notarized documents.</p> <p>FSC in the country of origin is missing.</p> <p>FSC of reference country.</p> <p>Provide complete details of manufacturing and QC processes.</p>

				<p>Provide shelf life studies for the claimed shelf life of 5 years.</p> <p>Provide essential principle checklist.</p> <p>Provide declaration of conformity. Provide the sizes/ codes of the applied device as per FSC (not provided).</p> <p>Provide labels of all applied codes.</p> <p>Product details.</p> <p>Updated ISO 13485 certificate.</p>
110.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00049)</p> <p>Evaluator AD-III 3910</p>	<p>Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mounrtain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.</p> <p>FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023</p>	<p>Flexicare Ventilator Breathing System (Ventilator breathing system adult)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes: As per FSC</p>	<p>Deferred for provision of following info/documents:</p> <p>Credentials of manufacturer abroad, MRP of the device.</p> <p>LOA, FSC of china provided are copies.</p> <p>FSC of UK MHRA provided is scanned copy and without the list of devices.</p> <p>Labels of applied codes.</p> <p>Apply separately for other type i.e pediatric type.</p>
111.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi</p> <p>(ELI-00049)</p> <p>Evaluator AD-III 3911</p>	<p>Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mounrtain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.</p> <p>FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023</p>	<p>Flexicare Non-rebreathing Mask</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes mentioned on LOA: 032-10-070 032-10-071 032-10-072 032-10-072NC 032-10-072SM 032-10-073 032-10-076 032-10-078 032-10-078NC</p>	<p>Deferred for provision of following info/documents: Credentials of manufacturer abroad, MRP of the device.</p> <p>LOA, FSC of china provided are copies.</p> <p>FSC of UK MHRA provided is scanned copy and without the list of devices.</p> <p>Labels of applied codes.</p> <p>Apply separately for other type i.e pediatric type.</p>
112.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00049)</p>	<p>Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mounrtain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical</p>	<p>Flexicare Post-Operative Therapy T-Piece Kit Oxygen</p> <p>Class-B</p> <p>Shelf life: 5 years</p>	<p>Deferred for provision of following info/documents: Credentials of manufacturer abroad.</p> <p>Stability studies of claimed shelf life.</p>

	<p>Evaluator AD-III 3912</p>	<p>(Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.</p> <p>FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023</p>	<p>Codes mentioned on LOA: 032-10-540 032-10-541 032-10-560</p>	<p>MRP of the device.</p> <p>LOA, FSC of china provided are copies.</p> <p>FSC of UK MHRA provided is scanned copy and without the list of devices.</p> <p>Declaration of conformity.</p> <p>Labels of applied codes.</p> <p>Apply separately for other types.</p>
113.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00049)</p> <p>Evaluator AD-III 3913</p>	<p>Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.</p> <p>FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023</p>	<p>Flexicare Venturi Mask</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes: As per FSC</p>	<p>Deferred for provision of following info/documents: Credentials of manufacturer abroad.</p> <p>Stability studies of claimed shelf life.</p> <p>MRP of the device.</p> <p>LOA, FSC of china provided are copies.</p> <p>FSC of UK MHRA provided is scanned copy and without the list of devices.</p> <p>Declaration of conformity.</p> <p>Updated FQA certificate.</p> <p>Labels of applied codes.</p> <p>Apply separately for other types.</p>
114.	<p>Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi.</p> <p>(ELI-00049)</p> <p>Evaluator AD-III 3914</p>	<p>Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.</p> <p>FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023</p>	<p>HepaShield Mechanical / Bacterial Vira Breathing Filter</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes mentioned on LOA 038-41-370 038-41-375 038-41-380 038-41-385</p>	<p>Deferred for provision of following info/documents: Credentials of manufacturer abroad.</p> <p>Stability studies of claimed shelf life.</p> <p>MRP of the device.</p> <p>LOA, FSC of china provided are copies.</p> <p>FSC of UK MHRA provided is scanned copy and without the list of devices.</p> <p>Declaration of conformity.</p> <p>Updated FQA certificate.</p>

				Labels of applied codes. Apply separately for other types.
115.	Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00049) Evaluator AD-III 3915	Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China. FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023	Flexicare Reservoir Bag Class-B Shelf life: 5 years Codes mentioned on LOA 038-81-820NL 038-81-830NL 038-82-805NL 038-82-810NL 038-83-820NL	Deferred for provision of following info/documents: Credentials of manufacturer abroad. Stability studies of claimed shelf life. MRP of the device. LOA, FSC of china provided are copies. FSC of UK MHRA provided is scanned copy and without the list of devices. Declaration of conformity. Updated FQA certificate. Labels of applied codes.
116.	Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00049) Evaluator AD-III 3916	Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China. FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023	Mapleson Circuit (Mapleson C adult bagging circuit system) Class-B Shelf life: 5 years Codes: As per FSC	Deferred for provision of following info/documents: Credentials of manufacturer abroad. Stability studies of claimed shelf life. MRP of the device. LOA, FSC of china provided are copies. FSC of UK MHRA provided is scanned copy and without the list of devices. Declaration of conformity. Updated FQA certificate. Labels of applied codes. Apply separately for other types.
117.	Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00049) Evaluator AD-III 3917	Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China.	MaxiNeb Nebulizer (Nebulizer with T-Piece Mouthpiece and 2.1m oxygen tubing) Class-B Shelf life: 5 years Codes mentioned on LOA: 032-10-005	Deferred for provision of following info/documents: Credentials of manufacturer abroad. Stability studies of claimed shelf life. MRP of the device.

		Guangdong Province, 523460 China. FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023	032-10-019 032-10-121	LOA, FSC of china provided are copies. FSC of UK MHRA provided is scanned copy and without the list of devices. Declaration of conformity. Updated FQA certificate. Labels of applied codes. Apply separately for other types.
118.	Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00049) Evaluator AD-III 3918	Legal Manufacturer: Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, United Kingdom Manufacturing site: Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460 China. FSC China validity 17-03-2023 FSC MHRA UK Valid Upton: 07-07-2023	Thermoshield Heat and Moisture Exchanger (HME) Filters Class-B Shelf life: 5 years Codes mentioned on LOA: 038-41-330 038-41-335 038-41-350 038-41-335 038-41-156	Deferred for provision of following info/documents: Credentials of manufacturer abroad. MRP of the device. LOA, FSC of china provided are copies. FSC of UK MHRA provided is scanned copy and without the list of devices. Labels of applied codes. Apply separately for other types with catheter and mini types.
119.	ACP Systems Pakistan, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi. (ELI-00001) Evaluator AD-III 4524	Legal Manufacturer: Shanghai Microport Medical (Group) Co., Ltd. 501 Newton Road, ZJ Hi-Tech park, 201203, Shanghai P.R. China. FSC China Valid Till 2-12-2022 FSC Netherland validity 26-05-2024	FIREHAWK Rapamycin Target Eluting Coronary Stent System Class-D Shelf life: 2 years Codes as per FSC	Deferred for provision of following info/documents: Clarification/provision of valid and original notarized Letter of Authorization from ACP Systems Pakistan, Karachi and M/s Otuska, Karachi with the legal manufacturer mentioned in column (III).
120.	M/s. Freesia Enterprises Address: First Floor, 104 Dawn Plaza, Bank Road, saddar, Rawalpindi ELI:00201 Evaluator: AD-III 1051-P	Legal Manufacturer: M/s. WRP Asia Pacific Sdn.Bhd Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Valid till: 18.04.2020	Foley Cath-2 way standard NR latex balloon catheter sterile Class-B Shelf Life: 3 years Codes as per FSC	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • Provide Brand name of the device. • Provide valid LOA, duly notarized. • Provide original and valid FSC in the country of origin, duly attested. • Provide FSC of Reference country as the device is not from reference country, duly attested.

