No.F.4-3/2022-MD (M-47)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
*****

Islamabad the 23rd May, 2022.

Subject:- **REGISTRATION OF MEDICAL DEVICES FOR IMPORT - SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS.**

The applications of following applicants were placed before the Medical Device Board (MDB) in its 47th meeting held on 29th March, 2022 and the same have been deferred being deficient of the information / documents as specified in column (5) of the Table below.

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

Sr.#	Applicant, ELI & Dossier. #	Manufacturer's Details:	Product's name, Class & Shelf life.	Decision
(1)	(2)	(3)	(4)	(5)
1.	M/s Intek Corporation, Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI:00034. -1903-	**Legal Manufacturer & mfg. site:** Endocor GmbH, SteinburgstraBe 17, 25348 Gluckstadt, Germany. FSC: Germany (Scanned Copy) Date of issue: 13.06.2017.	AVANT Plus (Paclitaxel-Eluting PTA Balloon Catheter) Code & Sizes: As per FSC. Class-D Shelf Life: 36-months	**Deferred for provision of: -** • valid & original FSC. • LoA duly notarized. • justifiable shelf life data. • valid ISO-13485 & FQA certificates. • Labels.
2.	M/s Intek Corporation, Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI:00034. -1908-P.	**Legal Manufacturer & mfg. site:** Endocor GmbH, SteinburgstraBe 17, 25348 Gluckstadt, Germany. FSC: Germany (Scanned Copy) Date of issue: 13.06.2017.	SERENITY (Peripheral Self-expandable Nitinol Stent System) Code & Sizes: As per FSC Class-C Shelf Life: 36-months	**Deferred for provision of: -** • valid & original FSC. • LoA duly notarized. • Labels. • justifiable shelf life data. • valid ISO-13485 & FQA certificates.
3.	M/s Intek Corporation, Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI:00034. -1911-P.	**Legal Manufacturer & mfg. site:** Endocor GmbH, SteinburgstraBe 17, 25348 Gluckstadt, Germany. FSC: Germany	ENDO-GUIDE (PTA Balloon Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 48-months	**Deferred for provision of: -** • valid & original FSC. • LoA duly notarized. • Labels. • justifiable shelf life data. • valid ISO-13485 & FQA certificates.

		(Scanned Copy) Date of issue: 13.06.2017.		
4.	M/s Intek Corporation Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI-00034 943-P **Evaluator** AD-III	**Legal Manufacturer:** TERUMO CORPORATION 44-1, 2-Chome, Hatagaya, Shibuya-Ku, Tokyo 151-0072 JAPAN **Manufacturing Sites** TERUMO CORPORATION ASHITAKA FACTORY Address: 150, Maimaigi- Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan. TERUMO VIETNAM CO., LTD. Lot 44a-44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi CITY, VIETNAM FSC Japan issuance 18-02-2020	Radifocus Guide Wire M (Catheter Guide Wire) Class-D Shelf life: 3 years Codes as per FSC	**Deferred** for provision of following documents:- • Valid Design Examination certificate. • ISO 13485 of Vietnam manufacturing site is missing. • It is to mentioned here that the same brand name device has already been registered by MDB in its 28th meeting by the same importer (codes are different) with different legal manufacturer i.e M/s Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium with same manufacturing sites (TERUMO CORPORATION • ASHITAKA FACTORY • Address: 150, Maimaigi- Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan. • TERUMO VIETNAM CO., LTD. Lot 44a-44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi CITY, VIETNAM)
5.	M/s Intek Corporation, Office # 517, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi ELI: 00034 {2778} Evaluator: [AD-VIII] 2778	**Legal Manufacturer:** Lepu Medical Technology (Beijing) Co., Ltd, No, 37 Chaoqian Road, Changping District, Beijing, China FSC: China Valid till: 19.07.2023	**Partner Sirolimus Eluting Stent System** (Drug Eluting Stent System) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for the provisions of following deficiencies/ documents:** i. Submit a differential fee of rupees 25,000 since this is a new application under MDR 2017. ii. Provide the Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. The firm provided Chinese FSC a non-reference regulatory authority. iii. The firm stated that MD doesn't contain Drug/poison, therefore, submit revised form-7A since that the MD contains drug, or otherwise clarify. iv. The provided stability study has scope "*this validation protocol involves the stability and reliability of Partner® Sirolimus-eluting Coronary Stent System within two years useful life.*" However, the firm requested to grant 3 years shelf life as per form-7A. v. Provide the DECLARATION (on stamp paper) as per form-7A.
6.	M/s MOD Scientific Traders, 3- syed Mouj Darya Road (Edward Road) Lahore ELI 00655. -2766-	**Legal Manufacturer & mfg. site:** M/s Diagast Parc 251, Avenue Eugene Avinee 59210 Loos/France FSC: France (Scanned Copy)	DIAGAST (ANTI-D) (RHI-IgMI) Codes & Sizes: As per FSC. Class-D Shelf Life: 24-months	**Deferred for provision of: -** • valid & original FSC. • Address on LoA is different from the ELI-issued. • LoA not notarized. • valid ISO-13485 certificate. • QC-details alongwith CoAs. • Correction of application form required.

