		FSC Spain issued on 3-9-2018	1200305 (200 tests) Class C Shelf Life: 30 months	not found in any dossier and in each Form it is written "original already submitted" Clarify in which dossier have the original documents been submitted along with documentary evidence. Otherwise you are required to submit the original documents. • Valid and notarized ISO13485. • Full QA certificate issued by CAB notified in NANDO Database for the applied product . • Design Examination certificate issued by CAB notified in NANDO Database for the applied product . • Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided. The document provided is safety data sheet not EPSP. • Declaration of Conformity (DOC) provided for the product does not have product Class mentioned on it. Provide complete EU DOC having Classification drawn by the manufacturer to claim CE marking of the applied product. • Instructions for use (IFU) of applied product not provided.
163.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 **Evaluator**: AD-VII	Legal Manufacturer: M/s SD Biosensor, Inc, C-4 &5 Floor, 16 Deogyeong-daero 15556beon-gil, Yeongtong-gu, Suwon-si, Syeonggi-do, 16690, Republic of Korea FSC: Korea Date of issue: 29.05.2020 Valid for one year	SD Check GOLD Test Strips Blood Glucose Mointoring System Class-C *Shelf Life: 9 years* 1717	**Deferred** for provision of the following documents:- • The product is from nonreference country, Provide original, valid and embassy attested FSC in the country of origin, since it is not provided also Provide valid and embassy attested FSC of Germany, since only a copy provided which has been expired. • Provide valid and notarized ISO 13485 and FQA certificates, only copies provided. • Provide stability study of the strips and accordingly write on Form-7A separately for all components of the blood glucose monitoring system along with the codes. Furthermore, the documents provided are of SD CHECK GOLD AND SD CHECK GOLD 2, However the firm has applied for general brand name SD Check GOLD Test Strips. Clarify the brand names along with codes and components.
164.	-do- **Evaluator**: AD-VII	Legal Manufacturer: M/s SD Biosensor, Inc, C-4 &5 Floor, 16 Deogyeong-daero 15556beon-gil, Yeongtong-gu, Suwon-si, Syeonggi-do, 16690, Republic of Korea FSC: Korea	STANDARD Q DENGUE DUO TEST (Rapid Test Kit for Dengue NSI Atigen/1GG/1GM Antibody) Codes & Sizes: As per FSC	**Deferred** for provision of the following documents:- • The product is from nonreference country, Provide original, valid and embassy attested FSC in the country of origin, the firm has provided FSC where it is written that "*.....the following items is permitted to be freely sold in overseas markets*" Provide valid and embassy attested FSC of Germany, since only a copy provided which is expired. • Provide notarized LOA.

		Date of issue: 29.05.2020	Class- C Shelf Life: 24 months	• Provide valid and notarized ISO 13485 and FQA certificates, only copies provided.
165.	-do- Evaluator AD-VIII 1534-P	**Legal Manufacturer** Anhui Kangning Industrial (Group) Co., Ltd., South of Latitude three-way, west of longity 61 zone 239300 Tianchang, Anhui, People's Republic of China **EU Representative:** Shanghai International Holding Corp. (Europe) Eiffestrasse 80, D-20537, Hamburg, Germany FSC: China valid till: 01-03-2023	**Disposable Blood Transfusion Set with Needle** **Model:** KN/TS-01 KN/TS-02 KN/TS-03 KN/TS-04 Class-B Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: i. Submit revised properly filled application form containing relevant information against relevant field. ii. Provide the details of manufacturing and quality control processes. iii. Provide the shelf-life & storage conditions, i.e., justified with stability studies. iv. Provide Original FSC in the country of origin duly attested by Embassy of Pakistan. v. Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. vi. Complete list of various configurations to be registered supported with Free Sale Certificate or CE Marking Documents or WHO Prequalification Certifications etc. vii. Clarify discrepancy in model numbers of applied **"Disposable Blood Transfusion Set with Needle"** as per DoC (KN/TS-01; KN/TS-02; KN/TS-03; & KN/TS-04) and FSC (KN-BT-01, KN-BT-02) or otherwise justify. viii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure for each applied model. ix. ISO 13485 is expired now. Provide valid copy. x. Full Quality Assurance is expired now. Provide valid copy.
166.	M/s Ameer Sons, 305-A, Upper Mall, Lahore ELI: 00058 **Evaluator**: AD-VII	Legal Manufacture M/s Cooper Vision Manufacturing Ltd South Point Hamble Southampton SO31 4RF UK Manufactruirng Site: Cooper Vision Lens Care Ltd. Mace Industrial Estate Mace Lane, Ashford Kent, TN24 8EP UK FSC: UK (Original) Date of Issue: 16.04.2019	DELTA PLUS ™ (Rigid Gas permeable Contac Lens Care Product) Codes & Sizez: As per FSC Class-C Shelf Life: 3 years	**Deferred** for provision of the following documents:- • Provide valid ISO 13485 and Full Quality assurance certificate. the firm has submitted copy which has been expired • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided

167.	-do- 2421-P **Evaluator:** AD-III	**Legal Manufacture:** M/s Cooper Vision Manufacturing Ltd South Point Hamble Southampton SO31 4RF UK FSC UK Date of Issue: 14-10-2020	Cooper Vision Proclear Multifocal (Soft Contact Lens) Class-B Shelf Life: 7 years Model: Soft Contact Lens	**Deferred** for provision of Form-7A (duly signed and stamped), valid ISO 13485, Full Quality Assurance Certificate and MRP
168.	-do- **Evaluator:** AD-VII	Legal Manufacturer: M/s Fengh Medical Co., Ltd D3 No. 6, Dongsheng West Road, Jiangyin National High-tech Zone, 214437, China China fsc valid till 11.03.2021 FSC: MHRA Date of issue: 24.10.2019	Fengh (Disposable Linear Cutter Stapler & Reloads (All models) Dispsable Linear Stapler & Reloads (all models) Class-C Shelf llfe: 36 months	**Deferred** for provsionof the following documnsts:- The grouping of device is not clear The firm has not clearly mentioned the applied type of MD on FORM 7A. Therefore, clearly mention the exact type or Justify for Family system/ grouping. The firm has submitted fee for the brand name *Endoscopic linear cutter stapler*, while the names written on Form7 A are different. Provide valid ISO 13485 certificate expired after submission
169.	M/s Sudais Associates Sudais House, Street No. 7, House No. 1, Khan Bahadur Colony, Duran Pur, Peshawar (ELI: 00031) Evaluator AD-II [1656-KP]	**Legal Manufacturer** Zhejiang Kawamoto Health Care Products Co, Ltd No. 508 Xiuxin Road, Xiuzhou Industrial Park, Jiaxing, Zhejiang, China **(FSC)** Original, Embassy attested: **China** Valid till 25-02-2020 **(expired even on submission)**	Algisorb Alginate Dressing (Alginate Dressing) Sizes: As per FSC Class-C Shelf Life: As per stability data	**Deferred** for provision of following documents:- • Dressing piece and Alginate non-adherent pad with adhesive plaster are applied in single application; give priority for this application and submit a separate application for the second type. • Differential fee Rs. 25,000/- is required • Original and valid Free sale certificate in the country of origin and of any RRA as per rule 67, duly attested by embassy of Pakistan. Already submitted embassy attested original FSC from China **is expired even upon submission.** • Shelf-life & storage conditions, i.e., justified with stability studies: • Proposed MRP of medical device • Complete list of various configurations to be registered; • Complete description with intended use, Key functional elements, formulation & composition with functionality. • Essential principle of safety and performance. • Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorised distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. The already submitted LoA is

				expired now but valid upon submission. • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted embassy attested original ISO 13485 certificate is expired **even upon submission**. • Contraindications & Warnings to inform on specific risk or hazard to use medical device; • Instruction for use (IFU). • Information on validation for medical devices with sterile or with measuring function.
170.	-do- Evaluator [AD-VIII] 1657-KP	Legal Manufacturer Zhejiang Kawamoto Health Care Products Co. Ltd No. 508 Xiuxin Road, Xiuzhou Industrial Park, Jiaxing, Zhejiang, China FSC: China Valid till 2020/02/25	Flexisorb Hydrocolloid Dressing (Hydrocolloid Dressing) Codes and sizes: as per FSC Class-C Shelf Life: as per stability Data	**Deferred** for the provision of deficient document / clarification: i. Differential fee Rs. 25,000/- ii. Provide the details of manufacturing and quality control processes. iii. Shelf-life & storage conditions, i.e., justified with stability studies. iv. Provide valid Letter of Authorization duly notarized in the country of origin. The already submitted LoA is expired now but valid upon submission. v. Original and valid Free sale certificate (FSC) in the country of origin and of any RRA as per rule 67, duly attested by embassy of Pakistan. Already submitted embassy attested copy of FSC from China is expired even upon submission. vi. Proposed MRP of medical device vii. Complete list of various configurations to be registered viii. Complete description with intended use, Key functional elements, formulation & composition with functionality. ix. Essential principle of safety and performance. x. Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted embassy attested original ISO 13485 certificate is expired even upon submission. xi. Contraindications & Warnings to inform on specific risk or hazard to use medical device xii. Instruction for use (IFU). xiii. Information on validation for medical devices with sterile or with measuring function.
171.	M/s RA Healthcare (SMC) (Pvt) Ltd, Room # 2,2nd Floor, Building # 50 Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad. (ELI: 00482)	**Legal Manufacturer:** M/s Hangzhou Alltest Biotech Co., Ltd, # 550, Yinhai Street, Hangzhou Economic &	ALLTEST COVID-19 Antigen Rapid Test (Oral Fluid) Ref # ICOV-802-Professional Kits Codes: ICOV-802	**Deferre**d for provision of following documents:- (i) Original, valid, Embassy attested FSC from country of origin for the applied product since copy is provided. (ii) Details of QC (iii) Declaration as per form 7A on stamp

	Evaluator AD-II [2791]	Technological Development Area, Hangzhou, 310018 P.R. China FSC: **Netherlands** (original, embassy attested) **Validity: May 26, 2022** Export only certificate China **(copy)** valid till 19-05-2023	Class-C Shelf Life: 2 years	paper.
172.	-do- Evaluator AD-II [2790]	**Legal Manufacturer:** M/s Hangzhou Alltest Biotech Co., Ltd, # 550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China FSC: **Germany** (original, embassy attested) **Validity: May 26, 2022** **Export only certificate China** (copy) valid till **19-05-2023**	ALLTEST SARS-COV-2 ANTIGEN RAPID TEST (NASAL SWAB) Professional Kits Codes: INCP 502-N Class-C Shelf Life: 2 years	**Deferred** for provision of following documents:- (i) Original, valid, Embassy attested FSC from country of origin for the applied product since copy is provided. (ii) Details of QC (iii) Declaration as per form 7A on stamp paper.
173.	-do- Evaluator AD-II [2792]	Legal Manufacturer: M/s Hangzhou Alltest Biotech Co., Ltd, # 550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China FSC (original embassy attested): **Germany** **Date of issue:** September 29, 2021	ALLTEST COVID-19 Antigen Rapid Test (Oral Fluid)-Self testing Kits Codes: ICOV-802H Class-C Shelf Life: 2 years	**Deferred** for provision of following documents:- (i) Original, valid, Embassy attested FSC from country of origin for the applied product since copy is provided. (ii) Declaration as per form 7A on stamp paper.
174.	-do- Evaluator AD-II [2793]	Legal Manufacturer: M/s Hangzhou Alltest Biotech Co., Ltd, # 550, Yinhai Street, Hangzhou Economic & Technological	ALLTEST SARS-COV-2 Antigen Rapid Test (Nasal Swab))- Self testing Kits Codes: INCP 502H	**Deferred** for provision of following documents:- (i) Original, valid, Embassy attested FSC from country of origin for the applied product since copy is provided. (ii) Declaration as per form 7A on stamp paper.

		Development Area, Hangzhou, 310018 P.R. China FSC: **Germany** (original embassy attested in ALLTEST COVID-19 Antigen Rapid Test (Oral Fluid)-Self testing Kits (Ref # ICOV-802H) **Date of issue:** September 29, 2021	Class-C Shelf Life: 2 years	
175.	Medisurg Innovatives Health Care, 1/6-N, Block-6, PECHS, Main Shahrah e Faisal Karachi. (ELI-00242) Evaluator AD-II [4331]	Optimed Medizinsche instrumente GmbH, Ferdinand-Porsche-Straβe 11, 76275 Ettlingen, Germany **FSC (Original):** Germany **Date of Issue:** 28-9-2020	Exchange Guidewires (Stainless steel) Codes and sizes: As per FSC Class-D Shelf Life: 5 years	**Deferred** for provision of following documents:- (i) Only codes for uncoated stainless-steel exchange guidewires shall be considered on this dossier, Apply separately for PTFE coated Exchange Guidewires. (ii) Valid Design Examination certificate and DoC.
176.	-do- Evaluator AD-II [4332]	Optimed Medizinsche instrumente GmbH, Ferdinand-Porsche-Straβe 11, 76275 Ettlingen, Germany **FSC (copy):** Germany **Date of Issue:** 28-9-2020	Black and white (Nitinol guidewires, PTFE coated) Codes and sizes: 1125-0130 1125-0140 1125-0150 1124-0151 1125-0145 1125-1320 Class-D Shelf Life: 5 years	**Deferred** for provision of valid Design Examination Certificdate and Declaration of Conformity.
177.	-do- Evaluator AD-II [4333]	Optimed Medizinsche instrumente GmbH, Ferdinand-Porsche-Straβe 11, 76275 Ettlingen, Germany **FSC (copy):** Germany **Date of Issue:** 28-9-2020	Nitinol guidewires Codes and sizes: As per FSC Class-D Shelf Life: 5 years	**Deferred** for provision of valid Design Examination Certificdate and Declaration of Conformity.
178.	-do- Evaluator AD-II [4330]	Optimed Medizinsche instrumente GmbH, Ferdinand-Porsche-Straβe 11, 76275 Ettlingen, Germany	Plywire Guidewire Codes and sizes: 1124-0320 1124-0330 1124-0400	**Deferred** for provision of following documents:- ▪ The scope of provided FSC and FQA certificate does not cover the applied MD. Provide original, valid, Embassy attested FSC from country of origin for the applied product;

		FSC (copy): Germany **Date of Issue:** 28-9-2020	Class-D Shelf Life: 5 years	▪ Full QA certificate or equivalent, duly notarized by the country of origin. ▪ Valid Design examination certificate duly notarized by the country of origin, ▪ Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person, since Design Examination certificate and Declaration of Conformity are expired even upon submission.
179.	The Aesthetic Alliance, H# 418, Col. Sher Khan Shaheed Road, F-11/3, Islamabad. (ELI: 00811) Evaluator AD-II [2814-P]	Legal Manufacturer: M/s Genoss Co., Ltd, 1F, Gyeonggi R&DB Center 226, GSaBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-270, Korea FSC: Korea Date of Issue: 18-10-2021	MONALISA Lidocaine Filler (Sterile Absorbable Injectable dermal filler) Codes & Sizes: As per FSC Class-D Shelf Life: 2 years	**Deferred** for provision of following documents:- ▪ Original and valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. ▪ Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Provide the Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. Already submitted is scanned copy. ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ Full QA certificate or equivalent, duly notarized by the country of origin.
180.	-do- Evaluator AD-II [2815-P]	Legal Manufacturer: M/s Genoss Co., Ltd, 1F, Gyeonggi R&DB Center 226, GSaBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-270, Korea FSC: Korea Date of Issue: 18-10-2021	MONALISA Filler (Sterile Absorbable Injectable dermal filler) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents:- ▪ Original and valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. ▪ Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Provide the Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. Already submitted is scanned copy. ▪ Production Quality Management System

				Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ Full QA certificate or equivalent, duly notarized by the country of origin.
181.	M/s Medical Equipment & Systems, 60/61 F.C.C Syed Maratiib Ali Road, Gulberg IV, Lahore. ELI: 00554 Evaluator AD-II [2851-P]	Legal Manufacturer: M/s IVY Biomedical System Inc. 11 Business Park Drive, Branford, CT 06405, USA FSC **(original and legalized):** USA Valid till: 24.01.2023	Cardiac Trigger Monitor (Model 7800) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- ▪ Fee Rs. 50,000/- is submitted by M/s Medequips SMC Pvt Ltd, Lahore instead of M/s Medical Equipment & Systems. Deposit full fee for the registration of Medical device. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies data ▪ Provide the Design examination certificate (if applicable), duly notarized by the country of origin.
182.	M/s Latif Instruments (Pvt), Ltd., 14 Commercial Buildings Shahrah-e-Quaid-Azam Lahore ELI: 00118 Evaluator AD-II [2265-P]	**Legal Manufacturer:** M/s Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany **Manufacturing Site:** M/s Carl Zeiss Meditec Production, LLC 1040 South Vintage Ave., Bldg. A Ontario, CA 91761, USA **FSC** (Original, embassy attested): **Germany** Date of issue: 25.08.2020	IOL CT Lucia 221P, 201P, 621P, 621PY (Posterior Chamber Intraocular Lenses IOL) Codes & Sizes: As per FSC Class-C Shelf life: 3 years	**Deferred** for provision of following documents:- ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Details of manufacturing and quality control processes. ▪ Grouping of medical devices. ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Original and valid Free sale certificate in the country of origin/ of any RRA as per rule 67 duly attested by Embassy of Pakistan. Already submitted is photocopy. ▪ Instructions for Use (IFU) ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted original notarized which is expired now but valid upon submission ▪ Provide the Essential principle of safety and performance. ▪ Provide the Declaration of conformity (DoC), for 221P, 621P and 621PY printed on manufacturer letterhead, filled and duly signed by responsible person. ▪ Label (as approved in the country of origin) and its packaging, promotion material and brochure for all the applied codes.