				<ul style="list-style-type: none"> • Provide manufacturing and QC testing of the device. • Clearly state the codes required and submit the labels of all applied codes. Provide MRP of the device.
121.	Shirazi Trading Company (Pvt) Ltd., 114-C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi (ELI-00263) Evaluator AD-III 2361	Legal Manufacturer: M/s GE Medical Systems Information Technologies, Inc. 8200 West Tower Avenue, Milwaukee, WI 53223, USA Manufacturing Site: M/s GE Medical Systems Information Technologies Critikon de Mexico S. de R.L. de C.V. Calle Valle del Cedro 1551, Juarez 32575, Mexico FSC Germany Issuance Date (14-12-2018)	Carescape One (Patient monitor w/ Arrhythmia detection) Class-C Shelf life: N/A Model MBZ101	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. • Provide valid ISO 13485 and FQA certificate, duly notarized. • Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan.
122.	Shirazi Trading Company (Pvt) Ltd., 114-C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi (ELI-00263) Evaluator AD-III 2347	Legal Manufacturer: M/s GE Medical Systems Co. Ltd, no.1 Yong Chang North Road, Economic Technological Development Zone, Beijing, PR China FSC China Valid Till (25-03-2021)	Brivo OEC 865 (OEC Brivo Plus) Class-C Shelf life: N/A Model: Brivo OEC 865	Deferred for provision of following info/documents: <ul style="list-style-type: none"> • Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. • Provide valid FSC in the country of origin, duly attested as the provided FSC has been expired. • Provide valid FSC of reference country as the device is not on free sale in reference country, duly attested. • Provide valid ISO 13485 and FQA certificate, duly notarized. • Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan.

				<ul style="list-style-type: none"> Provide label of applied device, approved in country of origin.
123.	<p>M/s Shirazi Trading Company (Pvt) Ltd., 114-C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi</p> <p>(ELI-00263)</p> <p>Evaluator AD-III</p>	<p>Legal Manufacturer: GE Medical Systems, LLC 3000 N Grandview BLVD. Waukesha, WI USA 53188</p> <p>Manufacturing sites: GE Medical sytems, LLC 30012 West Radio Dr.Florence SC USA 29501 and GE Healthcare (Tianjin) Company Limited No. 266 Jingsan Road Tianjin Airport Economic Area Tianjin, Tianjin China 300308</p> <p>(FSC USA valid 27-06-2020)</p>	<p>Optima MR450w 1.5T Full-body MRI System, Superconducting Magnet</p> <p>Class B</p> <p>Shelf Life: No Shelf Life limitation</p> <p>Sizes & Codes as Per FSC</p> <p>Optima MR450w 1.5T</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. Provide valid and original FSC in the country of origin, duly attested by the Embassy of Pakistan. Provide valid ISO 13485 and QA certificate of Legal Manufacturer M/s GE Medical system, LLC Wisconsin, USA, duly notarized. Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan.
124.	<p>M/s Shirazi Trading Company (Pvt) Ltd., 114-C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi</p> <p>(ELI-00263)</p> <p>Evaluator AD-III 1722</p>	<p>Legal Manufacturer: GE Healthcare (Tianjin) Company Limited No.266 jiangsan Road, Tianjin Airport Economic Area.</p> <p>(FSC China valid 18-06-2020)</p>	<p>Signa Creator Full-body MRI System, Superconducting Magnet</p> <p>Class B</p> <p>Shelf Life: No Shelf Life Limitation.</p> <p>Sizes & Codes as Per FSC</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. Provide valid and original FSC in the country of origin and FSC of reference country as per Rule 71 of MDR, 2017, duly attested by the Embassy of Pakistan. Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan.
125.	<p>Shirazi Trading Company (Pvt) Ltd., 114-C, Al-</p>	<p>Legal Manufacturer:</p>	<p>Revolution CT Full-body CT System</p>	<p>Deferred for provision of following info/documents:</p>

	<p>Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi.</p> <p>(ELI-00263)</p> <p>Evaluator AD-III 2348</p>	<p>M/s GE Medical Systems LLC, 3000 North Grandview Blvd, Waukesha, USA</p> <p>FSC USFDA Valid Till (23-01-2021)</p>	<p>Class-C</p> <p>Shelf life: N/A</p> <p>Model:</p>	<ul style="list-style-type: none"> • Provide Letter of Authorization with clear validity as the given LOA is mentioning the distribution agreement expiry date, which is not provided. • Provide valid FSC in the country of origin, duly attested as the provided FSC has been expired. • If the manufacturing site is Japan then provide the ISO 13485 and FQA certificate of manufacturing site. • Provide valid ISO 13485 and FQA certificate, duly notarized. • Provide details of manufacturing and QC/product performance report of the applied product and not general quality plan. • Provide label of applied device with reference no mentioned on, approved in country of origin. • Provide Reference manual and IFU of the applied device.
126.	<p>M/s. Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi. (ELI-00034).</p> <p>Evaluator AD-VI -1055-P</p>	<p>Legal Manufacturer: MicroVention Inc. USA. Manufacturing Site: MicroVention Inc. Costa Rica. FSC: U.S.A Valid till: 27/01/2022.</p>	<p>AZURE Peripheral Embolization Coil System. (Pushable) Codes & Sizes: As per FSC Class-C Shelf life: 03-years</p>	<p>Deffered for provision of following info/documents:</p> <ul style="list-style-type: none"> • Original and valid LoA, valid 13485 and Full QA.
127.	<p>Roche Pakistan Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi (ELI-00009)</p> <p>Evaluator AD-VI -2023-</p>	<p>Legal Manufacturer & mfg. site: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany</p> <p>FSC Germany Issuance Date (09-01-2019)</p>	<p>ROCHE COBAS Electrodes and Reagents of 9180 Analyzer 34 Week, 28Weeks, 22Weeks, 20Weeks, 52Weeks, 30Weeks, 36Weeks. Codes & Sizes as per FSC. 3110419180, 3110338180, 3110451180, 3110664180, 3110354180, 3112306180, 3112284180, 3112349180, 3111555180, 3110362180, 3112888180, 3110249180.</p>	<p>Deffered for provision of following info/documents:</p> <ol style="list-style-type: none"> Provide the original and valid agency agreement. The applied products of 'cluster' does not fall in the in the same category and methodology table of 'grouping', as per rule (11) of MDR, 2017, clarification/justification is required. As per 4 (vii) & (x) of Form-7A, you have submitted the in-use and