7.	M/s MOD Scientific Traders, 3- syed Mouj Darya Road (Edward Road) Lahore ELI-00655. -2767-	**Legal Manufacturer & mfg. site:** M/s Diagast Parc 251, Avenue Eugene Avinee 59210 Loos/France. FSC: France (Scanned Copy)	DIAGAST (ANTIGEN-B BLOOD GROUPING ABO SYSTEM) Codes & Sizes: As per FSC Class-D Shelf Life: 24-months	**Deferred for provision of: -** • valid & original FSC. • Address on LoA is different from the ELI-issued. • LoA not notarized. • valid ISO-13485 certificate. • QC-details alongwith CoAs. • Correction of application form required.
8.	M/s MOD Scientific Traders, 3- syed Mouj Darya Road (Edward Road) Lahore ELI-00655. -2768-	**Legal Manufacturer & mfg. site:** M/s Diagast Parc 251, Avenue Eugene Avinee 59210 Loos/France FSC: France (Scanned Copy)	DIAGAST (AGH MAESTRIA IGG+C3d) Codes & Sizes: As per FSC. Class-D Shelf Life: 24-months.	**Deferred for provision of: -** • valid & original FSC. • Address on LoA is different from the ELI-issued. • LoA not notarized. • valid ISO-13485 certificate. • QC-details alongwith CoAs. • Correction of application form required.
9.	M/s. Biosorin (Private) Limited, 19- Usman Block, Boulevard New garden Town, Lahore. ELI:00186. -2797-	**Legal Manufacturer & mfg. site:** M/a Altona Diagnostics GmbH, Morkenstr. 1222767 Hamburg, Germany FSC: Germany Date of Issue: 12.07.2021.	ALTOSTAR ® HCV RT-PCR Kit 1.5 (AltoStar ® HCV RT-PCR Kit 1.5) Class-D Shelf Life: 12 months. Codes & Sizes: As per FSC.	**Deferred for provision of** Original Letter of Authorization.
10.	M/s. Biosorin (Private) Limited, 19- Usman Block, Boulevard New garden Town, Lahore. ELI:00186. -2800-	**Legal Manufacturer & mfg. site:** M/a Altona Diagnostics GmbH, Morkenstr. 1222767 Hamburg, Germany FSC: Germany Date of Issue: 12.07.2021.	ALTOSTAR® HIV RT-PCR Kit 1.5 (AltoStar® HIV RT-PCR Kit 1.5) Class-D Shelf Life: 15-months. Codes & Sizes: As per FSC.	**Deferred for provision of** Original Letter of Authorization.
11.	M/s. Biosorin (Private) Limited, 19- Usman Block, Boulevard New garden Town, Lahore. ELI:00186. -2801-	**Legal Manufacturer & mfg. site:** M/a Altona Diagnostics GmbH, Morkenstr. 1222767 Hamburg, Germany FSC: Germany Date of Issue: 12.07.2021.	ALTO STAR ® HBV PCR Kit 1.5 Class-D Shelf Life: 15-months. Codes & Sizes: As per FSC	**Deferred for provision of** Original Letter of Authorization.
12.	M/s. Verizon, 60-D, FFC, Zahoor Elahi Road, Gulberg IV, Lahore ELI-00087 -2772-	**Legal Manufacturer & mfg. site:** M/s William Cook Europe ApS, Sandet 6, DK- 4632 Bajaeverskov, Denmark FSC: Denmark Valid Till: 31.10.2021	COOK CELECT Vena Cava Filter Sets (Vena Cava Filter Sets) Class-D Shelf Life: 03-years. Codes & Sizes: As per FSC	**Deferred for Provision of: -** • valid FSC of Denmark. • Provide the Valid Letter of Authorization, duly notarized by the country of origin. • Provide the valid ISO-13485 and Full Quality Assurance certificates. • The Authorization given by M/s. Cook, Ireland, while manufacturer mentioned on Form-7A is M/s. William Cook, Denmark, clarification is required. •
13.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st	**Legal Manufacturer:** Medtronic Inc.710 Medtronic Parkway,	MEDTRONIC Open Pivot Heart Valve	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy

	Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI: 00273 (1191-K)	Minneapolis, MN 55432 USA FSC: U.S.A Valid till: 18-02-2021.	Model: 501DM (AP Mitral) Mitral bi-leaflet mechanical heart valve prosthesis. Class-D Shelf Life: 05-years. Codes & Sizes: As per FSC	**(Submitted certificate was expired before submission of dossier).** • Clarify and Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products). •
14.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI: 00273 {1193 (K)}	**Legal Manufacturer:** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA. **Mfg. site** Mdt Mexio SRI, Tijuana Medtronic Mexico S. DE.R.I DeCV Av, Paseo Cucapah 10510 EILago, Tijuana, Baja California C.P 22210. Mexico FSC: USA Valid till: 12 November, 2020	BROCKEN-BROUGH curved Needle (Cardiac transseptal needle). Code: EP003994S-EP003997S Class-D Shelf Life: 02-years. Codes & Sizes: As per FSC.	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier).** • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).
15.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI: 00273 (1194 (K))	**Legal Manufacturer:** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Mfg. site:** Medtronic Singapore Operations Pte. Ltd 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore FSC: USA Valid till: 1st July, 2020	REVEAL XT (Impedance Cardiograph) Model: 9529. Class-D Shelf Life: 12-months. Codes & Sizes: As per FSC	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier).** • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).

16.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 {1341-(K)}	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA. **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC: USA Date of Issue: March 09, 2018 Valid Till: March 08, 2020	DLP® Rigid Suction Tube (Suction system catheter) Code:10061-10062. Class-D Shelf Life: 03 Years.	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier).** • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).
17.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 {1344-(K)}	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA. **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC USA: Date of Issue: March 09, 2018 Valid Till: March 08, 2020	VC2 Atrial Caval Venous Cannulae (Cardiopulmonary bypass Canuula arterial). Code: 93438-93438C 93448-93448C-93451-93451C-93463-93463C -93464-93464C Class-D Shelf Life: 03-Years	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier).** • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).
18.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 {1346-(K)}	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA. **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC: USA Date of Issue: March 09, 2018 Valid Till: March 08, 2020	DLP® Double Lumen Aortic Root Cannula with Vent Line (Cardioplegia Cannula) Code:30401- 30402 Class-D Shelf Life: 03-Years	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier).** • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier).** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).