183.	-do- Evaluator AD-II [2264-P]	**Legal Manufacturer:** M/s Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany **Manufacturing Site:** M/s Medicel AG, Dornierstrasse 11, CH-9423 Altenrhein, Switzerland FSC:Germany Date of issue: 25.08.2020	Bluemix 180 (Intraocular Lenses IOL Inserter) Codes: As per FSC Class-C Shelf life: 3 years	**Deferred** for provision of following documents:- ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Grouping of medical devices ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted original notarized which is expired now but valid upon submission ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate of M/s Medicel AG, Dornierstrasse 11, CH-9423 Altenrhein, Switzerland duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ Essential principle of safety and performance.
184.	-do- Evaluator AD-II [2316-P]	**Legal Manufacturer:** M/s Carl Zeiss Meditec AG, GoeschwitzerStrasse 51-52, 07745 Jena, Germany **Manufacturing Site:** M/s Carl Zeiss Meditec AG, Carl-Zeiss-Promenade 10 07745 Jena Germany FSC **(copy):** Germany Date of Issue: 27.11.2020	MEL 90 (Ophthalmic Laser) Codes & Sizes: As per FSC Class: C Shelf Life: 2 years	**Deferred** for provision of following documents:- ▪ Only MEL 90 ophthalmic laser shall be considered in this application, separate applications for accessories need be submitted. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Provide the details of manufacturing and quality control processes. ▪ Grouping of medical devices ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Original and valid Free sale certificate in the country of origin/ or any RRA as per rule 67 duly attested by Embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. ▪ Provide Design examination certificate (if applicable), duly notarized by the country

				of origin ▪ Essential principle of safety and performance. ▪ Label (as approved in the country of origin) and its packaging, promotion material and brochure.
185.	-do- Evaluator AD-II [2319-P]	**Legal Manufacturer:** M/s Carl Zeiss Meditec AG, GoeschwitzerStrasse 51-52, 07745 Jena, Germany **Manufacturing Site:** M/s Carl Zeiss Meditec AG, Carl-Zeiss-Promenade 10 07745 Jena Germany FSC **(copy):** Germany Date of Issue: 27.11.2020	VisuMax (Ophthalmic Laser) Codes & Sizes: As per FSC Class: C Shelf Life: 2 years	**Deferred** for provision of following documents:- ▪ Only VisuMax ophthalmic laser shall be considered in this application, separate applications for accessories need be submitted. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Grouping of medical devices ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Original and valid Free sale certificate in the country of origin/ or any RRA as per rule 67 duly attested by Embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin ▪ Essential principle of safety and performance. ▪ Label (as approved in the country of origin) and its packaging, promotion material and brochure.
186.	-do- Evaluator AD-II [2321-P]	**Legal Manufacturer:** M/s Carl Zeiss Meditec AG, GoeschwitzerStrasse 51-52, 07745 Jena, Germany **Manufacturing Site:** M/s Carl Zeiss Meditec AG, Carl-Zeiss-Promenade 10 07745 Jena Germany FSC **(copy):** Germany Date of Issue: 27.11.2020	VISULAS Trion YAG III (Ophthalmic Laser) Codes & Sizes: As per FSC Class: C Shelf Life: N/A	**Deferred** for provision of following documents:- ▪ Only VISULAS YAG III ophthalmic laser shall be considered in this application, separate applications for VISULAS TRION and accessories need be submitted. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Details of manufacturing and quality control processes. ▪ Grouping of medical devices ▪ Original and valid Free sale certificate in the country of origin/ of any RRA as per rule 67 duly attested by Embassy of Pakistan. ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder

				(MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. Already provided is expired even upon submission. ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted original notarized which is expired now but valid upon submission ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ Declaration of conformity (DoC), printed on manufacturer letterhead, filled and duly signed by responsible person.
187.	-do- Evaluator AD-II [482-P]	**Legal Manufacturer**: M/s Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany **Manufacturing Sites:** M/s Carl Zeiss Meditec AG, Max-Dohrn-Strasse 8-10 10589 Berlin Germany M/s Carl Zeiss Meditec SAS, 27 Avenue Paul Langevin 17180 Perigny France FSC (copy): Germany Date of issue: 25.08.2020	AT LISA tri 839MP, AT LISA tri toric 939M, AT LISA tri toric 939MP (Posterior Chamber Intraocular Lenses IOL) Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Details of manufacturing and quality control processes. ▪ Grouping of medical devices ▪ Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ Declaration of conformity (DoC), printed on manufacturer letterhead, filled and duly signed by responsible person.
188.	M/s Future D Pakistan House No. 482-G-3, Johar Town, Lahore ELI: 00568 Evaluator AD-II [2467-P]	Legal Manufacturer: M/s AGS Medikal Urunleri 1th. Tie, A.S, Kosuyolu Mah. Katip Salih Sk. No: 111.34178 Kadikoy-Istanbul/Turkey Manufacturing Site: Seyit Ahmet Mahallesi 1 No. lu Caddesi No: 8, Besikduzu, Trabzon-Turkey FSC **(original**	Implance Bone Level Dental Implant system (Dental Implant system, Components and Surgical Drill) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- ▪ Multiple products are applied in single application and two grouping categories are mentioned on Form-7A which are Single and System. Kindly provide clarification or send your technical person having complete knowledge of relevant subject. ▪ Class-A devices should be applied separately on Form-6A. ▪ The device is from Non-reference country, submit original and valid FSC of any RRA country as per Rule 67 of MDR, Rules 2017, duly attested.

		embassy attested): Turkey Date of issue: 28.12.2020		▪ Manufacturing and Quality Control tests details performed on the applied device. ▪ Shelf life studies for the claimed shelf life. ▪ Valid original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. ▪ Design examination certificate (if applicable), duly notarized by the country of origin. ▪ List of MD, constituents-components that are grouped together. ▪ List of various configurations to be registered. ▪ Complete description with intended use, Key functional elements, formulation & composition with functionality. ▪ Labels of all applied codes as per FSC approved in the country of origin. ▪ Contraindications & Warnings to inform on specific risk or hazard to use medical device; ▪ Instruction for use (IFU). ▪ Information on validation for medical devices with sterile or with measuring function.
189.	M/s Sy'ah Impex, 1-6/15 Sector No. 5 Korangi Industrial Area Karachi. (ELI-00440) 4239 **Evaluator** AD-III	**Legal Manufacturer:** Jiangsu Webest Medical Equipment Co. Ltd No. 5 Yimgchun Rd, Industrial Park 211700 Xuyi, Jiangsu, China. FSC China validity 12-07-2023	Shifa IV set (Disposable IV Burette set) Class-B Shelf life: 5 years Models: 50ML, 100ML, 150ML	**Deferred** for provision of FSC of reference country or CE mark documents.
190.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi (ELI-00051) 1703 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Incto Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Zhelin Town, FengxianDistrict, Shanghai, China. (FSC China validity 06-02-2023)	Classic ECG Electrodes Model Class B Shelf Life: 4 Years Codes as per FSC	**Deferred** for provision of FSC of reference country or CE mark documents.
191.	M/s 3M Surgicals, Plot 5/172 Street 172, Sarwar Road, Rawalpindi. ELI: 00122	**Legal Manufacturer:** M/s Brasuture Industria Comerio Importaco e Exportacao Ltda,	POLYGLYCOLIC (Absorbable Polyglycolic Acid) Class-D	**Deferred** for provision of FSC of any reference country or CE marked documents and stability studies.

	2505-P **Evaluator** AD-III	Rua Vereador Jose Vasconcellos dos Reis, n 642- Distrito Industiral- Sao Sebastiao da Grama- SP- ZIP FSC Brazil Valid Till: 01.04.2024	Shelf Life: 5 years Codes & Sizes as per FSC	
192.	**Deleted due to duplication at serial No. 192 (Sprint)**			
193.	-do- 2506-P **Evaluator** AD-III	**Legal Manufacturer:** M/s Brasuture Industria Comerio Importaco e Exportacao Ltda, Rua Vereador Jose Vasconcellos dos Reis, n 642- Distrito Industiral- Sao Sebastiao da Grama- SP- ZIP FSC Brazil Valid Till: 01.04.2024	Steel Monofilament (Steel Suture) Class-C Shelf Life: 5 years Codes & Sizes: List provided	**Deferred** for provision of FSC of any reference country or CE marked documents and stability studies.
194.	M/s Cardiac Care, 848-C, Shadman-1, Lahore ELI: 00070 2427-P **Evaluator** AD-III	**Legal Manufacturer:** Vygon, 5 rue Adeline-95440 Ecouen-France FSC France Date of Issue: 08.10.2019	Vygon Endotracheal tube (Endotracheal tube with cuff) Class-B Shelf Life: 5 years Codes & Sizes as per FSC	**Deferred** for provision of valid ISO 13485, Full Quality Assurance Certificate and real time shelf life studies. Apply separately for un-cuffed ET tubes
195.	M/s Trowmedic International, Building No 117, Sagian T No 4, Opposite Sanda Stop Band Road, Lahore. ELI-00069 2945-P **Evaluator** AD-III	**Legal Manufacturer:** M/s M&G Products Co., Ltd No. 968 Mingzhuwan Yangzhong, Jiangsu, China. FSC China Date of Issue: 10.12.2020 Valid for 2 years FSC Germany issuance 29-10-2021	Trow Ject disposable syringes (disposable Syringes) Class-B Shelf Life: 5 years Sizes: 1ml, 10ml, 20ml, 50ml, 60ml	**Deferred** for provision of all original legal documents i.e. Letter of Authorization, ISO 13485, Full Quality Asurance Certificate and DoC.
196.	-do- 2423-P **Evaluator** AD-III	**Legal Manufacturer:** M/s M&G Products Co., Ltd No. 968 Mingzhuwan Yangzhong, Jiangsu, China.	Trow Set Burette set (Burette type infusion set) Class-B Shelf Life: 5 years	**Deferred** for provision of all original legal documents i.e. Letter of Authorization, ISO 13485, Full Quality Asurance Certificate and DoC.

		FSC China Date of Issue: 10.12.2020 Valid for 2 years FSC Germany issuance 29-10-2021	Sizes: 100ml, 150ml	
197.	-do- 35-P (Renewal) **Evaluator** AD-III	Legal Manufacturer: M/s M&G Products Co., Ltd No. 968 Mingzhuwan Yangzhong, Jiangsu, China. FSC China Date of Issue: 10.12.2020 Valid for 2 years FSC Germany issuance 29-10-2021	Trow Set Infusion set (infusion set) Class-B Shelf Life: 5 years Sizes: Classic type	**Deferred** for provision of all original legal documents i.e. Letter of Authorization, ISO 13485, Full Quality Asurance Certificate and DoC.
198.	-do- 547-P **Evaluator** AD-III	**Legal Manufacturer:** M/s M&G Products Co., Ltd No. 968 Mingzhuwan Yangzhong, Jiangsu, China. FSC China Date of Issue: 10.12.2020 Valid for 2 years FSC Germany issuance 29-10-2021	Trow Urine bag Infusion set (Urine Bag) Class-A Shelf Life: 5 years Models: 100ml, 500ml, 2000ml	**Deferred** for provision of all original legal documents i.e. Letter of Authorization, ISO 13485, Full Quality Asurance Certificate and DoC.
199.	Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Plot No. 3, MCHS, Shaheed-e-Millat, Karachi. (ELI-00274) 2070 **Evaluator** AD-III	**Legal Manufacturer:** M/s Dirui Industrial Co. Ltd., No.95 Yunhe Str. New & High-Tech Development Zone, Changchun, China FSC China Valid Till (22-10-2020) FSC Netherland validity 26-05-2022	Urinalysis Control Class-B Shelf life: 12 Months Codes: Urinalysis Positive control (8mL) Urinalysis Negative control (8mL)	**Deferred** for provision of following documents:- • Valid Free Sale Certificate of China. • Valid Free Sale Certificate of Netherland. • Full Qaulity Assurance Certificate.
200.	S. Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2791 **Evaluator**	**Legal Manufacturer:** JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE.	JMS Blood Bag CPDA-I (Single) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years	**Deferred** for provision of the FSC of reference country or CE marked documents.

	AD-III	FSC Singapore issuance 08-04-2020	Code: 811-5004	
201.	-do- 2770 **Evaluator** AD-III	**Legal Manufacturer:** JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Double) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-4018	**Deferred** for provision of the FSC of reference country or CE marked documents.
202.	-do- 2676 **Evaluator** AD-III	**Legal Manufacturer:** JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Triple) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5307	**Deferred** for provision of the FSC of reference country or CE marked documents.
203.	-do- 2677 **Evaluator** AD-III	**Legal Manufacturer:** JMS Singapore Pte Ltd 440 Ang Mo Kio Industrial Park 1, Singapore 569620, SINGAPORE. FSC Singapore issuance 08-04-2020	JMS Blood Bag CPDA-I (Quadruple) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5408	**Deferred** for provision of the FSC of reference country or CE marked documents.
204.	-do- Evaluator: AD-VIII 1235 (K)	Legal Manufacturer: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Strabe 76 35041 Marburg Germany FSC: Germany Date of issue: 29.04.2019	Siemen's Coagulation Factor VII Deficient Plasma Code: OTXV13 Class-C Shelf Life: 24 months	**Deferred** for the provision of deficient document / clarification: i. Provided LOA is expired now. Provide valid original LOA. ii. Provided photocopy of FSC having date of Issue 29 April, 2019. Provide valid original FSC. iii. The firm is required to explain whether "Control Plasma N, Control Plasma P, standard human plasma, Dade Owren's Veronal Buffer & Imidazole Buffer Solution" are only intended to be used with Coagulation Factor VII Deficient Plasma (OTXV13) to complete a specific intended purpose or these (Control Plasma N, Control Plasma P, standard human plasma, Dade Owren's Veronal Buffer & Imidazole Buffer Solution) can be used/imported as a separate medical device. iv. Provide Full Quality Assurance Certificate as the same was not provided with application.