				<p>real-time studies, it is requested to provide the stress/ accelerated studies of the products and IFU must mention the In-Use stability (i.e., of few weeks).</p> <p>iv. Provide the certifications of ISO-13485, FullQA and Declaration of conformity (DoC) referred the manufacturer(s) involved in the production.</p> <p>Provide original FCS.</p>
128.	<p>M/s. Roche Pakistan Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi.</p> <p>Evaluator AD-VI -1988-</p>	<p>Legal Manufacturer & mfg. site: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. FSC: 27.01/2022.</p>	<p>COBAS ELECSYS (Anti HBs-II Test Kit). Codes & Sizes: As per FSC Class-D Shelf life:15-months.</p>	<p>Deferred for provision of following info/documents: Original and valid agency agreement. The valid certifications of Full Quality Assurance, Design Examination and ISO-13485. The applied product falls in Class-D category and you have submitted fee of PKR. 5000/- So, it advised to submit differential fee for Class-D as per Schedule-C of MDR-2017.</p>
129.	<p>Roche Pakistan Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi (ELI-00009)</p> <p>Evaluator AD-VI 1986-K</p>	<p>Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany</p> <p>FSC Germany Issuance Date (15-03-2017)</p>	<p>ROCHE COBAS Electrodes and Reagents of b121 6.5 Month. 18 Month. 24 Month. Class-B Codes & Sizes as per FSC. 03111717180, 03111695180, 03111679180, 03111873180, 03111644180, 03111598180, 03111628180, 03111571180, 03144046001, 03144020001, 03144038001, 03321258001, 03321266001, 03321274001</p>	<p>Deferred for provision of following info/documents:</p> <p>i. Provide the original and valid agency agreement.</p> <p>ii. The applied products of 'cluster' does not fall in the in the same category and methodology table of 'grouping', as per rule (11) of MDR, 2017, justification is required.</p> <p>iii. Provide the certifications of ISO-13485, Full Quality Assurance and Declaration of conformity (DoC).</p> <p>Provide original FSC.</p>
130.	<p>Medtronic Pakistan (Pvt) Ltd., Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)</p> <p>Evaluator</p>	<p>Legal Manufacturer & mfg. site: Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA.</p>	<p>IMPLANTABLE leads Accessories (Lead End Cap & Service Kit) Codes and sizes as per FSC. Class-D Shelf life:04-years.</p>	<p>Deferred for provision of following info/documents:</p> <ul style="list-style-type: none"> • brand name and valid & original FSC of country of origin and/or RRA. • valid ISO-13485.

	AD-VI -3542-			<ul style="list-style-type: none"> • Original Letter of Authorization. • Stability studies and QC-details & Certificate of compliance. <p>Clarification is required for the different kits or accessories have been applied in single application.</p>
131.	<p>M/s Fresenius Medical Care Pakistan Pvt. Ltd.; TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan</p> <p>ELI-00315.</p> <p>Evaluator AD-VI -1528-</p>	<p>Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA Address: 61346 Bad Homburg Germany Manufacturing Site: Nova Med GmbH Address: Antalya Serbest Bölgesi Merkez Subesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya, Turkey. FSC: Germany. Date of issue: 23-07-2019.</p>	<p>MULTIFILTRATE Pro TAPE Blood Line. Code: F00006432</p> <p>Class-B</p> <p>Shelf Life: 03-years</p>	<p>Deffered for provision of following info/documents:: Original and valid agency agreement.</p> <p>The valid certificates of Full QA, Design Examination and ISO- 13485.</p> <p>The subject of the fee submission is 'Fee for Additional size' and doesn't contain the product name, while the application is for new registration. Hence you're advised to submit the fee for applied product as per MDR-2017.</p>
132.	<p>M/s Fresenius Medical Care Pakistan Pvt. Ltd.; TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan</p> <p>ELI-00315</p> <p>Evaluator AD-VI -1529-</p>	<p>Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA :61346 Bad Homburg Germany. Manufacturing Site Name: Nova Med GmbH Antalya Serbest Bölgesi Merkez Subesi No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya, Turkey. FSC: Germany Date of issue: 11-06-2019.</p>	<p>HEMOFLOW F6 HPS [5007061]</p> <p>Hemoflow F8 HPS Code:5007081</p> <p>(Dialysers/Filters</p> <p>Class-C</p> <p>Shelf Life; 03-years</p>	<p>Deffered for provision of following info/documents:-</p> <p>Original and valid agency agreement.</p> <p>The valid certifications of Full Quality Assurance, Design Examination and ISO-13485.</p> <p>The subject of the fee submission is 'Fee for Additional size' and doesn't contain the product name, while the application is for new registration. Hence you're advised to submit the fee for applied product as per MDR-2017.</p>
133.	<p>M/s Fresenius Medical Care Pakistan Pvt. Ltd.; TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan</p> <p>ELI-00315. Evaluator AD-VI -1530-</p>	<p>Legal Manufacturer & Mfg. site: Fresenius Medical Care AG & Co. KGaA :61346 Bad Homburg Germany.</p> <p>FSC: Germany. Date of issue: 08/01/2020.</p>	<p>HEMOFLOW F10 HPS (Dialysers/Filters Codes & Sizes: As FSC Class-B</p> <p>Shelf Life; 03-years</p>	<p>Deffered for provision of following info/documents: Original and valid LOA. valid certifications of FullQA, Design Examination and ISO- 13485.</p> <p>The subject of the fee submission is 'Fee for Additional size' and doesn't contain the product name, while the application is for new registration. Hence you're advised to</p>

				submit the fee for applied product as per MDR-2017.
134.	M/s Fresenius Medical Care Pakistan Pvt. Ltd.; TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan ELI-00315 Evaluator AD-VI -1843-	Legal Manufacturer & Mfg. site: M/s Fresenius Medical Care AG&co., KGaA, 61346 Bad Homburg Germany FSC: Germany Date of issue: 14. 06.1993	ADAPTER HANSEN male/ Luer-lock male (5016881) (Accessories for HD Sterilised by ETO) Class -B Shelf Life: 03-years	Deferred for provision of following info/documents: Original and valid agency agreement, FSC, valid certifications of Full Quality Assurance, Design Examination and ISO-13485.
135.	M/s Fresenius Medical Care Pakistan Pvt. Ltd.; TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan ELI-00315. Evaluator AD-VI -2593-	Legal Manufacturer: Fresenius Medical Care, Deutschland, Obererelenbach Plant Steinmuhlstrasse 24 61352 Bad Homburg Germany FSC: Germany Date of Issue: 20/03/2020	MULTIFILTRATE Kit Ci-Ca post CVVHDF 1000 (Therapy sets for acute dialysis treatments) Codes & Sizes: As per FSC Class-C Shelf Life: 03-years	Deferred for provision of following info/documents: Original and valid agency agreement, valid certifications of Full Quality Assurance, Design Examination and ISO-13485.
136.	M/s Fresenius Medical Care Pakistan (Pvt) Ltd. TAMC, First Floor, 27-C III, M.M Alam Road Gulberg III, Lahore ELI: 00315. Evaluator AD-VI -603-	Legal Manufacturer: M/s Fresenius Medical Care AG & Co., KGaA, 61346 Bad Homburg, Germany. FSC: Germany. Date of Issue: 14.06.1993.	DALI Priming Solution 3000 ml. (Priming Solution) Codes & Sizes: As per FSC Class-A Shelf Life: 02-years	Deferred for provision of following info/documents: Original and valid agency agreement, FSC, valid certificates of Full QA, Design Examination and ISO-13485.
137.	M/s Fresenius Medical Care Pakistan (Pvt) Ltd. TAMC, First Floor, 27-C III, M.M Alam Road Gulberg III, Lahore ELI: 00315 Evaluator AD-VI -611-	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany FSC: Germany Date of Issue: 06.02.2020	STAY SAFE Organizer & Stay safe Holder for Organizer (PD Accessories) Codes & Sizes: As per FSC Class-A Shelf Life: 05-years	Deferred for provision of following info/documents: Original and valid agency agreement, valid certificates of Full Quality Assurance, Design Examination and ISO-13485.
138.	M/s Claris Medical Unit No. 27, Twin City Plaza, 1-8 Markez, Islamabad. ELI: 00269 Evaluator AD-VI -1855-	Legal Manufacturer & mfg. site: M/s MEDISTIM ASA Okernveien 94 No-0579 Oslo, Norway. Manufacturing Site: Bromsveien 17 3183 Horten, Norway. FSC (copy): Norway Date of issue: 02.03.2020.	MEDISTIM Doppler Probe. (Doppler Probes to Measure Blood Flow Velocity) Class-B Shelf Life: ----- Codes and Sizes as per FSC.	Deferred for provision of following info/documents: • Differential fee as the product fall in class-C, while firm applied in class-B. • Original and Valid FSC of country of origin & any RRA and Letter of authorization. • valid ISO-13485 Certificate of all manufacturing sites; Justifiable stability study data with protocols.
139.	M/s Medisurg Innovatives Health Care, 1/6-N, Block-6, PECHS, Main Nursery, Shahrah e Faisal, Karachi.	Legal Manufacturer & mfg. site: The Legal MFG: Contract Medical International	FORTRESS Introducer Sheath System. Codes and Sizes as per FSC.	Deferred for provision of following info/documents: Original & valid agency agreement, ISO-13485 and