19.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) -2032-	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Pkwy. Minneapolis, MN 55432, USA **Manufacturer:** M/s Medtronic Perfusion Systems 7611, Northland Dr Minneapolis, MN 55428, USA FSC USFDA Valid Till (27-02-2021)	BIOTREND Oxygen Saturation & Hematocrit System, 220 Volt Class-D Codes & Sizes as per FSC	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier)**. • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier)**. • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate of the products that are missing in the application dossiers. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).
20.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) -2033-	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Pkwy. Minneapolis, MN 55432, USA **Manufacturer:** M/s Medtronic Perfusion Systems 7611, Northland Dr Minneapolis, MN 55428, USA FSC USFDA Valid Till (27-02-2021)	REVEAL LINQ (Model LNQ11) patient monitoring system. Class-D Codes & Sizes as per FSC	**Deferred** for provision of following documents: - • Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy **(Submitted certificate was expired before submission of dossier)**. • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products **(Submitted certificate was expired before submission of dossier)**. • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer. • Design examination certificate. • Provide the technical documents like stability studies, QC-details & Certificate of compliance labels of all the variants of the subject machine/device applied for the registration (You have submitted the documentation of the similar products).
21.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) -3542-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA. **Mfg. site**: Medtronic peurtp rico operations Co., Villalba Rd149, Km, 56.3, Call Box6001, VillalbaPR00766 USA. **FSC: USFDA (copy-Valid till 22 June 2022)**	Implantable leads Accessories. (Lead End Cap & Service Kit) Class-D Shelf life..... Codes and sizes as per FSC	**Deferred** for provision of following documents: - • Provide the brand name and valid & original FSC of country of origin and/or RRA. • Clarify and Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production activities of subject products. • Provide the Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details & Certificate of compliance. Clarification is required for the different kits or accessories have been applied in single application for the product at Sr. No. 01.
22.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton,	**Legal Manufacturer & Mfg. site**: Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA	Adjustable Valve. (Hemostatic valve). Class-D Shelf life: 03-years Codes and sizes as per FSC	**Deferred** for provision of following documents: - • Provide the brand name and valid & original FSC of country of origin and/or RRA. • Provide the valid ISO-13485/ latest GMP report of all manufacturing sites involved in the production

	Karachi (ELI-00273) -3543-			activities of subject products. • Provide the Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details & Certificate of compliance. Clarification is required for the different kits or accessories have been applied in single application for the product at sr. no. 01.
23.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 Evaluator: [AD-VIII] 1347-k	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA **FSC** USA **Date of Issue:** March 09, 2018 **Valid Till:** March 08, 2020	DLP® Femoral Venous Cannulae (Cardiopulmonary bypass cannula, femoral) **Code:** 58517-58521 **Class:** D **Shelf Life:** 03 Years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide original and valid embassy attested FSC. The provided FSC was expired before submission of application. ii. Provide valid ISO 13485 and Full Quality Assurance Ceretificate. iii. Provide Design examination certificate.
24.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI: 00273 Evaluator: [AD-VIII] 1196-K	**Legal Manufacturer:** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing site:** Medtronic Inc. 3800 Annapolis Lane, Minneapolis MN 55447, USA. FSC: USFDA Valid till: 18th Feb, 2021	Medtronic Open Pivot ™ Heart Valve Model: 501 DA (AP Aortic) bi-leaflet mechanical heart valve prosthesis Class-D Shelf Life: 5 years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide original and valid FSC. The provided one is expired now but valid upon submission having validity upto 18th Feb, 2021. ii. Provide valid ISO 13485. The provided one is expired now but valid upon submission having validity upto 31st Jan, 2021. iii. Provide valid Design Examination Certificate. Since the provided one was valid upto 22nd Feb, 2020 (Expired upon submission).
25.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 Evaluator: [AD-VIII] 1346 (B)-K	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA FSC: USA Valid Till: March 08, 2020	DLP® Silicone Single Stage Venous Cannula with inflatable cuff, 37 Fr. (Cardiopulmonary bypass cannula, arterial) Code: As per FSC Class: D Shelf Life: 03 Years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide original and valid embassy attested FSC. The provided one was expired upon submission of application. ii. Provide valid ISO 13485 which was valid upto 31st March, 2020 (Valid upon submission). iii. Provide valid Full Quality Assurance certificate. The provided one is expired now but valid upon submission with validity of 15th December, 2020. iv. Provide valid Design examination certificate duly notarized by the country of origin.

26.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 Evaluator: [AD-VIII] **1106-K**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA M/s. Manufacturer Site: Medtronic Puerto Rico Operations Co., Villalba Rd, 149 Km. 56.3, Call Box 6001, Villalba, PR 00766, USA FSC USA **Date of Issue:** August 16, 2018 **Valid Till,** August 15, 2020	CapSure VDD-2 Lead **(Steroid-eluting,** implantable, tined, bipolar, atrial/ventricular, transvenous lead) Code: 5038-58; 5038-65; 5038 S-52; 5038 S-58; 5038L-65 Class: D Shelf Life: 02 Years	**Deferred for the provisions of following deficiencies/ documents:** i. The firm stated that MD doesn't contain Drug, the statement seems contrary as mentioned in the technical manual (CapSure VDD-2 5038, **Steroid-eluting,** implantable, tined, bipolar, atrial/ventricular, transvenous lead) therefore, submit revised Form-7A since that the MD contains drug, or otherwise clarify. ii. Provide shelf life test report for CapSure VDD-2 5038 **Steroid-eluting,** implantable, tined, bipolar, atrial/ventricular, transvenous lead, since the firm provided shelf life test result for model 10366 leads after 24 months or otherwise clarify. iii. The address of importer/agent on provided photocopy of LOA is different than Establishment license, clarify or provide updated one as per law. iv. Provide original and valid FSC. v. Provide valid ISO 13485 since the provided one is expired on 31st May, 2020 (Valid upon submission).
27.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 2512	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. **FSC: Netherlands Validity: July 01, 2020**	Calria MRI Quad CRT-D SureScan (DTMA2QQ) Cardiac Resynchronizatoin therapy implantable defibrillator **Class-D** **Shelf life: 18 Months**	**Deferred for the provisions of following deficiencies/ documents:** i. Provide Quality control details of applied model of Claria MRI Quad CRT-D SureScan (DTMA2QQ). ii. The firm provided photocopy of expired FSC upon submission of file therefore provide original FSC notarized and embassy attested in the country of origin. iii. Provide label as approved in the country of origin. Provided one doesn't mention name of manufacturer and country of origin. iv. ISO 13485 expired. Provide valid and notarized certificate. v. Provide notarized ISO 13485, design examination certificate and Full Quality Assurance Certificate. The firm has provided copy of these documents.
28.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 2488	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA Manufacturing site: M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. **FSC: Netherlands Validity: July 01, 2020**	**Attesta L DR MRI SureScan (ATDRL1)** Dual Chamber Implantable Pace Maker, rate-responsive **Class-D** **Shelf life:** 18 Months	**Deferred for the provisions of following deficiencies/ documents:** i. Provide Manufacturing and Quality control details of applied model of Attesta L DR MRI SureScan (ATDRL1). ii. The firm did not provide the stability studies, therefore required to provide the stability study to justify the shelf life of the applied medical device. iii. The firm provided photocopy of FSC which is now expired but valid upon submission of file therefore provide original and valid FSC. iv. ISO 13485 is expired now but valid upon submission. Therefore, provide valid certificate. v. Provide notarized ISO 13485, design examination certificate and Full Quality Assurance Certificate. The firm has provided photocopy of these documents. vi. Provided label states that the product ATDRL1 is manufactured in Singapore, while other documents (Credentials, FSC, ISO, FQA, DEC) mentions M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland as manufacturer, need clarification.