205.	M/s Intra Health, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi. (ELI-00049) 1781 **Evaluator** AD-III	**Legal Manufacturer:** M/s. Weifang Kawa Medical Products Co. Ltd., 117 Xingan Road, Shouguang Development Zone, Shandong, China. FSC China	Kawa Auto Disable Disposable Syringe with needle Class-B Shelf life: 5 years Sizes: 3ml, 5ml	**Deferred** for provision of Free Sale Certificate of any reference country or CE mark documents.
206.	M/s K.M Enterprises, KM Mansion, 605 D, Block MA Johar Town Lahore 08-P Renewal **Evaluator** AD-III	**Legal Manufacturer:** Changzhou Medical Appliances General Factory, Co, Ltd Hengshanqioa Town, Changzhou Jiangsu, China FSC: China Valid till: 2022.08.14	AMD I.V Cannula with wings and Injection Port, (I.V CANNULA) Class-B Shelf Life: 5 years Sizes: 18G,20G, 22G, 24G	**Deferred** for provision of Free Sale Certificate of any reference country or CE mark documents issued by any certification body notified in NANDO Database.
207.	-do- **Evaluator** AD-III 36-P Renewal	**Legal Manufacturer:** Changzhou Medical Appliances General Factory, Co, Ltd Hengshanqioa Town, Changzhou Jiangsu, China FSC: China Valid till: 2022.08.14	AMD I.V Burette Infusion Set with needle (I.V. Burette Infusion Set) Class-B Shelf Life: 5 years	**Deferred** for provision of Free Sale Certificate of any reference country or CE mark documents issued by any certification body notified in NANDO Database.
208.	-do- **Evaluator** AD-III 37-P Renewal	**Legal Manufacturer:** Changzhou Medical Appliances General Factory, Co, Ltd Hengshanqioa Town, Changzhou Jiangsu, China FSC: China Valid till: 2022.08.14	AMD Auto Disable Syringe (Auto Disable Syringe) Class-B Shelf Life: 5 years Sizes: 1ml, 2ml, 2ml, 5ml, 10 ml,	**Deferred** for provision of Free Sale Certificate of any reference country or CE mark documents issued by any certification body notified in NANDO Database.
209.	-do- **Evaluator** AD-III 38-P Renewal	**Legal Manufacturer:** Changzhou Medical Appliances General Factory, Co, Ltd Hengshanqioa Town, Changzhou Jiangsu, China FSC: China Valid till: 2022.08.14	AMD Insulin Syringe (Insulin Syringe) Class-B Shelf Life: 5 years Size: 100 IU	**Deferred** for provision of Free Sale Certificate of any reference country or CE mark documents issued by any certification body notified in NANDO Database.
210.	M/s Verizon. 60-D F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore (ELI-00087) Evaluator [AD-VIII]	Legal Manufacturer: M/s Taewoong Medical Co. Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea	**Niti-S (Esophageal Covered Stent Bare-Type)** Codes & sizes: As per FSC Class-C	**Deferred** for the provision of deficient document / clarification: i. Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which

	2890	FSC: Korea Date of Issue: 07.02.2019	Shelf Life: 3 years	exclusive Authorization has been granted by the manufacturer to importer ii. FSC from reference country provided does not have product codes in it. Provide original, valid, Embassy attested FSC from one of the reference countries mentioned in rule 67 with the product name, types and codes mentioned on it. iii. FSC from country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify. iv. ISO 13485 expired now. Provide valid certificate v. Provide EU DOC for the applied product vi. Provide the technical documentation to differentiate between codes and variants applied of the subject product.
211.	-do- Evaluator [AD-VIII] 2891	**Legal Manufacturer:** M/s Taewoong Medical Co.Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea FSC: Korea Date of Issue: 07.02.2019	Niti S (Enteral Colonic Covered Stent End Bare-Type) Codes & sizes: As per FSC Class-C Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: i. Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer ii. FSC from reference country provided does not have product codes in it. Provide original, valid, Embassy attested FSC from one of the reference countries mentioned in rule 67 with the product name, types and codes mentioned on it. iii. FSC from country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify. iv. ISO 13485 expired now. Provide valid certificate v. Provide EU DOC for the applied product vi. Provide the technical documentation to differentiate between codes and variants applied of the subject product.
212.	-do- Evaluator [AD-VIII] 2891	**Legal Manufacturer:** M/s Taewoong Medical Co.Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea FSC: Korea Date of Issue: 07.02.2019	NITI-S-Enternal Colonical Uncovered Stent (D-Type) (Colonic Stent) Coes & sizes: As per FSC Class-C Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: i. Original documents attached in file Niti-S-Enteral Colonic Covered Stent (Both Bare Type) ii. Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer iii. FSC from reference country provided does not have product codes in it. Provide original, valid, Embassy attested FSC from one of the reference countries mentioned in rule 67 with the product name, types and codes mentioned on it.

				iv. FSC from country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify. v. ISO 13485 expired now. Provide valid certificate vi. Provide EU DOC for the applied product vii. Provide the technical documentation to differentiate between codes and variants applied of the subject product.
213.	-do- Evaluator AD-VIII 1684-P	Legal Manufacturer: Cook Inc. 750 Daniels Way, Bloomington, IN USA 47404 FSC: FDA U.S FOOD &DRUG **Date of issue:** September 17, 2018 **Valid till:** September 16, 2020	CXI Support Catheter (Catheterization Catheter and Sets) Code: as per FSC Class-B Shelf Life: 3 years Fee submitted: 25000, Challan No.:1998782 dated 20 Mar, 2020	**Deferred** for the provision of deficient document / clarification: i. The firm claimed that original LOA has been submitted in file No. 35 Disposable Two Part Trocar Needle, therefore attached copy with this file. ii. The firm claimed that original FSC has been submitted in file No. 09 Torcon NB Advantage Catheter, therefore attached copy with this file. iii. Provided photocopy of LOA is expired now. Provide Original and valid letter of authorization (LOA) duly notarized by the country of origin. iv. Provided photocopy of FSC is expired now. Provide Original and valid FSC v. Provide IFU of the applied medical device. vi. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure of all codes, sizes and types applied as family.
214.	-do- Evaluator AD-VIII 1670-P	Legal Manufacturer: Cook Inc. 750 Daniels Way, Bloomington, IN USA 47404 FSC: FDA U.S FOOD &DRUG Date of issue: September 17, 2018 Valid till: September 18, 2020	**AMPLATZ EXTRA STIFF WIRE GUIDE** (Vascular Wire Guides) Code: as per FSC Class-B Shelf Life: 5 years	**Deferred** for the provision of deficient document / clarification: i. The firm claimed that original LOA has been submitted in file No. 35 Disposable Two Part Trocar Needle File, therefore attached copy with this file. ii. The firm claimed that original FSC has been submitted in file No. 16 Cook Transseptal Needle file, therefore attached copy with this file. iii. Provided photocopy of LOA is expired now. Provide Original and valid letter of authorization (LOA). iv. Provided photocopy of FSCs are expired now. Provide Original and valid FSC covering all the codes, sizes and types applied medical device as family. v. Explain the differences in applied codes like THSCF and THSF, similarly what is the difference between AES, AES-BH, AES-SGH & AES-SGH-BH. Justify the same with supporting documents. vi. Provide IFU of the applied medical device. vii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure of all

				codes, sizes and types applied medical device as family. viii. Provided DoC doesn't covers all the codes, sizes and types applied medical device as family. Therefore, provide latest DoC covering all. ix. The firm provide stability study of Teflon coated fixed core guide wires. Therefore, provide stability studies of t AMPLATZ EXTRA STIFF WIRE GUIDE to justify the claimed shelf life.
215.	-do- Evaluator AD-VIII 362-P	Legal Manufacturer: Wilson Cook Medical Inc. 4900 Bethania Station Rd Winston Salem, NC USA 27105 FSC: FDA U.S FOOD & DRUG Date of issue: June 20, 2019 Valid till: June 19, 2021	**Soehendra Biliary Dilation Catheter** Codes & sizes: as per FSC Class A (claimed as per DoC) Shelf Life: 3 Years Fee submitted: 5000, Challan No.:1998771 dated 07 Feb, 2020	**Deferred** for the provision of deficient document / clarification: i. The firm applied "Soehendra Biliary Dilation Catheter" as class A medical device, however, the subject product may fall in the higher risk class. Therefore, the firm asked to submit the differential fee and revise their application form as per MDR, 2017. ii. The firm claimed that original LOA has been submitted in file No. 35 Disposable Two Part Trocar Needle File, therefore attached copy with this file. iii. The firm claimed that original FSC has been submitted in file No. 27 Six Shooter Saeed Multi Band Ligator file, therefore attached copy with this file. iv. Provided photocopy of LOA is expired now. Provide Original and valid letter of authorization (LOA). v. Provided photocopy of FSC is expired now. Provide Original and valid FSC. vi. It is observed that the firm submitted real time stability study of only one variant/code i.e. SBDC-5, however applied various codes of product to be registered as family, need clarification.
216.	-do- Evaluator AD-VIII 2395-P	Legal Manufacturer: M/s Cook Ireland Limited O'Halloran Road National Technology Park, Limerick, Ireland FSC: Ireland Valid till: 13.08.2023	Cystotome™ Cystoenterostomy Needle Knife Codes & Sizes: CST-10 Class-C Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: i. The firm claimed that original LOA has been submitted in file No. 35 Disposable Two Part Trocar Needle File, therefore attached copy with this file. ii. The firm claimed that original FSC has been submitted in file No. 3 Cook HBS File, therefore attached copy with this file. iii. Provided photocopy of LOA is expired now. Provide Original and valid letter of authorization (LOA). iv. Provide the details of quality control processes. v. Provided ISO 13485 is expired now. Provide valid certificate. vi. The firm is required to provide the stability studies of applied medical device to the extent that the product shall remain sterile during the claimed period of Shelf Life i.e. 3 years.

				vii. It cannot be established that the Essential principles of safety and performance (EPSP) is for the applied product. Provide evidence or provide relevant EPSP.
217.	-do- Evaluator AD-VIII 2396-P	Legal Manufacturer: M/s Cook Ireland Limited O'Halloran Road National Technology Park, Limerick, Ireland FSC: Ireland Valid till: 13.08.2023	Geenen® Pancreatic Stent (Pancreatic Stents/Sets) Codes & Sizes: As per FSC Class-C Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: i. The firm claimed that original LOA has been submitted in file No. 35 Disposable Two Part Trocar Needle File, therefore attached copy with this file. ii. The firm claimed that original FSC has been submitted in file No. 3 Cook HBS File, therefore attached copy with this file. iii. Provided photocopy of LOA is expired now. Provide Original and valid letter of authorization (LOA). iv. Difference between GPSO and GPSOS is not clear from the provided documents. Therefore, clarify the same. v. Provide label (as approved in the country of origin), of all the codes/sized applied for registration and its packaging, promotion material and brochure vi. It cannot be established that the Essential principles of safety and performance (EPSP) is for the applied product. Provide evidence or provide relevant EPSP. vii. Provided ISO 13485 is expired now. Provide valid ISO 13485 certificate.
218.	-do- **Evaluator:** AD-IV [2895-P]	Manufacturer: M/s TaeWoong Medical Co. Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea 2 FSCs Netherlands valid till 25-3-2024	Niti-S Biliary Uncovered Stent (M-Type) Codes: As per FSC Class C Shelf Life: 3 years	**Deferred** for provision of following documents:- • Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer. • FSC country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify • Valid ISO 13485. • EU DOC for the applied product • Labels, brochure and other supporting material to explain the difference between M-type and other types of Niti-S Biliary Uncovered Stent and also the difference between the different codes applied on this application
219.	-do- **Evaluator:** AD-IV [2896-P]	Manufacturer: M/s TaeWoong Medical Co. Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do,	Niti-S Biliary Covered Stent (Both Bare Type) Codes: As per FSC Class C	**Deferred** for provision of following documents:- • Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide

		10022, Korea FSC UK MHRA issued on 7-2-2019	Shelf Life: 3 years	the names of the products for which exclusive Authorization has been granted by the manufacturer to importer. • FSC country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify • Vaid ISO 13485. • EU DOC for the applied product. • Labels, brochure and other supporting material to explain the difference between the applied type and other types of Niti-S Biliary Covered Stent and also the difference between the different codes applied on this application
220.	-do- **Evaluator:** AD-IV [2889-P]	Manufacturer: M/s TaeWoong Medical Co. Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea FSC UK MHRA issued on 7-2-2019	Niti-S Biliary Uncovered Stent (D-Type) Codes: As per FSC Class C Shelf Life: 3 years	**Deferred** for provision of following documents:- • Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer. • FSC country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify • Vaid ISO 13485. • EU DOC for the applied product. • Labels, brochure and other supporting material to explain the difference between the D-type and other types of Niti-S Biliary Uncovered Stent and also the difference between the different codes applied on this application
221.	-do- **Evaluator:** AD-IV [2893-P]	Manufacturer: M/s TaeWoong Medical Co. Ltd 14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea FSC Netherlands valid till 25-3-2024	Niti-S Pyloric Duodenal Uncovered Stent (S-Type) Codes: As per FSC Class C Shelf Life: 3 years	**Deferred** for provision of following documents:- • Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer. • FSC country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify • Vaid ISO 13485. • EU DOC for the applied product. • Labels, brochure and other supporting material to explain the difference between the S-type and other types of Niti-S Pyloric Duodenal Uncovered Stent and also the difference between the different codes applied on this application.
222.	-do- **Evaluator:**	Manufacturer: M/s TaeWoong Medical Co. Ltd	Niti-S Esophageal Covered Stent (Double Type)	**Deferred** for provision of following documents:-

	AD-IV [2894-P]	14 Gojeong-ro, Wolgot-myeon Gimpo-si, Gyeonggi-do, 10022, Korea FSC UK MHRA issued on 7-2-2019	Codes: As per FSC Class C Shelf Life: 3 years	• Distribution agreement refers to product list but the product list for which Authorization is given to importer is not provided. Similar products have been applied by another company. So, provide the names of the products for which exclusive Authorization has been granted by the manufacturer to importer. • FSC country of origin i.e Korea not provided. Is the product not registered in country of origin? Clarify • Vaid ISO 13485. • EU DOC for the applied product. • Labels, brochure and other supporting material to explain the difference between the applied type and other types of Niti-S Esophageal Covered Stent and also the difference between the different codes applied on this application
223.	M/s Al-Amin Associates, 125-Habitate Flats, Shadman-II, Lahore ELI: 00104 Evaluator [AD-VIII] 2433	Legal Manufacturer: M/s Ellex Medical Pyt Ltd 3-4 second Avenue Mawson Lakes SA 5095 Australia FSC: Australia Date of Issue: 19.01.2021	Ultra QLQ (P3106-U) Ultra Q Reflex LQ (P3106-U) (Laser Ophthalmic, Nd: YAG) Codes & Sizes: As per FSC Class-C Shelf Life: N/A	**Deferred** for the provision of deficient document / clarification: i. The application form must be filled with relevant and required information. The provided form is improperly filled and devoid of relevant information. ii. Provide the credentials of manufacturer abroad duly notarized from the country of origin. iii. Provide the details of manufacturing and quality control processes. iv. Provide the Shelf-life & storage conditions, i.e., justified with stability studies. v. The firm provided photocopy of LOA, therefore provide original notarized LOA. vi. Provide detailed explanation regarding differences of applied variants i.e. Ultra QLQ (P3106-U), Ultra Q Reflex LQ (P3106-U). vii. Proposed MRP of medical device viii. Complete description with intended use, Key functional elements, formulation & composition with functionality. ix. Essential principle of safety and performance. x. Provide valid ISO 13485 provided one is expired now but valid upon submission. xi. Contraindications & Warnings to inform on specific risk or hazard to use medical device xii. Instruction for use (IFU). xiii. Information on validation for medical devices regarding intended purposes. xiv. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure regarding applied variants i.e. Ultra QLQ (P3106-U), Ultra Q Reflex LQ (P3106-U). xv. Provide EU DoC as per law of Ultra Q Reflex LQ (P3106-U). The firm

				provided separate DoCs of . Ultra Q (P3106-U).
224.	-do- Evaluator [AD-VIII] 2431	Legal Manufacturer: M/s Ellex Medical Pvt Ltd 3-4 second Avenue Mawson Lakes SA 5095 Australia FSC: Australia Date of Issue: 19.01.2021	Integre Pro Scan LP6G Integre Pro Scan LP 6RG Integre Pro Scan LP6RY Integre Pro Scan LP6Y (Ophthalmic solid-State Laser System Photocoagulation) Codes & Sizes: As per FSC Class-C Shelf Life: N/A	**Deferred** for the provision of deficient document / clarification: i. The application form must be filled with relevant and required information. The provided form is improperly filled and devoid of relevant information. ii. Provide the credentials of manufacturer abroad duly notarized from the country of origin. iii. Provide the details of manufacturing and quality control processes. iv. Provide detailed explanation regarding differences of applied variants i.e. Integre Pro Scan LP6G, Integre Pro Scan LP 6RG, Integre Pro Scan LP6RY & Integre Pro Scan LP6Y. v. Proposed MRP of medical device vi. Complete description with intended use, Key functional elements, formulation & composition with functionality. vii. Essential principle of safety and performance. viii. Provide valid ISO 13485 provided one is expired now but valid upon submission. ix. Contraindications & Warnings to inform on specific risk or hazard to use medical device x. Instruction for use (IFU). xi. Information on validation for medical devices regarding intended purposes. xii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure regarding applied variants i.e. Integre Pro Scan LP6G, Integre Pro Scan LP 6RG, Integre Pro Scan LP6RY & Integre Pro Scan LP6Y.
225.	-do- Evaluator [AD-VIII] 2432	Legal Manufacturer: M/s Ellex Medical Pvt Ltd 3-4 second Avenue Mawson Lakes SA 5095 Australia FSC: Australia Date of Issue: 19.01.2021	Tango LT (5106-T) Tango Refelx LT (5106-T) Solo LT (5106-S) (Laser Ophthalmic, Nd: YAG, (Frequency Double) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study.	**Deferred** for the provision of deficient document / clarification: i. The application form must be filled with relevant and required information. The provided form is improperly filled and devoid of relevant information. ii. Provide the credentials of manufacturer abroad duly notarized from the country of origin. iii. Provide the details of manufacturing and quality control processes. iv. Provide the Shelf-life & storage conditions, i.e., justified with stability studies. v. Provide detailed explanation regarding differences of applied variants i.e. Tango LT (5106-T), Tango Refelx LT (5106-T) & Solo LT (5106-S). vi. Proposed MRP of medical device vii. Complete description with intended use, Key functional elements, formulation & composition with functionality. viii. Essential principle of safety and performance.