	ELI: 00242. Evaluator AD-VI -1388-K	GmbH Lauensteiner Strasse 37 01277 Dresden, Germany The actual MFG: Contract Medical International spol S.r.o Vazni 848 500 03 Haradec Kralove Czech Republic 2. Merit Medical Systems, Inc, 1600 West Merit Parkway, South Jordan, Utah, 84095, USA Manufacturer of critical component Steris AST CZ s.t.o Proumyslova zona, Kosikov 80, 59 501 Velka Bites Czech, Republic sterilization. FSC: Germany Date of issue: 14.05.2019.	Class: D Shelf Life: 3 years.	undertaking on stamp paper.
140.	M/s Treu-Dynamic International (Pvt), Ltd Office No. C-206, 2 nd Floor, City Towers, Main Boulevard Gulberg, Lahore. ELI: 00175 Evaluator AD-VI	Legal Manufacturer & mfg. site: ANTON HIPPI GmbH Annastrasse 25/1 78567 Frindingen/ Germany. FSC: Germany (copy) Date of issue: 01 st Dec.2017	MAXILLOFACIAL Osteosynthesis System. GMDN 16056. Class C Shelf Life: ----- Codes & Sizes as per FSC	Defferred for provision of following info/documents: <ul style="list-style-type: none">• Original FSC, ISO-13485 and DoC.• Justifiable validation and quality details. Firm asked to provide brand name as 'MAXILLOFACIAL' While on fee slip it is mentioned as CRANIOFACIAL, clarification required in this regard.
141.	AJ International Company Suite # 313, 3rd Floor, Mashriq Center, Gulshan- e- Iqbal Block 14, Karachi Pakistan. Evaluator AD-VI -3375-	Legal Manufacturer & mfg. site: Evolutis S.A.S Avenue De La Liberation 42720 Briennon France	CAPITOLE Cemented Dual Mobility Cup. Class: C Shelf Life: 5 Years Codes & Sizes as per FSC.	Defferred for provision of following info/documents: <ul style="list-style-type: none">• labels & EPSPs of the product; the valid ISO-13485 & Full QA Certificates.
142.	AJ International Company Suite # 313, 3rd Floor, Mashriq Center, Gulshan- e- Iqbal Block 14, Karachi Pakistan. Evaluator AD-VI -3376-	Legal Manufacturer & mfg. site: Evolutis S.A.S Avenue De La Liberation 42720 Briennon France	CAPITOLE I, T, R Dual Mobility Cup. Class: C Shelf Life: 5 Years Codes & Sizes as per FSC.	Defferred for provision of following info/documents: <ul style="list-style-type: none">• labels & EPSPs of the product; the valid ISO-13485 & Full QA Certificates.

Item No. XXIX. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A)

The following applications for grant of enlistment of medical devices for import on prescribed form 6A Under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB.

Decision: The Board discussed the below mentioned applications for registration of medical devices for import and decided as mentioned against each.

Sr. No.	Name & Address of Establishment	Name of Manufacturer	Name of Medical Devices With Size	Brief Description	Remarks	Decision
1.	FM Health Care, 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road, Karachi. (ELI-00082) Evaluator AD-III 179	Legal Manufacturer: M/s RLMOS S.r.l Viale Gramsci 29-41037 Mirandola (MO), Italy FSC Italy Issuance Date (25-11-2016)	IUI Cannula Ainseblue / Ainsewhite / Ainsegrey (Intra Uterine) Intrauterine Insemination Class-A Shelf life: 5 Years Codes & Sizes as per FSC	IUI Cannula/Catheter is primarily used in Assisted Reproductive laboratories for insemination of sperms in uterine cavity.	<ul style="list-style-type: none"> • Provide updated and original LOA, duly notarized. • Provide original FSC in the country of origin, duly attested. • Provided ISO 13485 is without notarization, submit notarized ISO 13485 certificate. • Provide valid FQA certificate, duly notarized. • Provide English version of stability studies of claimed shelf life. • Provide device detailed description in English version, the provided description is in Italian Language. • Provide labels of applied codes, approved in the country of origin as the provided labels are in Italian Language. 	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • updated and original LOA, duly notarized. • original FSC in the country of origin, duly attested. • ISO 13485 is without notarization, submit notarized ISO 13485 certificate. • valid FQA certificate, duly notarized. • English version of stability studies of claimed shelf life. • device detailed description in English version, the provided description is in Italian Language. • Provide labels of applied codes,

					<ul style="list-style-type: none"> Firm applied in Class-A, but need to be registered as Class-B, as cannula being registered in Class-B, so differential fee of 20,000/- to be submitted. 	approved in the country of origin as the provided labels are in Italian Language <ul style="list-style-type: none"> Firm applied in Class-A, but need to be registered as Class-B, as cannula being registered in Class-B, so differential fee of 20,000/- to be submitted.
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Decision: The Board discussed the below mentioned applications for registration of medical devices for import and decided as mentioned against each.