29.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 2508	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA M/s Medtronic Singapore Operations Pte. Ltd. 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056 **FSC: Netherlands Validity: July 01, 2020**	Viva CRT-P (C5TR01) Cardiac resynchronization therapy Implantable Pacemaker Cardiac resynchronization therapy implantable Pacemaker **Class-D** **Shelf life: 18 Months**	**Deferred for the provisions of following deficiencies/ documents:** i. Provide the details of manufacturing and quality control processes. ii. Provided FSC is copy, expired now valid upon submission mentions that "M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland" as manufacturer which is different than Form-7A. Therefore, provide Original and valid free sale certificate issued by **country of origin** and **by any RRA** as per rule 67 duly attested by embassy of Pakistan. iii. ISO 13485 is expired now but valid upon submission mentions that "M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland" as manufacturer which is different than Form-7A. Provide valid and notarized certificate of manufacturing site. iv. The provided FQA & Design Examination covers following facilities, clarification of manufacturing site(s) is required: *M/s Medtronic Singapore Operations Pte. Ltd. 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056.* *M/s Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland.* v. Provide notarized ISO 13485, design examination certificate and Full Quality Assurance Certificate. The firm has provided copy of these documents. vi. Provided label states that manufacturer is "Tolochenaz, Switzerland" clarification of manufacturing site(s) is required.
30.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (EL-00273) Evaluator: [AD-VIII] 3128	Legal Manufacturer: M/s Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht The Netherlands FSC: Netherlads Validity: Jan 1, 2024	Vitatron Q-Series DR MRI Surescan (IPG) Dual-Chamber pacemaker, rate- responsive Model: Q70A2 Class-D **Shlef life:** Not given	**Deferred for the provisions of following deficiencies/ documents:** i. Provide updated credentials of manufacturer abroad duly notarized from the country of origin. Provided one is photocopy having outdated address of importer. ii. The firm applied Medical Device with name "Vitatron Q-Series DR MRI Surescan IPG" (as per form-7A) however name of medical device on manufacturing process/FSC is "Vitatron Q70 DR MRI SureScan Q70A2", need clarification. iii. The firm applied Medical Device with name "Vitatron Q-Series DR MRI Surescan IPG" however firm submitted following titled document to justify shelf life "Phoenix IPG System Design Verification Test Report". Therefore, provide stability studies for applied product. Furthermore, shelf life not given on form-7A. iv. The firm applied Medical Device with name "Vitatron Q-Series DR MRI Surescan IPG" however name of medical device on FSC is "Vitatron MRI SureScan, Q70A DR, Model Q70A2", need clarification. v. Provide ISO 13485 for all the manufacturing sites (including Singapore & Switzerland as per Form-7A) involved in manufacturing of Vitatron Q-Series DR MRI Surescan IPG. vi. As per Form-7A the firm mentions "VSF21 Application Software" as to be registered, however the same is not mentioned on Free sale certificate and design examination.

31.	Medtronic Pakistan (Pvt) Ltd. Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton. Karachi (EL-00273) Evaluator: [AD-VIII] 3129	**Legal Manufacturer:** M/s Micro Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo way Irvine, CA 92618 USA. FSC: Netherland Validity: April 13, 2020	Solitaire AB Neurovascular Remodeling Device **Codes & Sizes:** SAB-3-20 SAB-3-30 SAB-4-15 SAB-4-20 SAB-4-30 SAB-4-40 SAB-5-20 SAB-5-30 SAB-5-40 SAB-6-20 SAB-6-30 Class-D	**Deferred for the provisions of following deficiencies/ documents:** i. Provide updated credentials of manufacturer abroad duly notarized from the country of origin. Provided one is photocopy having outdated address of importer. ii. The LOA is photocopy and doesn't cover "Micro therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 USA", which is a legal manufacturer as per form-7A. Provide original LOA with clarification. Provide original and valid LOA. iii. Provide original, Valid and embassy attested FSC. Since the provided FSC was expired even upon submission of file. iv. Provide valid ISO 13485 and Full Quality Assurance Certificates. Since the provided one are expired now but valid upon submission.
32.	Medtronic Pakistan (Pvt) Ltd. Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton. Karachi (EL-00273) Evaluator: [AD-VIII] 3137	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Design Site:** Medtronic Inc. (formerly d.b.a ev3 Inc) 2300 Berkshire Lane North Plymouth MN 55441 USA **Manufacturing Site:** ev3 Inc 4600 Nathan Lane North, Plymouth MN 55442, USA. **Pakistani Supplier:** Medtronic Trading NL BV, Earl Bakkenstraat 10 6422 PJ Heerlen Netherland. FSC: Ireland Validity: March 09, 2021	Protege RX Self Expanding Nitinol Peripheral Stent System Codes and sizes: As per FSC Class D Shelf life: 3 Years	**Deferred for the provisions of following deficiencies/ documents:** i. Submit revised Form-7A regarding clearly identifying the "Legal Manufacturer, Designing Site, Manufacturing site, etc." as per documents attached (LOA, FSC, ISO 13485, Full Quality Assurance, ii. Provide credential of all design & manufacturing sites of "Protege TM RX Self Expanding Peripheral Stent System" notarized from the country of origin. The firm provided credentials of manufacturer of irrelevant medical devices i.e. "ClosureRFG Radiofrequency Generator (RFG) & ClosureFast EndoVenous Radiofrequency Ablation Catheter". iii. Provide the details of manufacturing and quality control processes of Protege RX Self Expanding Nitinol Peripheral Stent System as the firm provided details of "Protege GPS Self Expanding Peripheral Stent System". iv. Provide Stability of applied medical device as the firm provided the same for "Protege GPS Self Expanding Peripheral Stent System." v. Provide Original & Valid LOA duly notarized by the country of origin vi. Provide original, valid FSC (Country of origin & RRA) duly attested by the country of origin. vii. Provide notarized and valid design examination certificate the provided one is expired before submission on March 11, 2020 viii. The firm intends to import all sizes (including straight & Tapered) of "Protege RX Self Expanding Nitinol Peripheral Stent System" however DoC states that "Approved indications: Peripheral (all sized excluding Tapered stents), need clarification" ix. Provided Declaration of Conformity (DoC) is issued on 20 Oct 2020; therefore, provide latest DoC.
33.	Medtronic Pakistan (Pvt) Ltd. Ocean Tower, 21st Floor, Plot No. G-3,	**Manufacturer:** Medtronic Inc. (Mounds View) 8200 Coral Sea Street NE	TYRX Absorbable Anti-bacterial Envelope	**Deferred for the provisions of following deficiencies/ documents:** i. The applied product contains Rifampicin (102µg/cm2), and Minocycline (102µg/cm2),