				ix. Provide valid ISO 13485 provided one is expired now but valid upon submission. x. Contraindications & Warnings to inform on specific risk or hazard to use medical device xi. Instruction for use (IFU). xii. Information on validation for medical devices regarding intended purposes. xiii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure regarding applied variants i.e. Tango LT (5106-T), Tango Refelx LT (5106-T) & Solo LT (5106-S). xiv. Provide EU DoC as per law of Tango Ophthalmic laser and accessories (model: LT5106-T). The firm provided DoC of Ellex Tangoreflex Ophthalmic laser and accessories (model: LT5106-T) & Ellex Solo Ophthalmic laser and accessories (Model: LT5106-S).
226.	K.S. Agencies Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) 2682	**Legal Manufacturer:** M/s Shandong Haidike Medical Products Company Limited, Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China	**SuperLene** Sterile, Single use Non-Absorbable Polypropylene Surgical Suture – With or without needle. **Codes & Sizes** USP 2#, 1#, 0#, 2-0#, 3-0#, 4-0#, 5-0#, 6-0#, 7-0#, 8-0#, 9-0#, 10-0# Needle Shape: Round bodied, Cutting, Reverse Cutting, Straight, Taper cutting Needle Radian: 1/2 circle, 3/8 circle, straight Needle size: 2mm-9mm (single and double needle) with standard suture length Class-C Shelf Life: 5 Years	**Deferred** for provision of following documents:- i. Details of manufacturing and quality control processes. ii. Credentials of manufacturer abroad duly notarized from the country of origin. iii. Original Agency agreement or letter of authorization duly notarized by the country of origin. The already submitted LoA is photocopy. iv. The submitted unattested photocopy of FSC of China which is expired now but valid upon submission and does not cover "suture without needle" the same also states that the "[…] have been registered to be manufactured and exported in china.", need clarification and provide valid, original embassy attested FSC covering all variants of applied medical device. v. Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. vi. Shelf-life & storage conditions, i.e., justified with stability studies. vii. Complete list of various configurations to be registered supported with Free Sale Certificate or CE Marking Documents or WHO Prequalification Certifications etc. viii. Valid ISO Certification of Sterilization site duly notarized by the country of origin.. ix. Complete description with intended use, Key functional elements, formulation & composition with functionality. x. Essential principle of safety and performance. xi. Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Already submitted embassy

				attested original ISO 13485 certificate is expired now but valid upon submission. xii. Contraindications & Warnings to inform on specific risk or hazard to use medical device xiii. Instruction for use (IFU). xiv. Notarized copy of FQA. Furthermore, provide reference/link of certifying body. xv. Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Furthermore, provide reference/link of certifying body. xvi. Provided label (as approved in the country of origin) and its packaging, promotion material and brochure of all applied variants to be registered as family. xvii. Latest EU
227.	M/s MEDTRADE, 16-G, AL-RIAZ SOCIETY, JUSTICE INAMULLAH ROAD, KARACHI-74800, PAKISTAN ELI: 00564 Evaluator AD-VIII 1389-K	**Legal Manufacturer** Double Medical Technology, Inc. No. 18, Shanbianhong East Road, Haicang District, Xiamen, 361026 P.R China FSC: China Date of Issue: 26.02.2020	**Double Medical Technology Inc.** **(Orthopeadic Implants &Instruments)** **Class-C** **Shelf Life: N/A**	**Deferred** for the provision of deficient document / clarification: i. Mention the brand name of applied medical device along with complete list of various configurations to be registered supported with Free Sale Certificate or CE Marking Documents or WHO Prequalification Certifications etc. ii. Clarification is required regarding Letter of Authorization (LOA) where the manufacturer has authorized two distributors i.e. "Medtrade Ltd. / **Jokhio Enterprises**, Justice Inamullah Road, 74800, Karachi, Pakistan" Furthermore, there is discrepancy in the addresses in LOA & ELI. iii. Provide Original and Valid LOA duly notarized in the country of origin, since the provided one photocopy is expired now but valid upon submission. iv. Provide original and valid FSC duly attested by Embassy of Pakistan in the country of origin. The firm provided photocopy of FSC in China which was expired even upon submission of application. Furthermore, highlight the desired medical device to be imported. v. Provide the details of manufacturing and quality control processes of specific product. vi. Provide the credentials of manufacturer abroad duly notarized from the country of origin on format as approved by MD-Board. vii. Provide Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. viii. Clarify that applied products are sterilized, if Yes, then provide valid

				ISO Certification of Sterilization site duly notarized by the country of origin. ix. Provide Complete description with intended use, Key functional elements, formulation & composition with functionality. x. Provide Essential principle of safety and performance. xi. Provide Contraindications & Warnings to inform on specific risk or hazard to use medical device xii. Provide Instruction for use (IFU). xiii. The firm submitted Full Quality Assurance is not attached with application therefore provide notarized copy of valid FQA. Furthermore, provide reference/link of certifying body. xiv. Provided label (as approved in the country of origin) and its packaging, promotion material and brochure of all applied variants to be registered as family. xv. Provide latest EU DoC of applied medical device. xvi. Also Submit revised form-7 with all updated information.
228.	Otsuka Pakistan Limited. 30-B, Sindhi Muslim Cooperative Housing Society, Karachi (ELI-00243) Evaluator AD-VIII 3564	Legal manufacturer: Shanghai Micrport EP MedTech Co., Ltd. MicroPort (Electrophysiology) Building 23 & 28, Lane 588, Tianxiong Road, 201318 Shanghai, China EC Representative: Microport Medical B.V. Paasheuvelweg 25 1105 BP Amsterdam, The Netherlands. FSC: Netherland Valid upto 17 Sep 2023	**OptimAblate System** Codes and sizes: RF Generator: EPE-CRF-1A Irrigation Pump: EPE-IGP-1A Tubing Set: EPAB 3200 Class – C Shelf Life: Not mentioned	**Deferred** for the provision of deficient document / clarification: A. Following documents/requirements were not attached with the application, therefore: i. Provide the credentials of manufacturer abroad duly notarized from the country of origin ii. Provide the details of manufacturing and quality control processes iii. Provide the shelf-life & storage conditions, i.e., justified with stability studies: iv. Provide original, valid Letter of Authorization (LOA) duly notarized by the country of origin. v. Provide list of MD, constituents-components that are grouped together vi. Provide the Instruction for Use (IFU), catalogue & operational manual. vii. Provide the Essential principle of safety and performance. viii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure ix. Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. x. What is the current status of applied medical device in the country of origin i.e. china regarding registration and free sale. Provide relevant documents as per law.

				B. Provided photocopy of FSC issued by Netherland. Provide original FSC. C. It is required to highlight the relevant scope that covers applied medical device i.e. OptimAblate **System** (Cardiac RF Generator; Irrigation pump & Tubing Set) in following certificates Production Quality Assurance System (G2S 081711 0024 Rev. 00); Full Quality Assurance System (G2S 081711 0025 Rev. 00) & Design Examination Certificate (G2S 081711 0026 Rev. 00).
229.	-do- Evaluator AD-VIII 3562	Legal manufacturer: Shanghai Micrport EP MedTech Co., Ltd. MicroPort (Electrophysiology) Building 23 & 28, Lane 588, Tianxiong Road, 201318 Shanghai, China EC Representative: Microport Medical B.V. Paasheuvelweg 25 1105 BP Amsterdam, The Netherlands. FSC: Netherland Valid upto: 17 Sep 2023	FIREMAGIC Cardiac RF Ablation Catheter Codes and sizes as per FSC Class – D Shelf Life: Not mentioned	**Deferred** for the provision of deficient document / clarification: A. Following documents/requirements were not attached with the application, therefore: i. Provide the credentials of manufacturer abroad duly notarized from the country of origin ii. Provide the details of manufacturing and quality control processes iii. Provide the shelf-life & storage conditions, i.e., justified with stability studies: iv. Provide original, valid Letter of Authorization duly notarized by the country of origin. v. Provide list of MD, constituents-components that are grouped together vi. Provide the Instruction for Use (IFU), catalogue & operational manual. vii. Provide the Essential principle of safety and performance. viii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure ix. Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. x. Provide clinical evidences reports regarding applied medical device. xi. What is the current status of applied medical device in the country of origin i.e. china regarding registration and free sale. Provide relevant documents as per law. B. Provided photocopy of FSC issued by Netherland. Provide original FSC.
230.	-do- Evaluator AD-VIII 3563	Shanghai Micrport EP MedTech Co., Ltd. MicroPort (Electrophysiology) Building 23 & 28, Lane 588, Tianxiong	Columbus™ 3D EP Navigation Systems EPE-SYS-1A EPE-SYS-2A	**Deferred** for the provision of deficient document / clarification: A. Following documents/requirements were not attached with the application, therefore: i. Provide the credentials of manufacturer abroad duly notarized from the country of origin

		Road, 201318 Shanghai, China	External reference patch EPR-105-A Cardiac EP Stimulator DF-5A Class – C Shelf Life: Not mentioned	ii. Provide the details of manufacturing and quality control processes iii. Provide the shelf-life & storage conditions, i.e., justified with stability studies: iv. Provide original, valid Letter of Authorization (LOA) duly notarized by the country of origin. v. Provide list of MD, constituents-components that are grouped together vi. Provide the Instruction for Use (IFU), catalogue & Operational manual. vii. Provide the Essential principle of safety and performance. viii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure ix. Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. x. Provide clinical evidences reports regarding applied medical device. xi. What is the current status of applied medical device in the country of origin i.e. china regarding registration and free sale. Provide relevant documents as per law. B. Provided photocopy of FSC issued by Netherland. Provide original FSC. C. It is required to highlight the relevant scope that covers applied medical device i.e. Columbus **System** (3D EP Navigation System; External reference patch & Cardiac EP Stimulator) in following certificates Production Quality Assurance System (G2S 081711 0024 Rev. 00); Full Quality Assurance System (G2S 081711 0025 Rev. 00) & Design Examination Certificate (G2S 081711 0026 Rev. 00).
231.	-do- Evaluator: AD-IV [3565]	Manufacturer: Shanghai MicroPort EP MedTech Co., Ltd. Building 23 & 28, Lane 588, Tianxiong Road, 201318 Shanghai, China FSC Netherlands copy valid till 17-09-2023	EASYFINDER Steerable Curve Diagnostic Catheter Codes and sizes as per FSC Class D Shelf life: Not mentioned	Deferred for provision of following documents:- • Authority letter from owner/ CEO/ MD for Mr Attique Rahman for signing cover letter, form 7A, Declaration on stamp paper etc on behalf of the firm. • The product **EASYFINDER Fixed Curve Diagnostic Catheter** is already registered (MDIR-0001795) in your name so cannot be reconsidered. The product EASYFINDER Steerable Curve Diagnostic Catheter may be considered on this application. State the codes of EASYFINDER Steerable Curve Diagnostic Catheter required on this application and highlight on FSC, DOC, Design Examination and Full QA certificate Moreover, the Form-7A is not filled

				properly and most of the fields are not filled. Submit complete filled Form 7A for the EASYFINDER Steerable Curve Diagnostic Catheter • Original Letter of Authorization or Agency agreement with manufacturer abroad, duly notarized in the country of origin. Letter of Authorization or agreement shall be original, signed & stamped, having validity, correct names and addresses of both manufacturer and importer and having name of medical devices for which sole/exclusive authorization is given to importer. • Free Sale Certificate from country of origin not provided. Provide valid, original document with Embassy attestation having the applied product along with codes. • Free Sale Certificate from reference country is copy. Provide valid, original document with Embassy attestation having the applied product along with codes. • Details of manufacturing and QC for EASYFINDER Steerable Curve Diagnostic Catheter Clearly state the shelf life of EASYFINDER Steerable Curve Diagnostic Catheter and provide clear, conclusive stability studies supporting the claimed shelf life. • MRP of EASYFINDER Steerable Curve Diagnostic Catheter. • Technical details, product description along with instructions for use (IFU) for EASYFINDER Steerable Curve Diagnostic Catheter. • ISO13485, Full QA and Design Examination are copy. Provide certificates with original notarization. • Essential principles of safety and performance for EASYFINDER Steerable Curve Diagnostic Catheter. • Declaration of conformity (DOC) not provided. Provide DOC for the applied device on manufacturer's letter head signed and stamped by the responsible personnel • Labels of all the codes of EASYFINDER Steerable Curve Diagnostic Catheter required on this application.
232.	-do- Evaluator: AD-IV [4335]	Manufacturer: Eucatech AG, Rebgartenweg 27, 79576 Weil am Rhein, Germany FSC Not provided	Support-C Paclitaxel Eluting PTCA Balloon Catheter Class D Codes: as per FSC Shelf life: 36 months	**Deferred** for provision of following documents:- • Provide Authority letter from owner/CEO/MD for Mr Attique Rahman for signing cover letter, Form 7A, Declaration on stamp paper etc on behalf of the firm. • Agency agreement is copy and not notarized. Provide original notarized