Sr. No.	Name & Address of Establishment	Name of Manufacturer	Name of Medical Devices With Size	Brief Description	Reason for Defer	Remarks	Decision
1.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: AD-VI -3542-	Legal Manufacturer: Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA. Mfg. site: Medtronic peurtp rico operations Co., Villalba Rd149, Km, 56.3, Call Box6001, VillalbaPR00766 USA. FSC: USFDA (copy- Valid till 22 June 2022)	Implantable leads Accessories. (Lead End Cap & Service Kit) Class-D Shelf life..... Codes and sizes as per FSC	Pacing/defibrillation lead cap kit Torque Manipulation Device Pacing Defibrillation lead repair kit.	Deferred for provision of following documents: - <ul style="list-style-type: none"> Provide the brand name and valid & original FSC of country of origin and/or RRA. Clarify and Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved 	The firm submitted documents are still deficient.	Deferred for provision of deficient document

					<p>in the production activities of subject products.</p> <ul style="list-style-type: none"> • Provide the Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details & Certificate of compliance. <p>Clarification is required for the different kits or accessories have been applied in single application for the product at sr. no. 01.</p>		
2.	<p>M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.</p> <p>ELI: 00273</p> <p>3549 (K)</p> <p>Evaluator AD-IX</p>	<p>Legal Manufacturer</p> <p>Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA</p> <p>Manufacturing facility: Medtronic perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA</p> <p>Medtronic Mexico, S. De R.L. De C.V Av. Paseo Cucapah, 10510 El Lago C.P. 22210 Tijuana, Baja California, Mexico.</p> <p>FSC: US FDA (copy)</p> <p>Valid till: 01/04/2022</p>	<p>Affinity CP Centrifugal Blood Pump with Cortiva Bioactive Surface</p> <p>(Cardiopulmonary bypass system centrifugal pump)</p> <p>Class D</p> <p>Shelf Life: 2 years.</p> <p>Grouping: SMD</p> <p>()</p>	<p>This is a single use device. This device is intended to be connected to a drive unit (bot included) to circulate blood through the extracorporeal circuit of a non roller type cardiopulmonary bypass system, via a centrifugal force mechanism. For gas exchange and refusion, it may in addition be used in extracorporeal support system for ventricular support/circulatory assistance, It includes flow channels and a rotor driven by the system's drive unit. This device is used to pump blood through the extracorporeal bypass circuit</p>	<p>Deferred for:</p> <ul style="list-style-type: none"> • Provide original, legalized and valid Free Sale Certificate (FSC) since expired copy of FSC is submitted. • Provide notarized and valid production quality assurance certificate, design examination certificate and Declaration of conformity. • A brief discussion on the quantitative analysis is required with respect to the applied medical device <p>Stability studies for the medical devices supporting claim of 2 years shelf life with respect</p>	<p>The submitted documents are still deficient</p>	<p>Deferred for provision of deficient document.</p>

				for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 months).	to bioactive surface (Heparin).		
3.	<p>M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.</p> <p>ELI: 00273</p> <p>3547 (K)</p> <p>Evaluator AD-IX</p>	<p>Legal Manufacturer: Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA</p> <p>Manufacturing facility: Medtronic perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA</p> <p>Medtronic Mexico, S. De R.L. De C.V Av. Paseo Cucapah, 10510 El Lago C.P. 22210 Tijuana, Baja California, Mexico.</p> <p>FSC: US FDA (copy)</p> <p>Valid till: 01/04/2022</p>	<p>Affinity NT Integrated CVR / Membrane Oxygenator with Cortiva Bioactive Surface</p> <p>Class D</p> <p>Shelf Life: 2 years.</p> <p>Grouping: SMD</p> <p>0</p>	<p>This is a single use device. This device is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiectomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures upto 6 hours in duration.</p>	<p>Deferred for:</p> <ul style="list-style-type: none"> • MRP is not provided. • Since manufacturer has used Heparin based cortiva bioactive surface therefore, provide stability studies supporting 2 years shelf life and analytical procedures for routine analysis of the device with respect to Heparin, please, Moreover, provide the data related to the release studies of Heparin during the device's operation. • Original, legalized and valid FSC. • Design examination certificate is required. • Full quality assurance certificate is required. <p>Instruction for use</p>	<p>The submitted documents are still deficient</p>	<p>Deferred for provision of deficient document.</p>
4.	<p>M/s Medtronic Pakistan</p>	<p>Legal Manufacturer</p>	<p>Attain Performa Straight MRI SureScan</p>	<p>A sterile implantable flexible wire</p>	<p>Deferred for:</p>	<p>The submitted documents</p>	<p>Deferred for provision of deficient</p>

	<p>(Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.</p> <p>ELI: 00273</p> <p>3541 (K)</p> <p>Evaluator AD-IX</p>	<p>Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA Manufacturing facility: Medtronic Puetro Rico Operations Co., Villalba Rd/149, Km 56.3, call box 6001, Villalba, PR 00766, USA. FSC: US FDA (copy)</p> <p>Valid till: 22/06/2022</p>	<p>(Coronary venous pacing lead)</p> <p>Class D</p> <p>Shelf Life: 2 years.</p> <p>Grouping: Family</p> <p>(4398-78, 4398- 88)</p>	<p>with an electrode, insulated with non-conductive material except at its end, which serve as an electrical conductor to transmit pacing impulses from an implanted cardiac resynchronizati on therapy pulse generator to the left ventricle of the heart. It may also transmit electrical responses from the hear back to the pacemaker, it is not intended to conduct defibrillation impulses. The electrode introduced into a cardiac vein through transvenous approach via the coronary sinus. It is typically impregnated with a steroid intended to elute into the tissue to reduce inflammation.</p>	<ul style="list-style-type: none"> • Provide original, legalized and valid Free Sale Certificate (FSC) since copy of FSC is submitted. • Provide notarized production quality assurance certificate and Declaration of conformity. • A brief discussion on the deliverable quantity of Dexamethason e along with the relevant studies for measuring the quantity to be delivered. • Protocol and detailed testing method for the device as well as for Dexamethason e contained in the device. <p>Stability studies for the medical devices supporting claim of 2 years shelf life with respect to Dexamethasone.</p>	are still deficient	document.
5.	<p>M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.</p> <p>(ELI-00273)</p> <p>2514</p>	<p>Legal manufacturer: Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA</p> <p>Manufacturing sites: Medtronic Europe Sarl. Route du Molliau 31, Case Postale, 1131Tolochenaz, Switzerland</p>	<p>Attestat S DR MRI SureScan</p> <p>Dual Chamber Implantable Pace Maker, rate-responsive.</p> <p>Codes & Sizes as per FSC"</p> <p>Clasas-D</p> <p>Shelf Life: 18 months from the date of power</p>	<p>Intended Use: This device is indicated for use in patients who are experiencing exercise intolerance or exercise restrictions related to an arrhythmia. Using rate response modes may restore heart</p>	<p>Deferred for provision of following documents: -</p> <ul style="list-style-type: none"> ▪ Valid Full QA certificate or equivalent. ▪ Valid Declaration of Conformity (DoC) duly notarized from country of origin. ▪ Original and 	The submitted documents are still deficient	Deferred for provision of deficient document.