	Khayaban-e-Iqbal, Block 09, Clifton, Karachi (EL-00273) Evaluator: [AD-VIII] 3138	MN 55112 Mounds View, USA M/s Medtronic Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432 USA **FSC: Netherland** **Validity: May 26, 2024**	Contains Rifampicin (102µg/cm²); and Minocycline (102µg/cm²) Codes & Sizes: CMRM6122EU CMRM6133EU 6.3cm x 6.9cm (Medium) 7.4cm x 8.5cm (Large) Class: D Shelf life: 1 Year	which is contrary to the Form-7A. Submit revise form. ii. The provided label states following sites, need clarification: **Manufactured by:** TYRX, Inc. 1 Deer Park Drive Monmouth unction, NJ 08852 USA. **Manufactured at:** Medtronic Inc. Minneapolis, MN 55432 USA **EU Representative:** Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands However, the name of manufacturer is M/s Medtronic Inc. (Mounds View) 8200 Coral Sea Street NE MN 55112 Mounds View, USA as per Form-7A & FSC. iii. Provide the details of manufacturing and quality control processes of applied medical device. iv. Provide stability studies to justify the shelf-life & storage conditions applied medical device. v. The LoA is photocopy having Date of issue: Oct 10, 2019, however the same doesn't cover the manufacturing site. Need clarification and/or document as per law, keeping in view the para (i) above, as well. vi. As per Form-7A, approved Labels & FSC, the firm has applied "CMRM6122EU & CMRM6133EU" codes of medical device. However, the firm has submitted **Design Examination & DoC** of different codes CMRM6122INT & CMRM6133INT of products. vii. The as per FSC, ISO 13485, Full Quality Assurance & Design Examination the manufacturer is "M/s **Medtronic** Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432 USA", However the as per approved label the product is **manufactured by M/s TYRX, Inc. 1 Deer Park Drive Monmouth unction, NJ 08852 USA, need clarification**. Furthermore, M/s **TYRX** is not mentioned in any other technical document.
34.	M/s Medtronic Pakistan (Pvt) Ltd. Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (EL-00273) Evaluator: [AD-VIII] 3136	**Legal Manufacturer:** Invatec SpA - Via Martiri della Liberta 7, Ronacadelle, 25030 (BS), Italy FSC: Italy Dated: August 07, 2012	MO.MA ULTRA (Double Balloon)– Cerebral Protection Device Codes & Sizes: MOM0130069X6 MOM0130068X5 Class: D Shelf Life: 02 Years	**Deferred for the provisions of following deficiencies/ documents:** i. Submit separate application for product code i.e. MOM0130008X5 of MO.MA Ultra (Mono Balloon). ii. The LOA, FSC, ISO 13485, Full Quality Assurance and Design Examination certificate are notarized & Embassy Attested (Where applicable) in USA however the country of origin of applied product is Italy, need clarification. iii. Provide Valid and original FSC in country of origin and/or RRA duly attested by Embassy of Pakistan in the Country of Origin. Expired copy was provided.
35.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273)	**Year** **Legal Manufacturer:** M/s Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA M/s Medtronic Mexico S.de R.L. de CV, Av.	Solarice NC Rapid Exchange Balloon Dilatation Catheter Codes & Sizes: as per FSC Class-D Shelf life: 2	**Deferred for the provisions of following deficiencies/ documents:** i. The firm provided the stability study for Euphora RX Balloon Dilation Catheter, clarify. ii. Provide valid ISO 13485 notarized by the country of origin. iii. Provide original FSC. iv. Provide label (as approved in the country of origin) and its packaging, promotion material and

	Evaluator: [AD-VIII] 4351	Paseo Cucapah, Baja California, Mexico **FSC: Ireland** **Date of issue: 11-08-2021**		brochure.
36.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 4308	**Legal Manufacturer:** M/s Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA M/s Medtronic Mexico S.de R.L. de CV, Av. Paseo Cucapah, Baja California, Mexico **FSC: Ireland** **Date of issue: 11-08-2021**	Solarice Rapid Exchange Balloon Dilitation Catheter Codes & Sizes: as per FSC Class-D Shelf life: 2 Year	**Deferred for the provisions of following deficiencies/ documents:** i. The firm provided the stability study for Euphora RX Balloon Dilation Catheter, clarify. ii. Provide valid ISO 13485 notarized by the country of origin. iii. Provide original FSC.
37.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) **Evaluator**: AD-IV [2509]	Manufacturer: Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec H9R 5Z8 Canada. FSC Canada copy not Embassy attested issued on 22-10-2018) (FSC Netherlands valid till 31-3-2018)	Freezor Xtra (Cardiac CryoAblation Catheter) Class D Shelf Life: 3 years Codes: As per FSC	**Deferred** for provision of following documents: (i) FSC Canada is copy and not Embassy attested and FSC Netherlands was expired even upon submission (ii) Full QA and Design Examination certificate for the applied product from applied manufacturer are not provided. Provide valid and notarized certificates (iii) 217F2 Code mentioned on form is not found in any legal and technical document. Clarify the codes required (iv) Details of manufacturing and QC not provided (v) ISO 13485 expired now. Provide valid certificate.
38.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) Evaluator AD-IV [2511]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Astra XT SR MRI SureScan (Single chamber implantable pacemaker) Model: X2SR01 Class D Shelf Life: 18 Months	**Deferred** for provision of following documents: (i) Shelf life studies changed with hand which is not acceptable. Provide relevant stability studies of the applied product supporting claimed shelf life of 18 months (ii) Product details including its intended use, contraindications, warning precautions etc not provided in this dossier. Provide complete product details including instructions for use, user manual etc (iii) Details of manufacturing and QC not provided (iv) FSC and ISO13485 expired now. Provide valid certificates
39.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator**	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA	EOPA 3D® Arterial Cannulae (Cardiopulmonary bypass cannula arterial) Code:78220 -78222-78320-78322 Class: D Shelf Life:03 Years	**Deferred** for provision of:- I. Original, valid and embassy attested FSC in the country of origin since the FSC provided is expired before submission. II. notarized ISO 13485 certificate for manufacturing sites and Contract Manufacturing Site: M/s MedPlast Medical Inc. 620 Watson Street, S. W. Grand Rapids, Michigan 49504 USA. III. valid and notarized Full Quality Assurance certificate and design examination certificate. The already submitted are copies.