				document or provide original Letter of Authorization from manufacturer abroad, duly notarized in the country of origin. Letter of Authorization shall be original, signed & stamped, having validity, correct names and addresses of both manufacturer and importer and having name of medical devices for which sole/exclusive authorization is given to importer. • Free Sale Certificate from country of origin not provided. Provide valid, original document with Embassy attestation having the applied product along with codes. • ISO13485 not provided. Provide valid and notarized certificate • Full QA and Design Examination Certificate not notarized. Provide valid and notarized certificate. • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin • MRP not provided. Provide it. • Provide Essential principles of safety and performance for applied product.
233.	M/s Iqbal & Company, Alfalah Manzil Opp. Natinoal Police Foundation, Street No. 26, Sector E-II/4, Islamabad ELI: 00117 Evaluator: AD-VIII 1818 (P)	Legal Manufacturer: BD Switzerland Sarl, Terre Bonne Park-A4, Rout de Crassier 17, 1262 Eysins **Switzerland** Manufacturing Site: Plexus RO S.R.L Eugeniu Carada Street No, 2-4, Oradea, 410610, Bihor, **Romania.** **FSC: Switzerland** Valid Till: 02.12.2022	**Alaris ™ GH Plus Guardrails™ Syringe Pump** (Syringe Pump) Part Number: 8002TIG03-G Class-C Useful Life: 7 years	**Deferred** for the provision of deficient document / clarification: i. Application covering letter & Form 7A needs revision regarding change in the brand name of applied product from **Alaris ™ GH Syringe Pump to Alaris ™ GH Plus Guardrails™ Syringe Pump.** ii. The firm claimed that Original LOA & FSC are attached in Alaris™ GW800 Volumetric Pump. iii. Provide ISO & FQA certificates are expired now. Provide valid certificates. Furthermore, provided ISO certificate doesn't cover the manufacturing site i.e. Plexus RO S.R.L Eugeniu Carada Street No, 2-4, Oradea, 410610, Bihor, Romania. Therefore provide ISO certificate covering manufacturing site.
234.	M/s Medi Bridge, Office No. 500-D, M/A Johar Town Lahore Warehouse Address: 5, 2nd Floor, Royal Arcade, Qainchi, Ferozeput Road, Lahore ELI: 00558 Evaluator: AD-VIII 2378	**Legal Manufacturer:** M/s Zhejiang Haisheng Medical Device Co. Ltd, No. 8, Zhenyuan Road, Yuecheng District, 312071, Shaoxing City, Zhejiang Province, People's Republic of China FSC: China Valid till: 27.06.2022	Hisern (Disposable Blood Pressure transducer Monitoring device) Codes & Sizes: As per FSC Class-C Shelf life: 5 years	**Deferred** for the provision of deficient document / clarification: i. Specify Models/codes of medical device on application forms. ii. Provide detailed QC procedures of applied medical device. iii. Submit stability studies of applied medical device to justify the claimed shelf life. iv. Provide original FSC. v. Provide labels of all the variants/codes applied. vi. Provide European DoC. vii. Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or

				complete CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. viii. Firm claimed the registration on the basis of CE-Mark certifications of the subject product, But submit only the Full QA Certificate in this regard. Firm asked to submit the following documents as per NANDO Database for the subject category of the products: - ix. Product Family: *MD 1300 - Monitoring devices. Certificates or modules: a) Full quality assurance system. (Annex: II) b) EC type-examination. (Annex: III) c) EC verification. (Annex: IV) d) Production quality assurance. (Annex: V) e) Product quality assurance. (Annex: VI) x. The products applied in the category of 'Family' with multiple codes having different variants of the medical devices and accessories. Also, the products intended for different age groups are presented with different codes, separate packaging (as a separate medical device pack) and have variation in the class and number of accessories. So, the applied products can only be clubbed in a 'Family' with same variants/ accessories and in a same package. In this regard, you are advised to apply separately for different applications, in the light of Schedule-B of rule (11) of MDR, 2017.
235.	M/s Total Technologies (Pvt) Ltd. 696, J-2, Johar Town, Lahore ELI:00129 Evaluator: AD-VIII 2739	**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	iM Series Patient Monitor (Single-patient physiologic monitoring system) Model: iM8; iM20; iM50; iM60; iM70; iM80 Class-C Shelf Life: Not applicable	**Deferred** for the provision of deficient document / clarification: i. The submitted FSC doesn't cover all the applied models and the same was also expired even upon submission. Therefore, provide original, valid FSC duly attested by embassy of Pakistan in the country of origin covering all the models of applied medical device. ii. Provided ISO 13485 is expired now. Provide valid ISO 13485. iii. The provided User Manual (Chapter 3) doesn't cover iM8 and iM20 models of iM series Patient monitor. Furthermore, provide a detailed comparison (supported with documentary evidences, if applicable) of different type of models to ascertain their grouping in a single application. iv. Provide original LOA.

				v. Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or complete CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. vi. Mention the proposed MRP of applied medical device and submit revise application form. vii. Provided DoC doesn't cover iM8 and iM20 models of iM series. Furthermore, clarify difference between iM50 & M50 similarly for iM80 & M80. viii. Firm claimed the registration on the basis of CE-Mark certifications of the subject product, But submit only the Full QA Certificate in this regard. Firm asked to submit the following documents as per NANDO Database for the subject category of the products: - Product Family: *MD 1300 - Monitoring devices. Certificates or modules: a) Full quality assurance system. (Annex: II) b) EC type-examination. (Annex: III) c) EC verification. (Annex: IV) d) Production quality assurance. (Annex: V) e) Product quality assurance. (Annex: VI)
236.	-do- Evaluator: AD-VIII 2735 (P)	Legal Manufacaturer: 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	Fetal & Maternal Monitor (Foetal Cardiac Monitor) Codes & Sizes: As per FSC F6 F6 Express Class-C Shelf Life: Not applicable	**Deferred** for the provision of deficient document / clarification: i. Mention specific codes on application form to be registered. Submit revised form with completely filled relevant information. ii. Provide stability studies/validation studies/service life studies. iii. Provide original LOA since the firm attached photocopy with the application. iv. The submitted photocopy of FSC was expired even upon submission. Therefore, provide original, valid FSC duly attested by embassy of Pakistan in the country of origin. v. Provided ISO 13485 is expired now. Provide valid ISO 13485. vi. Firm claimed the registration on the basis of CE-Mark certifications of the subject product, But submit only the Full QA Certificate in this regard. Firm asked to submit the following documents as per NANDO Database for the subject category of the products: - Product Family: *MD 1300 - Monitoring devices. Certificates or modules:

				a) Full quality assurance system. (Annex: II) b) EC type-examination. (Annex: III) c) EC verification. (Annex: IV) d) Production quality assurance. (Annex: V) e) Product quality assurance. (Annex: VI) vii. The firm attached Label, DoC & Essential Principal of Safety and Performance of Central Monitoring System (FTS-6), therefore provide the same for applied medical device.
237.	M/s Nwill Healthcare office No. B9, Royal Garden Hotel Building-19,Birdwood Road Lahore. ELI: 00164 Evaluator: AD-VIII 2312 (P)	Legal Manufacturer: M/s Medevice 3S Joint Venture Co., Ltd Hamlet 5- Chon Thanh Town-Chon Thanh District Binh Phuoc, Vietnam FSC: Vietnam Date of Issue: 04.07.2011	Gallant (Contraceptive Device Condom) Codes & Sizes: As per FSC Class- C Shelf Life: As per stability study	**Deferred** for the provision of deficient document / clarification: i. Since the label of each variant (dotted, ribbed, etc.) is different therefore the firm is required to apply separately for each variant. ii. Provide original LOA. iii. The submitted photocopy of FSC was expired even upon submission and doesn't mentions any variant (dotted, ribbed, etc.). Therefore, provide original, valid FSC duly attested by embassy of Pakistan in the country of origin covering the applied variants. iv. Since the firm has applied registration of medical device on WHO pre-qualification basis. However, as per list of **UNFPA Prequalified Male Condom Manufacturing Sites** dated March 29, 2022 the name of applied manufacturer & site i.e. M/s Medevice 3S Joint Venture Co., Ltd Hamlet 5-Chon Thanh Town-Chon Thanh District Binh Phuoc, Vietnam, is not given, require clarification and latest evidence of WHO pre-qualification. v. Original and valid Free sale certificate (FSC) of any RRA, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017.
238.	M/s Meritorious, Business Solution (Pvt) Ltd, Office No. 202, 2nd Floor, 153-D, Block-D, Civic Center, Phase-$,Bahria, Town, Islamabad. ELI: 00208 Evaluator: AD-VIII 1775 (P)	Legal Manufacturer: Hangzhou Proprium Biotech Co,. Ltd, 3F Building , 2 No. 755 Yinhai Road Hangzhou Econimic & Technological Development Area, Hangzhou, 310018 China. FSC: China Validity: 04.08.2021	Chitinase-3-Like Protein 1-CHI3L1 Test Kit (Colloidal Gold) Class-C Shelf Life: One year	**Deferred** for the provision of deficient document / clarification: i. Submit properly filled revised application form against relevant field for relevant information. ii. Provide Original LOA. iii. Provide valid & Original Free Sale certificate of any RRA duly attested by the Embassy of Pakistan. iv. The firm submitted "**EC declaration of Conformity**" based on compliance with the **"Directive 98/79/EC"** assured via assessment of the Quality Management System by the NANDO Notified Body i.e.

				ENTE CERTIFICAZIONE MACCHINE SRL, Via Ca' Bella, 243/A - loc. Castello di Serravalle 40053 Valsamoggia (BO), Italy (Body No.: 1282). However, as per NANDO database of notified bodies, the said notified body is not authorized under EU **Directive 98/79/EC.** v. The Declaration of conformity submitted by the firm is invalid and not in-line with the international practices since the provided document is devoid of /misrepresenting regarding "name of EU representative, classification of IVD-MD and para 2-above". vi. The Free sale certificate is not issued by CFDA, China, but the same was issued by "China chamber of commerce for import & export of medicines & Health product", need clarification/justification. vii. Provide valid License stated that applied manufacturer is authorized to manufacture applied IVD-MD. viii. Provide valid Registration certificate issued in favor of manufacturer stating that the applied IVD-MD is duly registered in the country of origin. ix. Provide Performance Evaluation Report of applied IVD-MD. x. Provide certificate of analysis of applied IVD-MD. xi. Provided ISO 13485 certificate is expired now. Provide valid ISO 13485. xii. Provide the current status of applied IVD-MD in Europe as per EU Directive 98/79/EC. xiii. Provide Instruction for use of applied IVD-MD. xiv. The Unit carton/outer box of applied IVD-MD mentions M/s Proprium Biotech USA, 10900 NE 4th St, 23rd Floor, Bellevue, WA 98004, USA, explain the role of Proprium Biotech USA regarding applied IVD-MD. xv. Provide whether any "Chitinase-3-Like Protein 1-CHI3L1 Test Kit" is available and currently on Free Sale in any Reference Regulatory Authorities as per Rule 15(2) of MDR, 2017 or otherwise explain the novelty of the applied IVD-MD. Support the explanation with documentary evidences like FSC in RRA etc. xvi. The provided stability study report doesn't bear signature of authorized responsible person. Justify that submitted stability studies are in-line with international standards used for conducting stability studies of applied IVD-MD.

				xvii. Provide Essential Principle of Safety and Performance / Essential Requirements / Essential Checklist as per EU Directive 98/79/EC. xviii. Justify the classification of applied IVD-MD as per MDR, 2017 as Class-C medical device as stated on DoC. xix. Provide complete documentation related to the manufacturing and quality control processes.
239.	Genus, 220, Block:3 DMCHS, S. Abdul Tawwab road, Karachi Pakistan (ELI-00038) Evaluator: AD-VIII 4339 (K)	M/s Shanghai Kindly Medical Instruments Co., Ltd., NO. 925, Jinyuan No. 1 Road, Shanghai China FSC: Germany Date of issue: 26 Aug 2019	Path Finder (Guiding Catheter) Codes & Sizes: As pe FSC Class D Shelf Life: 24 months	**Deferred** for the provision of deficient document / clarification: i. Provide notarized credentials of manufacturer. ii. Specify the models/codes to be registered of applied medical device and submit revised application form. iii. Provided un-attested Photocopy of Free Sale Certificate (No. 20210031) issued by Country of Origins i.e. China doesn't cover applied medical device i.e. Guiding Catheter. Therefore, provide Original, valid FSC in the country of origin duly attested by the embassy of Pakistan, covering Path Finder (Guiding Catheter) & its model/codes. iv. Explain the differences between various codes of HI, STR, GC, SI & SR models of guiding catheter as these models are not covered under Technical data sheet attached with application for registration. v. Provide labels of all models/codes (as approved in the country of origin) and its packaging, promotion material and brochure. vi. The DoC mentions 385 different codes of Guiding Catheter however the FSC of Germany mentions only 220 codes, explanation is required. Also provide EU Declaration of KDL Guiding Catheter for corroboration. vii. The firm applied the Guiding catheter with brand name "Path Finder", However the technical file and DoC states the brand name as "KDL", please clarify the situation and submit harmonized documents mentioning the applied name or otherwise. viii. Provided ISO 13485 was expired even upon submission therefore, provide valid certificate. ix. Provide design examination of applied medical device covering the models and codes of Path Finder (Guiding Catheter).
240.	-do- Evaluator: AD-VIII	M/s Shanghai Kindly Medical Instruments Co., Ltd., NO. 925, Jinyuan No. 1 Road,	G-Track (Diagnostic Angiographic Catheter)	**Deferred** for the provision of deficient document / clarification: i. Provide notarized credentials of manufacturer.

	4340 (K)	Shanghai China FSC: Germany Date of issue: 26 Aug 2019	Codes & Sizes: As pe FSC Class D Shelf life 24 Months	ii. Specify the models/codes to be registered of applied medical device and submit revised application form. iii. Provided un-attested Photocopy of Free Sale Certificate (No. 20210031) issued by Country of Origins i.e. China doesn't cover applied medical device i.e. G-Track (Diagnostic Angiographic Catheter). Therefore, provide Original, valid FSC in the country of origin duly attested by the embassy of Pakistan, covering G-Track (Diagnostic Angiographic Catheter) & its model/codes. iv. Explain the differences between various codes & types of G-Track (Diagnostic Angiographic Catheter) as description of each code & type is not covered under Technical data sheet attached with application for registration. v. The firm applied the Diagnostic Angiographic Catheter with brand name "G-Track", However the technical file and DoC states the brand name as "KDL – NT", please clarify the situation and submit harmonized documents mentioning the applied name or otherwise. vi. Provided ISO 13485 was expired even upon submission therefore, provide valid certificate. vii. Provide design examination of applied medical device covering the models and codes of Path Finder (Guiding Catheter). viii. Provide labels of all models/codes (as approved in the country of origin) and its packaging, promotion material and brochure. ix. The DoC mentions 222 different codes of Guiding Catheter however the FSC of Germany mentions only 82 codes, explanation is required. Also provide EU Declaration of "KDL – NT" Diagnostic Angiographic Catheter for corroboration.
241.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi (ELI-00005) Evaluator [AD-VIII] 4141	BIOTEQUE COORPORATION 5F-6, NO. 23, Sec. 1, Chang-An E. Road, Taipei 104, Taiwan R.O.C FSC: Taiwan	BIOTEQ DOUBLE LUMEN CATHETER FOR HEMODIALYSIS (HEMODIALYSIS CATHETER KIT) Straight & Curved) Class: C Shelf Life: 3 Years	**Deferred** as the product is from Taiwan.
242.	-do-. **Evaluator:**	Manufacturer: M/s Shandong Wuzhou Medical Equipment Co., Ltd.,	YMS Auto disable syringe Class B Shelf life: 5 years	**Deferred** for provision of following documents:- • The document provided as Free Sale Certificate (FSC) is EXPORT ONLY

	AD-IV [4359]	Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R China Export only certificate	Sizes: 3ml, 5 ml	certificate and cannot be considered as FSC. The applied product "auto disable" is also not present in it • Reference country FSC is also not provided. Since product is export only in country of origin i.e China then reference country FSC should be provided having the applied product name, its codes etc • The Product QA certificate and ISO13485 (both non-notarized copies) has the term **sterile self-destruction safety syringes** for single use and NOT the applied product auto disable syringe so cannot be considered as CE marked. Provide the relevant, valid and notarized certificates with the applied product in it • The Declaration of Conformity (DOC) has the applied product auto disable syringe but the Notified body certificate number mentioned on it does not match with the number of the Production QA certificate provided. Clarify the ambiguity. Provide relevant certificates • Description provided is of conventional syringe and not of applied auto disable syringe. Provide relevant description • The manufacturing and QC details are in general and not of specifically of applied product. Provide it • It cannot be ascertained from the Essential principles of safety and performance document provided that it is of applied product auto-disable syringe. • Provide evidence • Letter of Authorization and credentials are copy and not notarized. • Provide Undertaking from the manufacturer abroad duly notarized in the country of origin that same product (product name) with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
243.	M/s Green Care Trading Pvt Ltd, Zarghoon Medical Store, Opp Bolan Medical Complex Hospital, Brewery Road, Chilton Town, Quetta. ELI-00313 **Evaluator:** AD-IV [2916]	Manufacturer: M/s. Changzhou Jinliyuan Medical Devices, Co., Ltd., No.6 West Xihe Road, Sanhekou, Zhenglu Town, Wujin District, 213115 Changzhou City, China	GREEN CARE Sterile Hypodermic Syringe for single use with needle Class B Shelf life: 5 years Codes: not provided	**Deferred** for provision of following documents:- • Form of insulin syringe is attached in this dossier instead of hypodermic syringe. Also, form is not signed by proprietor. Provide completely and properly filled Form 7A for GREEN CARE Sterile Hypodermic Syringe for single use with needle each page duly signed and stamped by owner. Clarify who has signed cover letter on behalf of proprietor? In case of