	<p>Evaluator: AD-II</p>	<p>FSC Netherlands valid till 01-07- 2020</p>	<p>source connection</p>	<p>rate variability and improve cardiac output. The Medtronic Attest DR MRI SureScan model ATDRS1 implantable pulse generator (IPG) is indicated for single use only.</p>	<p>Valid Free Sale Certificate of the country of origin duly attested by Embassy of Pakistan.</p> <ul style="list-style-type: none"> Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributor duly notarized by the country of origin. Credentials of manufacturer abroad duly notarized from the country of origin. Complete stability studies data supporting the claimed shelf life. 		
6.	<p>M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.</p> <p>(ELI-00273)</p> <p>2487</p>	<p>Legal manufacturer: Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA</p> <p>FSC Netherlands valid till 01-07- 2020</p>	<p>Claria MRI Quad CRT-D SureScan Cardiac resynchronizati on therapy implantable defibrillator Code: (DTMA2Q1)</p> <p>Class-D Shelf-life: 18 months</p>	<p>The Medtronic Model DTMA2Q1 Claria MRI Quad dual chamber, implantable cardioverter defibrillator with cardiac resynchronizat ion therapy (CRT-D) is multiprogram mable cardiac device that</p>	<p>Deferred for provision of following documents: -</p> <ul style="list-style-type: none"> Valid Full QA certificate or equivalent. Valid Declaration of Conformity (DoC) duly notarized from 	<p>The submitted documents are still deficient</p> 	<p>Deferred for provision of deficient document.</p>

	Evaluator: AD-II			monitors and regulates the patient's heart rate by providing single or dual chamber, rate-responsive bradycardia pacing; sequential biventricular pacing; ventricular tachyarrhythmia therapies; and atrial tachyarrhythmia therapies Intended Use: Claria MRI Quad system is indicated for use in patients who are at high risk of sudden death due to ventricular tachyarrhythmia's and who have heart failure with ventricular dyssynchrony. The device is intended to provide atrial and / or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and / or life-threatening ventricular tachyarrhythmia.	country of origin. ▪ Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. ▪ Details of manufacturing and quality control processes. ▪ Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributor duly notarized by the country of origin. ▪ Credentials of manufacturer abroad duly notarized from the country of origin.		
7.	M/s Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8,	Legal Manufacturer & mfg. site: Lorne Laboratories Ltd, Unit 1, Cutbush Park	LORNE Reagents for Cross-matching of Blood Transfusion. Class C Shelf Life:	Reagents for Cross-matching of Blood Transfusion.	Deferred in M-48 for provision of following documents: - <input type="checkbox"/> Original and valid FSC of SRA	The submitted documents are still deficient	Deferred for provision of deficient document.

	K.C.H.S.U. Shahrah-e-Faisal, Karachi. -1691- (ELI-00347) Evaluator: AD-VI	Industrial Estate, Danehill, Lower Earley, Reading, Bershire, RG6 4UT, United Kingdom. (FSC Valid ---)	Anti-human IgG (clear) 24 Months Anti-Human IgG (Green) 24 months A.H.G Elite (Clear) 24 months A.h.G Elite Green 24 months Anti-C3d Monoclonal 24 Months Serological Albumin 22% 24 Months Serological Albumin 30% 24 Months Control Precise Weak Anti-D 24 Months Buffer & Potentiators LISS Ready for use 12 Months LISS-ADD 24 Months PEG-ADD 24 Months		<input type="checkbox"/> Valid ISO-13485 certificate. <input type="checkbox"/> Original & valid agency agreement		
8.	M/s Excel Corporation, 435 BYJ Society, Bahadurabad, Karachi (ELI-00110) Evaluator AD-VI -3996-	Legal Manufacturer & mfg. site: Jiangxi Hongda Medical Equipment Group Ltd No. 39 South Shengli Road, Jinxian County, Jiangxi Province, China. FSC: China. Valid June, 2022.	STAR ONE Sterile Auto- Disable Syringe for Single Use. Class B Shelf Life: 05 years	Sterile Auto- Disable Syringe for Single Use.	Deferred IN M-40 for provision of following documents; <input type="checkbox"/> Firm asked to provide different brand name, real time stability studies data as per claimed shelf life. <input type="checkbox"/> Firm asked to provide QC details alongwith CoA, original and valid LOA, FSC any RRA as per Rule 15(2) MDR, 2017.	The firm submitted documents are still deficient	Deferred for provision of deficient document.
9.	M/s United Healthcare, Plot No. 330, 2nd Floor, DMCH, Bahadurabad, Karachi	Legal Manufacturer & mfg. site: M/s Shandong Caremed Medical	STAR FLO Auto Disable Syringe for Single Use 1ml, 3ml, 5ml, 10ml Class B	Sterile Self Destruction Safety Syringe for Single Use	Deferred in M-40 for provision of following documents; <input type="checkbox"/> Firm asked to provide different brand name, QC	The firm submitted documents are still deficient	Deferred for provision of deficient document.

	(ELI-00293) Evaluator AD-VI -4004-	Products Co., Ltd (Yan Tai) Industrial Park, DingTao County, (The East of Zhanqian Road) Heze 274100 Shandong P.R. China. Copy of FSC for export China.	Shelf Life: 05 years		details alongwith CoA, original and valid LOA, FSC of country of origin and any RRA as per Rule 15(2) MDR, 2017. <input type="checkbox"/> The shelf life is approved for 2 years and for extension / enhancement of shelf-life firm has to submit Real- Time Stability Date for corresponding claimed shelf-life.		
10.	M/s Medicamp Internatinal, Office No, 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi. ELI: 00200. -2425-	Legal Manufacturer & mfg. site: MMD Sp. ZO.O Grudizaa ka 159A, 87-100, Torun Poland FSC: Poland Date of Issue: 2020.06.05	MEDITAMP DENSO KIT (Absorbable Hemostat Oxidized Regenerated Cellulose) Codes & Sizes: As per FSC. Class-C Shelf Life: 24 months	Meditamp Denso Knit is to stop capillary bleeding and parenchymal bleeding as well as bleeding in resection areas during surgical procedures. It is applied to stop bleeding when other hemostatic procedures cannot be employed.	Deferred for provision of following documents:- <input type="checkbox"/> Original FSC of RRA or in accordance of rule 15(2) & as per Sr. No. (4) of Form-7(A). <input type="checkbox"/> Original agency agreement and FSC of country of origin. <input type="checkbox"/> Product description and complete technical data sheet as the product is absorbable. <input type="checkbox"/> Notarized ISO- 13485 certificate/ latest GMP report and QA certificate.	The firm submitted documents are still deficient	Deferred for provision of deficient document.
11.	M/s. IBL HealthCare Limited; 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi. (ELI-00119) 1393-K Evaluator: AD-VI	Legal Manufacturer:M /s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El- Awamer, Abnoub, Assiut, Egypt. FSC: Egypt.	ULTRAMED Infant Feeding Tube. Class-B Shelf life: 3 years	For neonatal and pediatric nutritional feeding. Closed distal end with two later eyes. Tube with radio-opaque line, marked at 20 cm from the tip for accurate placement.	Deferred for provision of following documents: • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original &	The firm submitted documents are still deficient	Deferred for provision of deficient document.

		Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022.		Soft, frosted and kink resistant PVC tubing. Color coded funnel end connector for easy identification of size. Tube Length: 40 cm.	valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.		
12.	M/s. IBL HealthCare Limited; 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi. (ELI-00119) 1396-K Evaluator: AD-VI	Legal Manufacturer: M/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022	ULTRAMED Infant Feeding Tube Class-B Shelf life: 3 years	For neonatal and pediatric nutritional feeding. Closed distal end with two later eyes. Tube with radio-opaque line, marked at 20 cm from the tip for accurate placement. Soft, frosted and kink resistant PVC tubing. Color coded funnel end connector for easy identification of size. Tube Length: 40 cm.	Deferred for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.	The firm submitted documents are still deficient	Deferred for provision of deficient document.
13.	M/s CSM Pakistan (Guarantee) Ltd, 23-C, Old Sunset Boulevard, Phase-2, GHA-Karachi ELI: 00418 -3112- Evaluator: AD-VI	Legal Manufacturer: M/s Altas Link (Beijing) Technology co. Ltd Room 811, Zeyang Plaza No. 166 Fushi Road, Shijingshan Dist. Beijing China FSC: China Valid till: 19/08/2020	XACT (One Step Pregnancy Test Strip) Codes & Sizes: As per FSC Class-B Shelf life: 24 months	Pregnancy Test Strip is to detect the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy.	Deferred in M-50 for the provision of following: - <input type="checkbox"/> Provided LOA does not mention the device name, present the original agency agreement having device applied. <input type="checkbox"/> Provide FSC in the country of origin,	The firm submitted documents are still deficient	Deferred for provision of deficient document.