	AD-VII	FSC USA: Date of Issue: March 09, 2018 Valid Till: March 08, 2020		
40.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator** AD-VII	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA	DLP® CURVED TIP ARTERIAL CANNUALE WITH WIREWOUND BODY Codes 87020,87022,87024,87920, 87922,87924,87324,87424, Class: D Shelf Life: 03 Years FSC USA: Valid Till : March 08, 2020	**Deferred** for provision of:- I. Original, valid and embassy attested FSC in the country of origin since the FSC provided is expired before submission. II. Notarized ISO 13485 certificate for manufacturing sites and Contract Manufacturing Site: M/s MedPlast Medical Inc. 620 Watson Street, S. W. Grand Rapids, Michigan 49504 USA. III. Valid and notarized Full Quality Assurance certificate and design examination certificate. The already submitted are copies.
41.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator** AD-VII	Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht The Neteherlands **Manufacturing Facility** Medtronic Singapore Operations Pte. Ltd 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore Medtronic Europe SArl Route du Molliau 31, case postale,1131 Tolochenaz, Switzerland.	Vitatron Q-series SR MRI Surescan (IPG) Model Q20A2 CLASS D Shelf Life 18 months Fsc Netherland Expired one June 1,2020	**Deferred** for provision of:- I. Valid, original and embassy attested Free sale Certificate since the the provided was expired before submission. II. Valid ISO 13485 certificate of the manufacturing site(s). The previously has been expired. III. Clarification of Stability studies since the provided are of *Phoenix IPG Device*
42.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator** AD-VII	Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht The Neteherlands Manufacturing Facility Medtronic Singapore Operations Pte. Ltd 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore Medtronic Europe SArl Route du Molliau 31, case postale,1131 Tolochenaz, Switzerland.	Vitatron G-Series DR MRI Surescan (IPG) Model G70A2 CLASS D SHELF LIFE 18 months	**Deferred** for provision of:- I. Valid, original and embassy attested Free sale Certificate since the the provided was expired before submission. II. Valid ISO 13485 certificate of the manufacturing site(s).The previously has been expired. III. Clarification of Stability studies since the provided are of *Phoenix IPG Device*
43.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3,	Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht	Vitatron G-Series SR MRI Surescan (IPG) Model G20A2 CLASS D	**Deferred** for provision of:- I. valid, original and embassy attested Free sale

	Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator** AD-VII	The Neteherlands Manufacturing Facility Medtronic Singapore Operations Pte. Ltd 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore Medtronic Europe SArl Route du Molliau 31, case postale,1131 Tolochenaz, Switzerland	SHELF LIFE 18months	Certificate since the the provided was expired before submission. II. valid ISO 13485 certificate of the manufacturing site(s).The previously has been expired. III. Clarification of Stability studies since the provided are of *Phoenix IPG Device*
44.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. ELI-00273 **Evaluator** AD-VII	Medtronic CoreValve LLC, 1851 E Deere Avenue Santa Ana, CA 92705 USA	EnVeo Pro Delivery Catheter System CLASS D Shelf Life 01 year	**Deferred** for provision of :- I. Valid, original and embassy attested Free sale.expired copy was submitted. II. The stability studies provided are of Enveo R Delivery System instead of EnVeo Pro Delivery Catheter System, provide clarification. III. Provide valid and notarized ISO 13485 certificate , Full Quality Assurance Certificate and Design examination certificate .the already submitted are copies.
45.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273) **Evaluator** AD-VII	Representative in Netherlands Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Manufacturer Medtronic CryoCath LP 9000 Autoroute Transcanadienne pointe-Claire, Quebec H9R 5Z8, Canada FSC: Netherlands Valid Till: 16-1-2022	Arctic Front Advance Pro Cardiac CryoAblation Catheter 2years Class D 4011 Model no AFAPRO23 AFAPRO28 FSC USA valid till May 10.2022	**Deferred** for provision of valid ISO 13485, and submit revised form7A having correct name as per FSC. Since the firm has applied for two codes AFAPRO23 AFAPRO28, with brand name Arctic Front Advance Pro Cardiac CryoAblation Catheter. However in FSC these codes are mentioned for the product Arctic Front Advance Pro only.
46.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI: 00273 3580-D-R&I 04.03.2020 **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Medtronic Heart** Valves Division 1851 E. Deere Avenue , Santa Ana Ca 92705. **Medtronic Mexico** S. DE R.L De CV Av. Paseo Cucapah 10510 El Lago, Tijuana, Baja California C.P 22210 Mexico. FSC: US FDA	Avalus ™ Bioprosthesis Model: 400 Aortic Heart Valve Bioprosthesis. Class D Shelf Life: 5 years. Grouping: Family (40019, 40021, 40023, 40025, 40027)	**Deferred for:** • Please provide full description of product along with the Instruction to Use. • Role of different manufacturing facilities engaged in the manufacturing of the applied product is not clear, please specify the role of each facility. • Please provide valid ISO-13485 since the submitted certificate is expired now. • Submission of valid Full Quality Assurance certificate is required since the submitted one is expired now. • Please provide stability aging studies' protocol and the results of the study casing the claimed shelf life. • Detail of quality control procedures is required. • The address of applicant is not correct in the submitted Form 7A. Therefore, you are required to submit revised Form 7A mentioning the correct address along with the revised copy of Establishment License.