		FSC Germany issued on 10-3-2020 Export only certificate of china (expired)		authorized person, provide Authority letter from owner. • Stability studies heading states it is real-time stability studies whereas in the body of text only accelerated studies data is provided which is not acceptable. Provide real time stability studies supporting claimed shelf life of 5 years for this product signed and stamped by responsible person of manufacturer. • Sizes/codes required on this application not clear. Mention on Form and they should also be present on Free Sale Certificate (FSC) Germany. • ISO 13485 and Production QA expired now. Provide valid certificates. • Undertaking on stamp paper is not signed and stamped by anyone. Provide undertaking on stamp paper signed and stamped by owner. • Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking and Free Sale Certificate of Europe on the letterhead signed and stamped by responsible personnel.
244.	-do- Evaluator: AD-IV [2917]	Manufacturer: M/s. Changzhou Jinliyuan Medical Devices, Co., Ltd., No.6 West Xihe Road, Sanhekou, Zhenglu Town, Wujin District, 213115 Changzhou City, China FSC Germany issued on 10-3-2020 Export only certificate of china (expired)	GREEN CARE Disposable Transfusion Set with needle Class B Shelf life: 5 years Codes: not provided	**Deferred** for provision of following documents:- • Form is not signed by proprietor. Provide completely and properly filled Form 7A for GREEN CARE Disposable Transfusion Set with needle each page duly signed and stamped by owner. Clarify who has signed cover letter on behalf of proprietor? In case of authorized person, provide Authority letter from owner. • Stability studies heading states it is real-time stability studies whereas in the body of text only accelerated studies data is provided which is not acceptable. Provide real time stability studies supporting claimed shelf life of 5 years for this product signed and stamped by responsible person of manufacture. • Sizes/codes required on this application not clear. Mention on Form and they should also be present on Free Sale Certificate (FSC) Germany. State the difference amongst the 2 codes present in FSC and provide pictures and labels of both codes. • ISO 13485 and Production QA expired now. Provide valid certificates. • Undertaking on stamp paper is not signed and stamped by anyone and is copy. Provide undertaking on stamp paper signed and stamped by owner • Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied

				to Pakistan as claimed for CE marking and Free Sale Certificate of Europe on the letterhead signed and stamped by responsible personnelpersonnel.
245.	-do- Evaluator: AD-IV [2918]	Manufacturer: M/s. Changzhou Jinliyuan Medical Devices, Co., Ltd., No.6 West Xihe Road, Sanhekou, Zhenglu Town, Wujin District, 213115 Changzhou City, China FSC Germany issued on 10-3-2020 Export only certificate of china (expired)	GREEN CARE Sterile Insulin Syringe for Single use Class B Shelf life: 5 years Codes: not provided	**Deferred** for provision of following documents:- • Form of hypodermic needle is attached in this dossier instead of insulin syringe. Also, form is not signed by proprietor. Provide completely and properly filled Form 7A for GREEN CARE Sterile Insulin Syringe for Single use each page duly signed and stamped by owner. Clarify who has signed cover letter on behalf of proprietor? In case of authorized person, provide Authority letter from owner. • Stability studies heading states it is real-time stability studies whereas in the body of text only accelerated studies data is provided which is not acceptable. Provide real time stability studies supporting claimed shelf life of 5 years for this product signed and stamped by responsible person of manufacturer. • Mention Sizes/codes required on Form and they should also be present on Free Sale Certificate (FSC) Germany. • ISO 13485 and Production QA expired now. Provide valid certificates. • Undertaking on stamp paper is not signed and stamped by anyone and is copy. Provide undertaking on stamp paper signed and stamped by owner. • Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking and Free Sale Certificate of Europe on the letterhead signed and stamped by responsible personnel
246.	-do- Evaluator: AD-IV [2919]	Manufacturer: M/s. Changzhou Jinliyuan Medical Devices, Co., Ltd., No.6 West Xihe Road, Sanhekou, Zhenglu Town, Wujin District, 213115 Changzhou City, China FSC Germany issued on 10-3-2020 Export only certificate of china (expired)	GREEN CARE Disposable Sterile hypodermic needle Class B Shelf life: 5 years Codes: not provided	**Deferred** for provision of following documents:- • Form of hypodermic syringe is attached in this dossier instead of hypodermic needle. Also, form is not signed by proprietor. Provide completely and properly filled Form 7A for GREEN CARE Disposable Sterile hypodermic needle each page duly signed and stamped by owner. Clarify who has signed cover letter on behalf of proprietor? In case of authorized person, provide Authority letter from owner. • Stability studies heading states it is real-time stability studies whereas in the body of text only accelerated studies data is provided which is not acceptable. Provide real time stability studies supporting claimed shelf life of 5 years for this product signed and stamped by responsible person of manufacturer.

				• Sizes/codes required on this application not clear. Mention on Form and they should also be present on Free Sale Certificate (FSC) Germany. Provide actual labels of product codes required. • ISO 13485 and Production QA expired now. Provide valid certificates. • Undertaking on stamp paper is not signed and stamped by anyone and is copy. Provide undertaking on stamp paper signed and stamped by owner. • Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking and Free Sale Certificate of Europe on the letterhead signed and stamped by responsible personnel.
247.	-do- ELI-00313 Evaluator: AD-IV [3057]	Manufacturer: M/s. Changzhou Jinliyuan Medical Devices, Co., Ltd., No.6 West Xihe Road, Sanhekou, Zhenglu Town, Wujin District, 213115 Changzhou City, China FSC Germany issued on 10-3-2020 Export only certificate of china (expired)	GREEN CARE Infusion Set for Single Use with needle Class B Shelf life: 5 years Codes: not provided	**Deferred** for provision of following documents:- • Form is not signed by proprietor. Provide completely and properly filled Form 7A for GREEN CARE Infusion Sets for Single Use with needle each page duly signed and stamped by owner. Clarify who has signed cover letter on behalf of proprietor? In case of authorized person, provide Authority letter from owner. • Stability studies heading states it is real-time stability studies whereas in the body of text only accelerated studies data is provided which is not acceptable. Provide real time stability studies supporting claimed shelf life of 5 years for this product signed and stamped by responsible person of manufacturer. • Sizes/codes required on this application not clear. Mention on Form and they should also be present on Free Sale Certificate (FSC) Germany. State the difference amongst the codes present in FSC and provide pictures and labels of those codes. • ISO 13485 and Production QA expired now. Provide valid certificates. • Undertaking on stamp paper is not signed and stamped by anyone and is copy. Provide undertaking on stamp paper signed and stamped by owner. • Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking and Free Sale Certificate of Europe on the letterhead signed and stamped by responsible personnel
248.	M/s Jafri Medical Suit No. 104, C-11, Maryam Heights, Block 7/8, KCHS, P.E.C.H.S, Shaheed-e-Millat Road, Karachi. Evaluator:	Manufacturer: ResMed Ltd 1 Elizabeth MacArthur Drive, Bella Vista NSW 2153, Australia FSC not provided	AcuCare F1-0 Hospital Non-Vented Full Face Mask	**Deferred** for provision of following documents:- • The product is class B medical device. Submit differential fee of Rs. 20,000/- for the applied product and submit COMPLETELY FILLED FORM 7A (not

	AD-IV [294(6A)]		Class A (should be class B) Shelf life: 5 years	Form 6A) with each duly signed and stamped by the owner. • The application at this stage is deficient in all respect i.e most of the fields of the Form are left empty, legal documents such as Letter of Authorization, Free Sale Certificate, ISO13485, Full QA certificate is either not provided or not notarized, attested as required and technical documents such as details of manufacturing and QC, stability studies, grouping, Essential principles of safety and performance etc not provided. Submit all the relevant documents as mentioned in Form 7A
249.	-do- Evaluator: AD-IV [295(6A)]	Manufacturer: ResMed Ltd 1 Elizabeth MacArthur Drive, Bella Vista NSW 2153, Australia FSC not provided	AcuCare F1-4 Hospital Vented Full Face Mask Class A (should be class B) Shelf life: 5 years	**Deferred** for provision of following documents:- • The product is class B medical device. Submit differential fee of Rs. 20,000/- for the applied product and submit COMPLETELY FILLED FORM 7A (not Form 6A) with each duly signed and stamped by the owner. . • The application at this stage is deficient in all respect i.e most of the fields of the Form are left empty, legal documents such as Letter of Authorization, Free Sale Certificate, ISO13485, Full QA certificate is either not provided or not notarized, attested as required and technical documents such as details of manufacturing and QC, stability studies, grouping, Essential principles of safety and performance etc not provided. Submit all the relevant documents as mentioned in Form 7A
250.	-do-. Evaluator: AD-IV [296(6A)]	Manufacturer: Great Group Medical CO., LTD No. 168 Xingong 2nd Rd, Tianzhing Township, Changhua County, Taiwan	High Flow Nasal Cannula Class A (should be class B) Codes: Not mentioned Shelf life: 5 years	**Deferred** as the product is from Taiwan.
251.	M/s Bajwa Sons 13-Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore ELI-00314 Evaluator: AD-IV [2779-P]	Manufacturer: M/s Hunan Pingan Medical Device Technology Co. Ltd., No. 8 industry AVE, Economic Development Zone, Li County, 415500 Changde, Hunan Province, P.R. China	Blood Transfusion Set Codes & Sizes: As per FSC Class B Shelf Life: 3 years	**Deferred** for provision of following documents:- • Brand name not provided. State the brand name of the product • Provide QC details/QC tests performed on Blood transfusion set • Original distribution agreement/Letter of Authorization, and Full Quality Assurance certificate is not provided, only copy is provided. Provide original documents • In Free Sale Certificate (FSC) the product codes are mentioned and not sizes. Clearly

		FSC China valid till 21.07.2021		state which codes of blood transfusion set are required on this application and provide information that what does this code represent i.e its size and specifications. Provide supporting documents to explain this. Also provide all labels of the said product • Stability studies/aging studies not provided. Provide stability studies supporting the claimed shelf of 3 years for blood transfusion set • FSC China expired now but the provided document is not original, it is copy. Provide original valid and Embassy attested FSC from country of origin for the applied product • Moreover, China is not a reference country so provide original and valid free sale certificate duly attested by Embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017. If the product is applied on the basis of CE mark documents then clearly state it • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin • ISO13485 certificate is copy. Provide certificate having original notarization • The undertaking from manufacturer abroad does NOT state the name of the product for which the undertaking is given and it is company and not original. Provide Undertaking (original) from the manufacturer abroad that same blood transfusion with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel. • Provide Essential principles of safety and performance for the applied device • Provide sterilization validation report for the applied product. The document provided in the dossier is just protocol and not report • Provide complete Declaration of conformity from the manufacturer issued as per European Directive for the applied product stating the device class, product codes, notified body etc signed and stamped by responsible personnel.
252.	-do- Evaluator: AD-IV [2780-P]	Manufacturer: M/s Hunan Pingan Medical Device Technology Co. Ltd., No. 8 industry AVE, Economic Development Zone, Li County, 415500 Changde, Hunan	IV Catheter Codes & Sizes: As per FSC Class B Shelf Life: 3 years	**Deferred** for provision of following documents:- • Submit fee of Rs. 25,000/- for the applied product • Brand name not provided. State the brand name of the product • Provide QC details/QC tests performed on IV Catheter

		Province, P.R. China FSC China valid till 21.07.2021		• Original distribution agreement/Letter of Authorization is not provided, only copy is provided. Provide original documents • In Free Sale Certificate (FSC) the only product types codes are mentioned and not their sizes. Provide FSC with product types and its sizes/codes. Then clearly state which type and codes of IV Catheter are required on this application and provide information that what does this code represent i.e its size and specifications. Provide supporting documents to explain this. Also provide all labels of the said product • Stability studies/aging studies not provided. Provide stability studies supporting the claimed shelf of 3 years for blood transfusion set • FSC China expired now but the provided document is not original, it is copy. Provide original valid and Embassy attested FSC from country of origin for the applied product with product types and its sizes/codes • Moreover, China is not a reference country so provide original and valid free sale certificate duly attested by Embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017. If the product is applied on the basis of CE mark documents then clearly state it • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin • ISO13485 certificate and Full QA certificate does not have IV catheter in its scope. Is the product not CE marked? Clarification is required from manufacture abroad. Provide relevant valid and notarized certificates having IV catheter in their scope, otherwise it will be considered as a Non-CE marked product • The undertaking from manufacturer abroad does NOT state the name of the product for which the undertaking is given and it is company and not original. If the product is CE marked then provide Undertaking (original) from the manufacturer abroad that same IV catheter with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel • Provide Essential principles of safety and performance for the applied device • Provide sterilization validation report for the applied product. The document provided in the dossier is just protocol and not report • Provide complete Declaration of conformity from the manufacturer issued

				as per European Directive for the applied product stating the device class, product codes, notified body etc signed and stamped by responsible personnel.
253.	-do- Evaluator: AD-IV [2269-P]	Manufacturer: M/s Hunan Pingan Medical Device Technology Co. Ltd., No. 8 industry AVE, Economic Development Zone, Li County, 415500 Changde, Hunan Province, P.R. China FSC China valid till 21.07.2021	IV infusion set Codes & Sizes: As per FSC Class B Shelf Life: 3 years	**Deferred** for provision of following documents:- • Brand name not provided. State the brand name of the product • Provide QC details/QC tests performed on IV Infusion Set • Original distribution agreement/Letter of Authorization is not provided, only copy is provided. Provide original documents • In Free Sale Certificate (FSC) the product codes are mentioned and not sizes. Clearly state which codes of IV infusion set are required on this application and provide information that what does this code represent i.e its size and specifications. Provide supporting documents to explain this. Also provide all labels of the said product • Stability studies/aging studies not provided. Provide stability studies supporting the claimed shelf of 3 years for blood transfusion set • FSC China expired now but the provided document is not original, it is copy. Provide original valid and Embassy attested FSC from country of origin for the applied product with product sizes/codes • Moreover, China is not a reference country so provide original and valid free sale certificate duly attested by Embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017. If the product is applied on the basis of CE mark documents then clearly state it • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin • ISO13485 certificate is copy. Provide certificate having original notarization • The undertaking from manufacturer abroad does NOT state the name of the product for which the undertaking is given and it is company and not original. Provide Undertaking (original) from the manufacturer abroad that same IV infusion set with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel • Provide Essential principles of safety and performance for the applied device • Provide sterilization validation report for the applied product. The document provided in the dossier is just protocol and

				not report • Provide complete Declaration of conformity from the manufacturer issued as per European Directive for the applied product stating the device class, product codes, notified body etc signed and stamped by responsible personnel.
254.	M/s Nipro Medical Private Limited, Building No. 24 Central Commercial Area, DHA Phase 8, Ex-Park View, Lahore. ELI-00530 **Evaluator** AD-IV [2685-P]	**Manufacturer**: M/s JMI Syringes & Medical Devices Ltd. Unique Heights, Level 11, 117, Kazi Nazrul Islam Avenue, Ramna, Dhaka, 1217 Bangladesh **Manufacturing site**: M/s JMI Syringes & Medical Devices Ltd. Noapara, Chauddogram, Cumilla, Bangladesh FSC Bangladesh issued on 10-08-2021. FSC Germany issued on 05-07-2021	JMI Small Wing with Injection IV Catheter Class B Sizes and codes: Not clear Shelf life: 5 years	**Deferred** for provision of following documents:- • Applied product and its codes are not clear and the name is incomplete and does not correspond with the documents provided. Clearly provide the name of the product, its codes, and they should also be mentioned and highlighted on FSC and CE mark documents. Provide its all labels, pictures • Free Sale Certificate (FSC) Germany is copy not original. Provide Original valid embassy attested FSC for the applied product • Manufacturer name and manufacturing site not mentioned on Form. Submit completely filled form 7A with each page duly signed and stamped from the proprietor and incase of Authorized person, also provide authority letter from owner. • Shelf life of the product not mentioned on Form.
255.	-do- **Evaluator:** AD-IV [1857-P]	Legal Manufacturer: Nipro Corporation 3-9-3 Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan Manufacturer: M/s Shibuya Corporation 2-232, Wakamiya, Kanazawa-shi, Ishikawa-ken, 920-0054, JAPAN FSC Japan issued on 22-6-2020	Nipro NCU-18 (Single patient dialysis machine) Class C Shelf Life:N/A Service life: 7 years	**Deferred** for provision of following documents:- • Valid ISO 13485. • The legal manufacturer and manufacturing site of the applied product is not clear. On Form 2 manufacturers are present. On FSC it is mentioned M/s Shibuya Corporation and the Letter of Authorization, EPSP, Label indicated M/s Nipro, credentials are also provided of Nipro. Some technical documents are issued by Nipro and some are issued by Shibuya. Clarify this ambiguity from manufacturer abroad and clearly state who is the legal manufacturer/ product owner of this applied product? The name and address of manufacturing site/sites? Why are some documents issued by one company and other by another company? The name applied is **Nipro** NCU-18 which is not supported by documents. Clarify and support the answers with evidence and legal documents • Is the product not CE marked? as Full QA certificate and EU DOC is not provided. • MRP not provided.