	III-				<input type="checkbox"/> Provided FSC of reference country as the product is not from reference, duly attested. <input type="checkbox"/> Provide valid ISO 13485 and FQA certificate, duly notarized. <input type="checkbox"/> Provide Contraindications and warnings to inform on specific risk or hazard to the medical device. <input type="checkbox"/> Provide validation for medical device with sterile or with measuring function.		
14.	M/s Med Lab Services, Office No. 1, First Floor, ABC, Plaza, commercial center, Satellite town, Rawalpindi ELI: 00056 Evaluator: AD-VI	Legal Manufacturer: M/s VIRCELL, S.L, Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) and Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1, 18320 Santa Fe, Granada, Spain. FSC: Spain.	VIRCELL Direct SARS-CoV-2 Real time PCR Kit. Codes & Sizes: As per FSC Class:B. Shelf Life: 18 months.	SARS-CoV-2 Real time PCR Kit	Approved subject to provision of the following: i. Provide the original letter of Authorization, Certificates of FQA and DoC. ii. Provide the stability studies data as per claimed shelf-life, manufacturing and QC details along with CoA. iii. The applied products fall in the class-C of the medical device's classification; Accordingly, firm required to submit the differential fee alongwith prescribed form, i.e., form-7A.	The firm submitted documents are still deficient	Deferred for provision of deficient document.
15.	M/s Hitec Corporation Office No. 2, 1st Floor, Ali Complex, Plaza NO. 77, Blue Area Fazal-e-Haq	Legal Manufacturer: Plasti-Med Plastik Medikal Urunler San Ve Tic. Ltd. Sti. Deri OSB Mahallesi Yan	Plasti-Med ® (Ureteral Stents) Codes & Size: As per FSC Class C	Ureteral Stents	Deferred. Firm shall provide valid & original certificates of FSC of any SRA & country of origin.	The firm submitted documents are still deficient	Deferred for provision of deficient document.

	Road Islamabad Evaluator: AD-VI -1990- ELI 00355	San Cad No: 13 Tuzla/Istanbul Turkiye FSC: Turkiye Date of issue: 27.11.2018	Shelf Life: 2-5 years				
16.	M/s MOD Scientific Traders, 3- syed Mouj Darya Road (Edward Road) Lahore ELI 00655. Evaluator: AD-VI -2768-	Legal Manufacturer: M/s Diagast Parc 251, Avenue Eugene Avinee 59210 Loos/France FSC: France	DIAGAST (AGH MAESTRIA IGG+C3d) Codes & Sizes: As per FSC Class-D. Shelf Life: 25 months	The AGH Maestria IGG+C3d are used for erythrocyte phenotyping with blood phenotyping reagents, in testing immune antibodies requiring an indirect antiglobulin test method.	Deferred in M-47 for provision of: - valid & original FSC. address on loa is different from the eli-issued. loa not notarized. valid iso-13485 certificate. qc-details alongwith coas. correction of application form required.	The firm submitted documents are still deficient	Deferred for provision of deficient document.
17.	M/s. Biotech Pakistan, Suite# 301 3rd Floor, Tahir Plaza KCHS Karachi (ELI-00424) -3969- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Erbe Elektromedizin GmbH. Waldhornlestr. 17 72072 Tubingen Germany FSC: Germany Issue date: 13-11-2019	ERBEJET Hydro-surgical Unit. Class-C Shelf Life: 07- years Codes & Sizes as per FSC.	The ERBEJET is a simple, easy-to-use waterjet surgery system. The ERBEJET 2 fits nicely into a standard VIO surgical system. With the ERBEJET system the patient experiences no thermal trauma to the tissues that are on the margins of the incisions. The extremely delicate, uniform, and precise water jet the system produces leaves surrounding tissue intact. In addition, water jet parameters are reproducible and are controlled by a foot switch that can be positioned by	Deferred in M-49 for provision of following documents: • Valid ISO- 13485 & Full QA certificates; • Original and Valid Letter of authorization. (Provided one expired). Justifiable stability / validation/ service life study data with protocols of applied products.	The firm submitted documents are still documents	Deferred for provision of deficient document.

				the operating table.			
18.	M/s Total Technologies Pvt. Ltd, 696-J2 Johar Town Lahore. ELI: 00129-2498- Evaluator: AD-VI	Legal Manufacturer: M/s Edan Instruments, Inc. # 15 Jinhui Road, Jinsha Community, Kengzi Sub-District, 518122 Shenzhen, P.R. China FSC: China Valid till. 01.03,2020	PC ECG (Interpretive Multichannel electrocardiograph) Codes & Sizes: As per FSC. Class-C Shelf Life: Not applicable	Interpretive Multichannel electrocardiograph.	Deferred IN m-48 for provision of following documents: - <input type="checkbox"/> Original and valid free sale certificate of country of origin and any RRA. <input type="checkbox"/> Valid ISO-13485 certificate/latest GMP report. <input type="checkbox"/> Justify the quality of the products with quality control details and validation studies.	The submitted documents are still deficient	Deferred for provision of deficient document.
19.	M/s. Hoora Pharma (pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. ELI: 00037 1248-K Evaluator: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Randox Laboratories Limited, 55 Diamond road Crumlin County Antrim, BT29 4QY, United Kingdom. FSC: UK (copy), valid till 31/12/2020	ADVIA Chemistry Cardio Phase High Sensitivity C-Reactive Protein Reagents (10283282) Advia Chemistry Cardio Phase High Sensitivity C-Reactive Protein Calibrator (10335897) Codes & Sizes: As per FSC Class-C. Shelf Life: 18 months	Used for in vitro diagnostic use in the quantitative determination of concentration of C-reactive protein in human serum and plasma. Measurement of CRP is useful for detection and evaluation of infection, inflammatory disorders and associated diseases and high sensitivity measurement may be used as an independent risk marker for the identification of individuals at risk for future cardiovascular diseases.	Deferred for: • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provide detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy	Firm submitted the expired and notarized ISO-13485 for both mfg. sites. LoA with clarification as below mentioned sites: - Legal Manufacturer: M/s Siemens Healthcare Diagnostics Products GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany. Manufacturing Sites: M/s Randox Laboratories Limited, 55 Diamond road Crumlin County Antrim, BT29 4QY,	Deferred.