		Valid till: 18TH Feb,2021.		
47.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No. G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 4823-R&I 18.03.2020 **Evaluator** AD-IX	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA **Contract manufacturing location:** M/s Medplast Medical Inc. 620 Watson street, S.W. grand Rapids, Michigan 49504, USA. **FSC:** US FDA **Valid Till :** March 08, 2020	DLP® Intracardiac Suction Tube (Suction system catheter, general purpose. **Code:** 10060 **Class:** B SMD **Shelf Life:** 03 Years	**Deferred for:** • Please provide full description of product along with the Instruction to Use. • Please provide notarized and valid full quality assurance certificate for the applied product and the facility. • Provide notarized Declaration of Conformity. • Submit original, legalized and valid free sale certificate (FSC) as the submitted FSC is expired now. • Define the role of each manufacturing facility and mention complete names and addresses in-lined with Form 7A and other attached certificates. • Submission of valid and notarized ISO-13485 since the submitted certificate is expired. Moreover, the scope of certificate must contain the name of the applied product. • Please provide stability aging studies' protocol in detail and the results of the study supporting the claimed shelf life. • You have claimed the applied product as Class D Medical Device while as per submitted Declaration of Conformity the product is classified in Class IIa (Class B), please clarify. • The address of applicant is not correct in the submitted Form 7A. Therefore, you are required to submit revised Form 7A mentioning the correct address along with the revised copy of Establishment License.
48.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 5525-R&I 19.02.2021 **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Puetro Rico Operations Co., Villalba Rd/149, Km 56.3, call box 6001, Villalba, PR 00766, USA. FSC: US FDA **Valid till:** 22/06/2022	Sprint Quattro (Endocardial Defibrillation lead) Class D Shelf Life: 2 years. Grouping: Family Class: D (6946M-72, 6946M-97)	**Deferred for:** Sprint Quattro (6946M) contains steroid (Dexanethasone) which is eluted upon exposure to body fluids from lead tip. Please provide following documents; 1. Stability studies for the medical devices supporting claim of 2 years shelf life. 2. A brief discussion on the dose delivery of Dexmethasone along with the relevant studies for measuring the quantity to be delivered. 3. Protocol and detailed testing method for the device as well as for Dexamethasone contained in the device.
49.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3544 (K) **Evaluator**	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Design facility:** Medtronic perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA	DLP Extension Line Adapter (Cardioplegia Solution Administration adopter) Class D Shelf Life: 2 years. Grouping: Family Class: B ()	**Deferred For:** • Clarification since as per Medical Devices Directive, the applied device falls under Class B (IIa) but you have classified the applied product as Class D, please justify. • Submission of original legalized and valid Free Sale Certificate is required. • Please submit protocol and stability study data. • Copies of ISO-13485, full quality assurance certificate, design examination certificate and

	AD-IX	**Contract manufacturing Location:** Viant Medical, Inc. 620 Watson SW GR, MI USA 49504 FSC: US FDA (copy) **Valid till:** 01/04/2022		Declaration of Conformity are submitted while notarized certificate are required.
50.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3549 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA Medtronic Mexico, S. De R.L. De C.V Av. Paseo Cucapah, 10510 El Lago C.P. 22210 Tijuana, Baja California, Mexico. FSC: US FDA (copy) **Valid till:** 01/04/2022	Affinity CP Centrifugal Blood Pump with Cortiva Bioactive Surface (Cardiopulmonary bypass system centrifugal pump) Class D Shelf Life: 2 years. Grouping: SMD ()	**Deferred for:** • Provide original, legalized and valid Free Sale Certificate (FSC) since expired copy of FSC is submitted. • Provide notarized and valid production quality assurance certificate, design examination certificate and Declaration of conformity. • A brief discussion on the quantitative analysis is required with respect to the applied medical device • Stability studies for the medical devices supporting claim of 2 years shelf life with respect to bioactive surface (Heparin).
51.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3547 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic perfusion systems, 7611 Northland Drive, Minneapolis, MN 55428, USA Medtronic Mexico, S. De R.L. De C.V Av. Paseo Cucapah, 10510 El Lago C.P. 22210 Tijuana, Baja California, Mexico. FSC: US FDA (copy) **Valid till:** 01/04/2022	Affinity NT Integrated CVR / Membrane Oxygenator with Cortiva Bioactive Surface Class D Shelf Life: 2 years. Grouping: SMD ()	**Deferred for:** • MRP is not provided. • Since manufacturer has used Heparin based cortiva bioactive surface therefore, provide stability studies supporting 2 years shelf life and analytical procedures for routine analysis of the device with respect to Heparin, please. Moreover, provide the data related to the release studies of Heparin during the device's operation. • Original, legalized and valid FSC. • Design examination certificate is required. • Full quality assurance certificate is required. • Instruction for use
52.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA	Attain Performa Straight MRI SureScan (Coronary venous pacing lead) Class D	**Deferred for:** • Provide original, legalized and valid Free Sale Certificate (FSC) since copy of FSC is submitted. • Provide notarized production quality assurance certificate and Declaration of conformity.

	ELI: 00273 3541 (K) **Evaluator** AD-IX	**Manufacturing facility:** Medtronic Puetro Rico Operations Co., Villalba Rd/149, Km 56.3, call box 6001, Villalba, PR 00766, USA. FSC: US FDA (copy) **Valid till:** 22/06/2022	Shelf Life: 2 years. Grouping: Family (4398-78, 4398-88)	• A brief discussion on the deliverable quantity of Dexamethasone along with the relevant studies for measuring the quantity to be delivered. • Protocol and detailed testing method for the device as well as for Dexamethasone contained in the device. • Stability studies for the medical devices supporting claim of 2 years shelf life with respect to Dexamethasone.
53.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3683 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Crome DR MRI SureScan (DDPC3D4) (Dual Chamber Implantable Defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DDPC3D4)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required.
54.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3679 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Crome HF Quad CRT-D MRI SureScan (DTPC2QQ) (Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DTPC2QQ)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required. • Submission of documents supporting the life span of 18 months for the applied medical device is required.
55.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA	Crome HF Quad CRT-D MRI SureScan (DTPC2Q1) (Cardiac resynchronization therapy implantable defibrillator)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted.