256.	-do- **Evaluator:** AD-IV [1860-P]	Legal Manufacturer:. M/s AMTEC CO., LTD. 1-27-9 Edobori, Nishi-Ku, Osaka, 550-0002, Japan Manufacturing site: M/s THAI AMTEC CO.,LTD. 88/6 Asia Industrial Estate, Suvarnabhumi, Moo 4 T. Khlongsuan Amphur Bangbo, Samutprakarn 10560, Thailand. **FSC Thailand** valid till 21-7-2022	Sanacide R-7 (Peracetic acid-base Disinfectant) Code: R7-001 Class C Shelf Life: 18 months	**Deferred** for provision of following documents:- • The legal manufacturer and manufacturing site of the applied product is not clear. On Form, manufacturer mentioned is Amtec Japan whereas FSC of Thailand is provided which states Amtec Thailand is manufacturer. The label indicates Japan to be manufacturer whereas FSC Japan or any reference country specified in rule 67 is not provided. DOC also indicated Japan to be manufacturer. Clarify this ambiguity from manufacturer abroad and clearly state who is the legal manufacturer/product owner of this applied product? The name and address of manufacturing site/sites? Clarify and support the answers with evidence and legal documents • Is the product not CE marked? as Full QA certificate DOESNOT have the applied product name and the name of manufacturer is Amtec Japan and not Thailand. Provide valid, relevant, notarized certificate • Stability studies provided are only for 52 days to support 18 months shelf life claim. Clearly state the shelf life of the product and provide real-time stability studies for the applied product supporting claimed shelf life
257.	M/s Shamco Traders (Pvt) Ltd, 174-A, Ahmad Block, New Garden Town Lahore ELI-00102 Evaluator: AD-IV [1898-P]	Manufacturer: M/s Weihai Weigao Blood Purification Products Co., Ltd No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Weihai, Shandong Province, 76229 China FSC China valid till 6.9.2022 FSC China valid till 16.4.2022 FSC Germany issued on 20-10-2020	WEGO Hollow Fiber Dialyzer Sizes: F12, F13, F14, F15,F16, F18, F20, HF14, HF15, HF18, HF19, HF14, MF16, MF18 Class C Shelf Life: 36 months	**Deferred** for provision of following documents:- • The product is class C medical device. Submit differential fee of RS. 25,000/- for the applied product • ISO 13485 has address Shandong Weigao whereas all other docs show Weihai Weigao.
258.	M/s Royal Medical, Office No. 26th, 3rd Floor United Trade Center, Plot # 5, Block 6, Gulshan-e-Iqbal Karachi (ELI-00691) Evaluator: AD-IV [4327]	Manufacturer: F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium FSC Belgium Issued on 4-11-2020	CR-Type Catheter (Radiofrequency thermocoagulation probes) Class C Codes: CR30KAB CR45i CR40i Shelf Life: 3 Years	**Deferred** for provision of following documents:- • Address of importer is different on agency agreement from manufacturer than that on Form 7A and ELI-00691 (Form-4). Clarify? Has the importer address changed? Provide relevant documents • Address of manufacturer on Form 7A and credentials is F Care Systems NV, Uitbreidingstraat 42-46, BE-2600 Berchem, Belgium whereas all the other legal documents such as Free Sale Certificate (FSC), Agency Agreement,

				ISO13485, CE marking documents it is F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium. Clarification is required from manufacturer abroad as to what is the address of manufacturer and manufacturing site? And provide relevant documents with correct address • MRP not provided.
259.	-do- Evaluator: AD-IV [4326]	Manufacturer: F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium FSC Belgium Issued on 4-11-2020	EVRF (Endo-Venous Radiofrequency) Thermocoagulator Class C Shelf Life: N/A Life span: 8 Years	**Deferred** for provision of following documents:- • Address of importer is different on agency agreement from manufacturer than that on Form 7A and ELI-00691 (Form-4). Clarify? Has the importer address changed? Provide relevant documents • Address of manufacturer on Form 7A and credentials is F Care Systems NV, Uitbreidingstraat 42-46, BE-2600 Berchem, Belgium whereas all the other legal documents such as Free Sale Certificate (FSC), Agency Agreement, ISO13485, CE marking documents INCLUDING PRDUCT LABEL it is F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium. Clarification is required from manufacturer abroad as to what is the address of manufacturer and manufacturing site? And provide relevant documents with correct address • MRP not provided
260.	-do- Evaluator: AD-IV [4328]	Manufacturer: F Care Systems NV, Oosterveldlaan 99, B-2610, Wilrijk, Belgium FSC Belgium Issued on 4-11-2020	HPR45i (Radiofrequency thermocoagulation probe) Class C Shelf Life: 3 Years	**Deferred** for provision of following documents:- • Address of importer is different on agency agreement from manufacturer than that on Form 7A and ELI-00691 (Form-4). Clarify? Has the importer address changed? Provide relevant documents • Address of manufacturer on Form 7A and credentials is F Care Systems NV, **UITBREIDINGSTRAAT 42-46, BE-2600 BERCHEM, BELGIUM** whereas all the other legal documents such as Free Sale Certificate (FSC), Agency Agreement, ISO13485, CE marking documents it is F Care Systems NV, **OOSTERVELDLAAN 99, B-2610, WILRIJK, BELGIUM**. Clarification is required from manufacturer abroad as to what is the address of manufacturer and manufacturing site? And provide relevant documents with correct address • MRP not provided
261.	M/s SES Associates, 148-Ejaz Park, Model Town Link Road, Lahore ELI-00041 **Evaluator:** AD-IV [2503-P]	Manufacturer: M/s AndraTec GmbH Simmerner Str. 70 D-56075 Koblenz, Germany FSC Germany issued on 11-2-2021	Optimus CoCr Stent Codes & Sizes: As per FSC Class C Shelf Life: 4 Years	**Deferred** for provision of following documents:- • Submit differential fee of Rs. 25,000/- for the applied product as it is class C medical device. • Letter of Authorization does not have validity mentioned on it. Provide original Letter of Authorization or Agency

				agreement with manufacturer abroad, duly notarized in the country of origin. Letter of Authorization or agreement shall be original, signed & stamped, having validity, correct names and addresses of both manufacturer and importer and having name of medical devices for which sole/exclusive authorization is given to importer. • Free Sale Certificate (FSC) is copy. Provide original Embassy attested FSC for the applied product. • Which codes/sizes of Optimus CoCr Stent are required on this application? These codes should also be mentioned on FSC. • Full QA certificate does not cover the applied product **Optimus CoCr Stent.** Provide relevant, valid and notarized certificate. • ISO13485 expired now. Provide valid certificate. • Credentials not notarized. Provide notarized credentials. • Instructions for use (IFU) not provided. Provide IFU for procedure pack applied or of each component and then also clearly state the purpose of this applied product. • QC details of each component of this procedure pack not provided. • Clearly state the shelf life of each component in the procedure pack and provide clear conclusive stability studies of each component and then state the shelf life of this pack based on the component with the shortest shelf life
262.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. **Evaluator:** AD-IV [2657]	**Manufacturer:** Roche Diabetes Care GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing site: Not Clear FSC Germany issued on date: 18-11-2019	Accu-Chek Guide Link mg/dl Kit (Blood Glucose monitoring System) Code: 08116083203 Shelf life: N/A Class C	**Deferred** for provision of following documents:- • Manufacturing site on Form is different than that mentioned on FSC and 2 sites are mentioned on FSC. Clearly state the manufacturing site of the applied product. Moreover, Full QA certificate (not notarized and expired now) covers Germany facility whereas sites on FSC is USA. Provide relevant, valid and notarized full QA having the applied product • On DOC incomplete code of the applied product is mentioned. Clarify? And provide relevant DOC • ISO13485 expired now. Provide valid certificate. • Manufacturing and QC details provided are in general and not specifically of the applied product. Provide Manufacturing and QC details of Accu-Chek Guide Link mg/dl Kit • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin

263.	Jasani Scientifics SC-45, Marium square, Chandni chowk, stadium road, Karachi ELI-00416 **Evaluator:** AD-IV [3236]	Manufacturer: PhysIOL S. A. Liege Science Park Allee des Noisetiers, 4 – 4031 Liege – Belgium FSC Belgium issued on 26-11-2019	PhysIOL Hydrophobic Acrylic Lens (Not clear) Codes: Not clear Class C Shelf life: 5 years (Not clear)	**Deferred** for provision of following documents:- • Multiple types of Hydrophobic Acrylic lens are applied on this application. • Select just **one** Hydrophobic Acrylic lens, state its Name, provide only its **specific** details including manufacturing and QC details, state its shelf life, provide stability studies clearly supporting the claimed shelf life, highlight that product on Free Sale Certificate, Letter of Authorization and Declaration of Conformity (DOC), provide its Instructions for use, Essential principles of safety and performance, label and brochure • Submit revised Form 7A having above mentioned information for one hydrophobic lens selected • ISO13485 expired even upon submission. Provide valid, notarized certificate.
264.	-do- **Evaluator:** AD-IV [3237]	Manufacturer: PhysIOL S. A. Liege Science Park Allee des Noisetiers, 4 – 4031 Liege – Belgium FSC Belgium issued on 26-11-2019	PhysIOL Hydrophilic Lens (Not clear) Codes: Not clear Class C Shelf life: 5 years (Not clear)	**Deferred** for provision of following documents:- • Multiple types of Hydrophilic Acrylic lens are applied on this application. • Select just **one** Hydrophilic Acrylic lens, state its Name, provide only its **specific** details including manufacturing and QC details, state its shelf life, provide stability studies clearly supporting the claimed shelf life, highlight that product on Free Sale Certificate, Letter of Authorization and Declaration of Conformity (DOC), provide its Instructions for use, Essential principles of safety and performance, label and brochure • Submit revised Form 7A having above mentioned information for one Hydrophilic lens selected • ISO13485 expired even upon submission. Provide valid, notarized certificate.
265.	-do- **Evaluator:** AD-IV [3239]	Manufacturer: PhysIOL S. A. Liege Science Park Allee des Noisetiers, 4 – 4031 Liege – Belgium FSC Belgium issued on 26-11-2019	PhysIOL TORIC Lens (Not Clear) Codes: Not clear Class C Shelf life: 5 years (Not clear)	**Deferred** for provision of following documents:- • Multiple types of Toric lens are applied on this application. • Select just **one** Toric lens, state its Name, provide only its **specific** details including manufacturing and QC details, state its shelf life, provide stability studies clearly supporting the claimed shelf life, highlight that product on Free Sale Certificate, Letter of Authorization and Declaration of Conformity (DOC), provide its Instructions for use, Essential principles of safety and performance, label and brochure • Submit revised Form 7A having above mentioned information for one Toric lens selected

				• ISO13485 expired even upon submission. Provide valid, notarized certificate.
266.	Rech International, M-10, Block-6, PECHS, Near Hotel Faran, Off Shahrah-e-Faisal, Karachi	Legal Manufacturer: M/s SERF., 85 Avenue des Bruyeres 69150 Decines Charpieu, France FSC France Issuance Date (27-08-2020)	Femoral Stems and Femoral Heads (Not clear) Class C Shelf life: 5 years Codes: Not clear	**Deferred** for provision of following documents:- • Copy of establishment license ELI (Form-4) not attached in the dossier • Letter of Authorization from the manufacturer abroad is not provided. Provide original Letter of Authorization or Agency agreement with manufacturer abroad, duly notarized in the country of origin. Letter of Authorization or agreement shall be original, signed & stamped, having validity, correct names and addresses of both manufacturer and importer and having name of medical devices for which authorization is given to importer • Name of the product is not clear. On form it is mentioned Femoral Stems and Femoral Heads and the product is applied as System. Clearly state the brand name of the system in which these Femoral Stems and Femoral Heads will be used supported by evidence. • Grouping not clear and the codes/ref no/cat no. required on this application are not clear. Provide list of codes required, HIGHLIGHT them on Free Sale Certificate (FSC), Declaration of Conformity, Full QA certificate, Design Examination Certificate, brochure, labels, instructions for use (IFU) etc. Also provide a justification of how these components are grouped as SYSTEM according to "System" definition as per schedule B of Medical Devices Rules, 2017 • State the shelf life of each of codes/ref no/cat no. required on this application. State whether they are sterile or not? And provide summary of statement of shelf life of the components from the manufacturer abroad signed and stamped by their responsible personnel. Also provide stability studies to support the claimed shelf life • Original documents i.e Free Sale Certificate, Design-Examination Certificate, Full QA certificate, ISO13485 are not provided. Moreover, ISO13485 and Full QA expired even at the time of submission. Provide valid and notarized certificate. Design-Examination Certificate expired now. Provide valid and notarized certificate • Declaration of conformity not provided in this dossier • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin

267.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi (ELI-00084) **Evaluator:** AD-IV [3488]	Manufacturer: TURKLAB Tibbi Mal. San Tic A.S ITOB 10017 Sokak No. 2 Tekeli – Menderes - Izmir/Turkey FSC Turkey valid till 3-11-2022	TOYO Anti-Syphilis Test (Kit) Class C Code: TTP02 Shelf life: 24 months	**Deferred** for provision of following documents:- • On Form it is mentioned that original credentials, Letter of Authorization, Free Sale Certificate is already submitted to DRAP but the copies provided are not notarized/embassy attested. Provide Copies of notarized/embassy attested certificates. • Letter of Authorization from the manufacturer abroad is expired now. Provide valid certificate • Moreover, Turkey is not reference country so provide original and valid free sale certificate duly attested by embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017. • Provide ISO13485 with original notarization.
268.	M/s Zam Zam Pharmaceutical, Suit No.16, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi (ELI-00623) **Evaluator:** AD-IV [3752]	**Manufacturer:** M/s Jiangxi Sanxin Medtec Co., Ltd., No.339, Sanjiang Road, Sanjiang Town, Nanchang, Jiangxi 330204, China FSC China does not have applied product	Sanximed Sterile Auto-Disable Syringe for fixed dose immunization Sizes: 0.5ml, 0.1ml, 1ml 2ml, 3ml & 5ml Class B Shelf Life: 05 Years	**Deferred** for provision of following documents:- • Free Sale Certificate from China DOES NOT have the applied product **Sterile Auto-Disable Syringe for fixed dose immunization**, also it is not issued by Chinese Food and Drug Administration. Provide original, valid and embassy attested Free sale certificate of the applied product HAVING sizes/codes required on this application from Chinese Food and Drug Administration. (Note: The certificate and its attachments should be in English language) • Also clarify that all the sizes applied will be used for fixed dose immunization? Provide Instructions for use (IFU) for the applied product • Moreover, China is not a reference country so provide original and valid free sale certificate duly attested by embassy of Pakistan from one of the reference countries provided in rule 67 of MDR, 2017 • The technical file as well as Essential principles of safety and performance provided is of disposable syringe and not of applied product Sterile Auto-Disable Syringe for fixed dose immunization. Provide technical file, details of manufacturing and QC details for the applied product. On the label it is mentioned that device is as per WHO PQS standard. Is the product WHO prequalified? If so provide WHO prequalification document and clearly explain on what basis is this claim made by the manufacturer? • Original documents i.e Credentials, Letter of Authorization (LOA), notarized ISO13485, notarized Full QA not present

				in the dossier. Moreover, LOA is expiring soon, so arrange fresh LOA and ISO expired now so submit valid certificate with original notarization and provide Full QA with original notarization. Also highlight the applied product in all the documents • In the Declaration of Conformity (DOC) from manufacturer, the certificate number of TUV mentioned for Full QA does not match with the Full QA certificate provided in the dossier and also does not have sizes/codes of the applied product and also refers to final inspection report of the device. Therefore, provide relevant DOC with all the above information including inspection report • Provide Undertaking from the manufacturer abroad that same product Sterile Auto-Disable Syringe for fixed dose immunization under the brand name SANXIMED Sterile Auto-Disable Syringe for fixed dose immunization with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel
269.	M/s Aston-Medical Pakistan, 4-A, 4th Floor, 38 C Bukhari Commercial Lane. 8 Phase 6, D.H.A, Karachi (ELI-00797) **Evaluator:** AD-IV [4391]	Manufacturer: Dirinco B.V. Ketelmeer 1, 5347 JX Oss The Netherlands FSC Netherlands valid till 26-5-2024	Citra-Lock Catheter Lock Solution 5ml PE vial Class C Shelf life: 3 years Codes/strength: not provided	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank and the documents are not indexed and not in proper order. Submit completely and properly filled form 7A with each page signed and stamped with proper indexing of documents • Strength of citra-lock solution required on this application is not provided whether the applied product is Citra-Lock 4%, Citra-Lock 30% and Citra-Lock 46.7%? • Explain clearly the differences between Citra-Lock 4%, Citra-Lock 30% and Citra-Lock 46.7% and provide supporting documents • QC details/tests of the applied product not provided • Instructions for use (IFU) of the applied product not provided • ISO13485 is copy. Provide ISO13485 with original notarization • Full QA certificate is incomplete and is copy. Provide complete Full QA certificate with original notarization • Provide CE technical file for the applied product • Essential principles of safety and performance for the applied device not provided • Label for the applied product not provided • MRP not provided • Copy of Establishment License to import medical devices is not attached in dossier

270.	-do- **Evaluator:** AD-IV [4396]	Manufacturer: ARTHESYS 4 rue Rene Razel 91400 Saclay France FSC France issued on 14-6-2021	Pegase Hydro Aspiration Catheter Class D Codes: Pegase Hydro 6F S ---- 04030101 Pegase Hydro 7F S ----04030102 Shelf life: 3 years	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank and the documents are not indexed and not in proper order. Submit completely and properly filled form 7A with each page signed and stamped with proper indexing of documents • Pegase Hydro Aspiration Catheter and its codes will be considered on this application. • Submit separate application for Pegase Hydro Stiff • Shelf life studies supporting claimed shelf life of 3 years not provided • MRP not provided • ISO13485 is copy. Provide ISO13485 with original notarization • Full QA certificate is incomplete. Provide complete Full QA certificate with original notarization • Copy of Establishment License to import medical devices is not attached in dossier
271.	Life Care, M-20, Mezzanine Floor Falaknaz Plaza Main Shahra-e-Faisal, Karachi (ELI-00077) **Evaluator:** AD-IV [4397]	Manufacturer: Phenox GmbH Lise-Meitner-Allee 31, D-44801 Bochum Germany FSC Germany issued on 30-8-2021	P64 Flow Modulation Device Class D Codes: Not mentioned Shelf life: not provided	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank and the documents are not indexed and not in proper order. Submit completely and properly filled form 7A with each page signed and stamped with proper indexing of documents • P64 Flow Modulation Device will be considered on this application. Submit separate application for other type. • Manufacturing site not mentioned on Form. • Details of manufacturing and QC tests and specs not provided for the applied product. • MRP not provided. • Shelf life not mentioned on form and stability studies not provided. • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin. • Clearly state the shelf life and provide stability studies supporting claimed shelf life • Letter of Authorization is not original. Provide original notarized letter also mentioning validity of Authorization. • Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation • Codes of applied product not mentioned on Form. Clearly state the codes of P64 Flow Modulation Device required on this application, these codes should also be mentioned on Free Sale Certificate (FSC)

				and also provide labels of all codes. • Product details including its intended use, contraindications, warning precautions etc not provided in this dossier. Also provide instructions for use (IFU) for the applied product • ISO 13485 and Full QA not notarized. Provide notarized certificates • Design-Examination certificates not provided. Provide valid and notarized certificates • Provide Essential Principles of safety and performance for the applied product • Declaration of conformity (DOC) not provided. Provide DOC for the applied device on manufacturer's letter head signed and stamped by the responsible personnel
272.	-do- **Evaluator:** AD-IV [4398]	Manufacturer: Phenox GmbH Lise-Meitner-Allee 31, D-44801 Bochum Germany FSC Germany issued on 30-8-2021	pITA-RX Neuro PTA Balloon Catheter Class D Codes: Not mentioned Shelf life: not provided	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank and the documents are not indexed and not in proper order. Submit completely and properly filled form 7A with each page signed and stamped with proper indexing of documents • Manufacturing site not mentioned on Form. • Details of manufacturing and QC tests and specs not provided for the applied product. • MRP not provided. • Shelf life not mentioned on form and stability studies not provided. • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin. Clearly state the shelf life and provide stability studies supporting claimed shelf life. • Letter of Authorization is not original. Provide original notarized letter also mentioning validity of Authorization. • Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation. • Codes of applied product not mentioned on Form. Clearly state the codes of P64 Flow Modulation Device required on this application, these codes should also be mentioned on Free Sale Certificate (FSC) and also provide labels of all codes. • Product details including its intended use, contraindications, warning precautions etc not provided in this dossier. Also provide instructions for use (IFU) for the applied product. • ISO 13485, Full QA and Design-

				Examination certificates not notarized. Provide notarized certificates. • Provide Essential Principles of safety and performance for the applied product. • Declaration of conformity (DOC) not provided. Provide DOC for the applied device on manufacturer's letter head signed and stamped by the responsible personnel.
273.	M/s Elate CC Pvt Ltd. Suite No. 1, 2, 3, Street No. 3, Block No. 3, Gulshan-e-Iqbal, Karachi (ELI-00294) **Evaluator:** AD-IV [4390]	Manufacturer: ATLAS MEDICAL S.A. 28C, Miaouli Str. 15344 Gerakas Athens-Greece FSC not provided	Premisut PGA Absorbable Surgical Suture Class D Shelf life: 5 years Codes/sizes: Not provided	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank and the documents are not indexed and not in proper order. Submit completely and properly filled Form 7A with each page signed and stamped with proper indexing of documents • Free Sale Certificate (FSC) not provided from regulatory authority of Greece rather it is given by manufacturer. Provide FSC from health authority of Greece having the applied product along with approved sizes and codes. • Moreover, Greece is not a reference country so provide original and valid free sale certificate duly attested by Embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017 • Codes of applied product not mentioned on Form. Clearly state the codes of Premisut PGA Absorbable Surgical Suture required on this application, these codes should also be mentioned on FSC and also provide labels of all codes. • Provide details of QC tests and specs specifically of the applied product • MRP not provided • Stability studies supporting claimed shelf life of 5 years not provided • Credentials of manufacturer abroad and Letter of Authorization are not original. Provide original and notarized documents • ISO13485, Full QA and Design-Examination certificates are not original. Provide certificate with original notarization • Provide Essential Principles of safety and performance for the applied product.
274.	Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) **Evaluator:** AD-IV [3760]	Legal Manufacturer: M/s Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel, Switzerland FSC Switzerland valid till 13-11-2023	Contour Plus ELITE Blood Glucose Monitoring System Class C Shelf life: N/A Code: Not provided	**Deferred** for provision of following documents:- • As mentioned on form, the Contour Plus ELITE Blood Glucose Monitoring System applied in this application consists of **meter, lancet and lancing device** whereas on Free Sale Certificate and Declaration of Conformity the same name Contour Plus ELITE Blood Glucose Monitoring System consists of **meter, test strips and control solution** and separate

				documents are provided for lancing device and lancet. So the applied product Contour Plus ELITE Blood Glucose Monitoring System consisting of **meter, lancet and lancing device is not present as system/kit in legal documents such as FSC, DOC etc.** Also clarify how the same name of the product has two different compositions? Provide relevant FSC, DOC, Full QA for this product having these applied components meter, lancet and lancing device. Also, it should contain information that on which site these individual components were manufactured and on which site the system/kit was assembled and final QC released so that the manufacturing site of final system/kit can be established. • In some instances, the word system is used, whereas in other instances the word kit is used. Clarify? • Aso provide the Cat No./ref no/code of the final system/kit • QC tests performed and product specs specifically of the applied device is not provided.
275.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. Evaluator [AD-VIII] 2570	Legal Manufacturer: M/s Bio-RAD Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618 USA FSC: France Date of Issue: 10 Jun 2020	Liquichek Torch Plus Controls (Infectious Disease Controls) Positive (3x3mL) – 227; Positive MiniPak (1x3mL) – 227x; Negative (3x3mL) – 228; Negative MiniPak (1x3mL) – 228x Class- C Shelf Life: 3 years	**Deferred** for the provision of Orignal, valid FSC of France duly attested by Embassy of Pakistan.
276.	-do- Evaluator [AD-VIII] 2573	Legal Manufacturer: M/s Bio-RAD Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618 USA FSC: U.S.A Expiry Date: 20 Aug 2022	Lyphochek whole Blood Immunosuppressant Controls (Multiple whole Blood Immunosuppressant Therapeutic Drug Monitoring IVD Control) Level 1 (6x2ml) – 274; Level 2 (6x2ml) – 275; Level 3 (6x2ml) – 276;	**Deferred** for the provision of valid notarized Full Quality Assurance Certificate covering applied IVD Medical Device.

			Level 4 (6x2ml) – 277; Level 5 (6x2ml) – 278; Level 5 MiniPak (5x2ml) – 279x Class-C Shelf Life: 3 years	
277.	M/s Pak Punjab Cardex Medical system, Ground Floor, 210-J/2 Block M.A Johar Town Lahore ELI: 00174 2826-P **Evaluator** AD-III	**Legal Manufacturer:** M/s Biotronik AG 6 Ackerstrasse, 8180, Bulach, Switzerland. FSC validity 07-12-2024	Orsiro Mission Sirolimus Eluting Coronary Stent System (Drug Eluting stent) Class D Shelf Life: 24 Months Codes as per FSC	**Deferred** for issuance of Show Cause Notice to M/s Medisurge Innovatives Health Care, 1/6-N, Block 6, PECHS, Main Nursery, Shahrah-e-Faisal, Karachi as the manufacturer has issued revocation letter to DRAP.
278.	M/s Meritorious Business Solution (PVt.) Ltd, Registered Office: House No. 39, College Road, Safari Villas 1, Bahria Town, Rawalpindi, Commercial Premises: Office # 202, 2nd Floor, 153-D, Block -D, Civic Center, Phase-4, Bahria Town, Rawalpindi ELI: 00208 Evaluator: AD-VIII 2829 (P)	Legal Manufacturer: M/s AccuBioTec h Co., Ltd Building 10, No 28 Yuhua Road, Beijing 101300 China FSC: Germany Date of issue: 19.04.2021	ACCU-TELL ® Rapid COVID-19 1gM/1gM (ACCU-TELL ® COVID-19 1gM/1gM) Codes & Sizes: ABT-IDT-B352 Class-C Shelf Life: 24 months	**Deferred** for the provision of original LOA and FSC.
279.	-do- Evaluator: AD-VIII 2830 (P)	Legal Manufacturer: M/s AccuBioTec h Co., Ltd Building 10, No 28 Yuhua Road, Beijing 101300 China FSC: Germany Date of issue: 19.04.2021	ACCU-TELL ® Rapid TB Cassette (ACCU- TELL® Cassette) Codes & Sizes: ABT-IDT-B260 Class-C Shelf Life: 24 months	**Deferred** for the provision of original LOA and FSC.
280.	-do- Evaluator: AD-VIII 2831 (P)	Legal Manufacturer: M/s AccuBioTec h Co., Ltd Building 10, No 28 Yuhua Road, Beijing 101300 China FSC: Germany	ACCU-TELL ® Rapid Dengus NS1 Antigen Test (ACCU- TELL ® Dengus NSI Antigen Test) Codes & Sizes:	**Deferred** for the provision of original LOA and FSC.

		Date of issue: 19.04.2021	ABT-IDT-B274 Class-C Shelf Life: 24 months	
281.	–do- Evaluator: AD-VIII 2833 (P)	Legal Manufacturer: M/s AccuBioTec h Co., Ltd Building 10, No 28 Yuhua Road, Beijing 101300 China FSC: Germany Date of issue: 19.04.2021	ACCU-TELL® Rapid Typhoid Test Cassette) (ACCU-TELL® Rapid Thphoid Test Cassette) Codes & Sizes: ABT-IDT-A263 Class-C Shelf Life: 24 month	**Deferred** for the provision of original LOA and FSC.
282.	M/s Alfa Scientific Store, Store-24-Maclogen Road, Lahore. ELI: 00148 2859-P Evaluator AD-III	**Legal Manufacturer:** Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada **Manicuring Site:** Zhejiang Orient Gene Biotech Co., Ltd 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China FSC Germany Date of Issue:13.05.2021	HEALSTONE (HIV 1/2 Ab RAPID DEVICE TEST Cassette) Class-D Shelf Life: 24 months	**Deferred** for clarification to provide the documents of the applied product, namely, Healstone.
283.		-do-	HEALSTONE (HCV RAPID TEST Cassette) Class-D Shelf Life: 24 months	**Deferred** for clarification to provide the documents of the applied product, namely, Healstone.
284.		-do-	HEALSTONE (HbsAg Rapid Test Cassette) Class-D Shelf Life: 24 months	**Deferred** for clarification to provide the documents of the applied product, namely, Healstone.
285.	Gene-Tech Laboratories 246/B, PECHS Block 6, karachi-75400 Pakistan (ELI-00089) Evaluator:	Legal Manufacturer: SHIN POONG PHARM. CO. LTD 161, Yeoksam-ro, Gangnam-gu, Seoul,	MEDICURTAIN 5ml "Hyaluronic acid (non-animal source) …10mg/ml"	**Deferred** for the provision of following documents: i. The firm provided un-attested photocopy of applied medical device issued by "Germany" an RRA as per MDR 2017.

	[AD-VIII] 3351	06246, Republic of Korea Manufacturing Site: SHIN POONG PHARM. CO. LTD 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea FSC: Korea Issue Date: 11-6-2020 Copy of FSC of Germany is provided	Codes & Sizes: As per FSC Class D Shelf Life: 3Year	Therefore, the firm is required to submit original valid FSC duly attested by Embassy of Pakistan. ii. The firm once again submitted the DECLARATION on c company's Letter Head however the firm was directed to submit the same on notarized Stamp paper.
286.	M/s Universal Enterprises, 29 Block-3, Overseas Co-Operative Housing Society, Stadium Road, Karachi. ELI-00079) **Evaluator**: AD-IV [3818]	**Manufacturer**: Terumo Cardiovascular System Corporation, 125 Blue Ball Road, Elkton, MD 21921, USA. FSC USFDA valid till 05-01-2023	Capiox NX19 Oxygenator with Integrated Arterial Filter and UltraPrime Technology Class B Shelf Life: 36 Months Codes: 3CX*NX19RE 3CX*NX19RW 3CX*NX19E 3CX*NX19W	**Deferred.** Board gave last opportunity for submission of stability studies.

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Secretary MDB
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14/7/22