					does contain the relevant information related to manufacturing facility and the applied product.	United Kingdom. Valid and original FSC [document no. CFS011158] of Ireland with expiry of document 23-09-2025, provided. Manufacturing flow chart provided. Quality Control procedures not provided.	
20.	M/s. Hoorah Pharma (pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. ELI: 00037 1248-K Evaluator: AD-IX	Legal Manufacturer: M/s Siemens Healthcare Diagnostics Inc. 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing site: 333 Coney Street East Walpole, MA, 02032, USA FSC UK MHRA valid till 30-12-2020	ADVIA Centaur NT-proBNP (Kit) Class C 1) ADVIA Centaur NT-proBNP Code: 10699449 Size: 100 Tests Shelf life: 12 Months 2) ADVIA Centaur NT-proBNP Code: 10699450 Size: 500 Tests Shelf life: 12 Months ADVIA Centaur Multi-Diluent 1 Code: 10311571 Size: 50mL/vial Shelf life: 12 Months ADVIA Centaur Multi-Diluent 1 Code: 10309941 Size: 2 x 25mL/Pack Shelf life: 12 Months. ADVIA Centaur Multi-Diluent 1 Code: 10309942 Size: 50mL/vial Shelf life: 12 Months.	An in vitro diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the ADVIA Centaur CP systems. In individuals suspected of having congestive heart failure (CHF) measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity.	Deferred for submission of clarification and provision of following documents:- • Grouping not clear. Three Multidiluent are applied on this application. Are these Multidiluent used specifically with the applied kit ADVIA Centaur NT-proBNP or they are used with other kits also? Clarify this and provide supporting evidence if these diluents are only used specifically for the applied reagent kit and if used in other kits also. • Details of manufacturing	The firm submitted documents are still deficient	Deferred for provision of deficient documents.

					<p>of the applied codes.</p> <ul style="list-style-type: none"> • Shelf life studies are not provided for codes 10699450 and 10309942, Please provide. • Valid FSC. • Valid ISO 13485. • EPSP provided are not of the applied product ADVIA Centaur NT-proBNP and EPSP of multidiluent also not provided • IFU of three applied multidiluent. <p>Labels of all 5 codes applied which shall be readable.</p>		
21.	<p>M/s. Hoorah Pharma (pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.</p> <p>ELI: 00037</p> <p>1248-K Evaluator: AD-IX</p>	<p>Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O. Box 6101, Newark, DE, 19714, USA</p> <p>Manufacturing site: Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O. Box 6101, Newark, DE, 19714, USA</p> <p>FSC UK MHRA valid till 03-05-2023</p>	<p>Dimension Myoglobin Flex reagent cartridge (Kit) Class C</p> <p>1. Dimension Myoglobin Flex reagent cartridge Code: RF422A / 10444907 Size: 120 Tests Shelf life: 12 Months</p> <p>2. Dimension Myoglobin Flex Calibrator Code: RC422 / 10445024 Size: 10x 1.0mL Shelf life: 18 Months.</p>	<p>The MYO method for Dimension® clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure myoglobin in human serum and heparinized plasma. Myoglobin measurements can be used as an aid in diagnosing myocardial infarction</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • The legal manufacturer and manufacturing site as per FSC, DOC, IFU, label is different than that provided on Form 7A. Clarify the legal manufacturer and manufacturing site of the applied product. • Details of QC of the applied codes. • ISO13485 of legal manufacturer and manufacturing 	<p>The firm submitted documents are still deficient</p>	<p>Deferred for provision of deficient documents.</p>

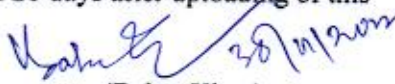
					site as per FSC, DOC, IFU, label not provided. Provide valid and notarized certificate		
22.	<p>Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)</p> <p>Evaluator: [AD-VIII] 3576</p>	<p>Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaying, Zhejiang, Peoples Republic of China</p> <p>EU representative: Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, 20537, Hamburg, Germany.</p> <p>FSC: Germany Date of Issue: April 24, 2024</p>	<p>Venous Disposable Anesthesia Kit (Epidural Kit)</p> <p>Codes and sizes as per FSC</p> <p>Class D Shelf Life: 5 YEARS</p>	<p>Disposable Anesthesia Kit (Epidural Kit)</p> <p>Epidural Kit for regional Anesthesia & Analgesia)</p> <p>All Sizes (G-25, 26, 27 & 29)</p>	<p>Deferred for the provisions of following deficiencies/ documents:</p> <p>i. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" hold godown at "Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi", However no such godown is mentioned on Establishment license, need clarification.</p> <p>ii. Since the documents attached with application covers full range of product being manufactured by manufacturer therefore it is required to highlight the applied products (BRAND name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturi</p>	<p>The firm submitted documents are still deficient</p>	<p>Deferred for provision of deficient documents.</p>

					<p>ng & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application.</p> <p>iii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure</p> <p>Provide the DECLARATION (on stamp paper) as per Form-7A.</p>		
23.	<p>M/s Mian Scientific Corporation (pvt) Ltd., 534-Jinnah Colony Faisalabad.</p> <p>ELI: 00442</p> <p>2208-P</p> <p>Evaluator: AD-IX</p>	<p>Legal Manufacturer: M/s Yasee Biomedical Inc. No.9 Xiuyuan road, High-tech development zone, Chengyang District, Qingdao, 266000 China.</p> <p>Manufacturing facility: M/s.</p> <p>FSC: China, valid till 05/06/2021. (Certificate No. 20200017). It was valid at the</p>	<p>Blood Glucose Test Strips</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life:</p>	<p>The system is designed for quantitative measurement of blood glucose level.</p>	<p>Deferred in M-48. Observations: The submitted Full quality assurance certificate is expired (validity 25/04/2022) but it was valid at the time of submission of dossier. Since the submitted Free Sale Certificate is from China which is not a reference regulatory authority, therefore, you are required to provide a free</p>	<p>Firm submitted EXPIRED FSC of China, DoC, EXPIRED CE documents (FQA) and IN COMPLETE DATA OF shelf life.</p>	<p>Deferred for provision of deficient documents with final opportunity.</p> <p>FSC of country of origin, CE document (FQA),</p>

		time of submission of dossier FSC:			sale certificate from a reference regulatory authority. Moreover, the submitted free sale certificate is expired, please submit original, legalized and valid FSC. Please provide Declaration of Conformity for the applied product from the manufacturer. Provide notarized and valid full quality assurance certificate since the submitted copy is expired. Provide stability studies of the applied product till claimed shelf life.		
24	M/s Mediland Pakistan Pvt Ltd Office No, B-09 Masood Arcade IJP Road Rawalpindi ELI: 00202	Legal Manufacturer: Maquet Cardiovascular, LLC 45 Barbour Pond Drive Wayne, NJ, USA 07470 FSC:US FDA valid till 24-07-2024.	Vasoview Hemopro 2 VH-4000 Endoscopic Vessel Harvesting Kit Class: D Shelf Life: 2 years	Endoscopic Vessel Harvesting Kit	Copies of FSC, LOA, ISO 13485, FQA Certificate are provided. Provide above said original valid documents with attestation as mentioned in Form-7A. Provide stability studies supporting 2 years of shelf life.	Deferred for provision of original & valid FSC, LOA, ISO 13485, FQA with attestation.	

2. In the light of decision of MDB in its 37th meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notrized/Embassy attested documents at the time of submission of applications for registration/enlistment and is excoired during the processing of application, such firms shall only submit valid and original (where applicable) Documents.

3. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.


(Babar Khan)
Additional Director (MDMC)/
Secretary MDB
051-9262180