	ELI: 00273 3682 (K) **Evaluator** AD-IX	**Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Class D Shelf Life: 18 months Grouping: SMD (DTPC2Q1)	• Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required. • Submission of documents supporting the life span of 18 months for the applied medical device is required.
56.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3678 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Crome HF CRT-D MRI SureScan (DTPC2D4) (Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DTPC2D4)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required. • Submission of documents supporting the life span of 18 months for the applied medical device is required.
57.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3687 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Crome HF CRT-D MRI SureScan (DTPC2D1) (Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DTPC2D1)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required.

58.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3681 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Cobalt XT HF CRT-D MRI SureScan (DTPA2D1) (Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DTPA2D1)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required.
59.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3684 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Cobalt XT HF CRT-D MRI SureScan (DTPA2D4) (Cardiac resynchronization therapy implantable defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DTPA2D4)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required
60.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3685 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C	Cobalt XT DR MRI SureScan (DDPA2D4) (Dual Chamber Implantable Defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DDPA2D4)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required.

		Application software: D00U005		
61.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3686 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Cobalt XT DR MRI SureScan (DDPC3D1) (Dual Chamber Implantable Defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DDPC3D1)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required.
62.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 3680 (K) **Evaluator** AD-IX	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing facility:** Medtronic Europe Sarl Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC: US FDA (copy) **Valid till:** 16/06/2022 Storage conditions: -18°C to 55°C Application software: D00U005	Cobalt XT DR MRI SureScan (DDPA2D1) (Dual Chamber Implantable Defibrillator) Class D Shelf Life: 18 months Grouping: SMD (DDPA2D1)	**Deferred for:** • Submission of original, legalized and valid Free Sale Certificate (FSC) since the copy of the certificate is submitted. • Notarized and valid ISO-13485 certificate, full quality assurance, design examination and declaration of conformity are required. • Submission of documents supporting the life span of 18 months for the applied medical device is required.
63.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 1190 (k) **Evaluator**: AD-II	Legal Manufacturer Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe- Claire, Quebec H9R 5Z8, Canada. FSC: Canada Date of issue: 24 May,2018	FlexCath Advance ™ (Catheter introducer) Model: 4FC12 (sterile) Cass D Shelf life: 2 years	**Deferred** for provision of original LOA and credentials of manufacturer abroad duly notarized, valid and notarized Full Quality Assurance and ISO-13485 Certificates.

64.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI-00273 1345-(K) Evaluator: AD-II	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA FSC: USA Date of Issue: March 09, 2018 Valid Till: March 08, 2020	DLP® Silicone RCSP Cannula with Auto inflate Cuff (Coronary Sinus cannula) Sterile **Code:** As per FSC **Class:** D **Shelf Life:** 03 Years	**Deferred** for provision of following documents: - • Original Letter of Authorization. • Original Credentials of manufacturer abroad. • Valid ISO-13485 and FQA certificate • Original, Valid Embassy attested Free Sale Certificate. • Design Examination Certificate.
65.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI-00273 1348 **Evaluator:** AD-II	**Legal Manufacturer:** M/s. Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturer Site:** M/s. Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA **FSC** USA **Date of Issue:** March 09, 2018 **Valid Till** March 08, 2020	DLP® Pericardial/Intracardiac Sump (Cardiopulmonary bypass cannula arterial) Sterile **Code:** 12112 **Class:** D **Shelf Life:** 03 Years	**Deferred** for provision of following documents: - • Original Letter of Autjhorization. • Original Credentials of manufacturer abroad. • Valid ISO-13485 and FQA certificate • Original, Valid Embassy attested Free Sale Certificate. • Design Examination Certificate.
66.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. ELI: 00273 1195 (K) **Evaluator:** AD-II	**Legal Manufacturer** Medtronic Inc.710 Medtronic Parkway, Minneapolis, MN 55432 USA **Design Facility:** Medtronic Perfusion systems 7611 Northland Drive, Minneapolis, MN 55428, USA **Manufacturing Facility:** Medtronic Mexico S.de R.L de CV Av. Paseo Cucapah FSC: USA Valid till: 8th March,2020	Next Generation Bio-Medicus TM Adult Venous Cannulae Kits Cardiopulmonary bypass cannula arterial Code: 96600-115-96600-117-96600-119-96600-121-96600-123-96600-125-96600-127-96600-129 Class-D Shelf Life: 4 years	**Deferred** for provision of following documents: - • Original Letter Of Autjhorization. • Original Credentials of manufacturer abroad. • Valid ISO-13485 and FQA certificate • Original, Valid Embassy attested Free Sale Certificate. • Design Examination Certificate
67.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal,	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA	Avigo Hydrophilic Guidewire (Peripheral vascular Guidewire, manual)	**Deferred** for provision of following documents: - • Valid and Original Agency agreement or letter of authorization. • Valid and Original Free sale certificate in the

	Block 09, Clifton, Karachi. (ELI-00273) 2996 **Evaluator**: AD-II	**Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Codes & Sizes: As per FSC Class-D Shelf Life: 3 years (1 Year Real time stability studies data provided)	country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP. • Valid Full Quality Assurance Certificate or equivalent. • Original and valid Design examination certificate duly notarized by the country of origin. • Stability studies data upto claimed shelf life.
68.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2997 **Evaluator**: AD-II	**Legal manufacturer and Manufacturing site:** Fuji System Coorporation, Shirakawa Plant. 200-2, Aza Ohira, Odakura, Nishigo, Nishi Shirakawa Gun Fukushima Japan FSC: Japan Valid till: 18-04.2019	CELLO Balloon Guide Catheter (Intravascular occluding balloon catheter, image-guided) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: - • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate. • Original and Valid Design Examination Certificate. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, duly notarized by the country of origin.
69.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2998 **Evaluator**: AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA **FSC:** Netherlands Valid till: 13-04-2020	PHENOM Catheter (Vascular Guide-Catheter) Single use Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: - • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate. • Valid Full Quality Assurance certificate or equivalent. • Valid Declaration of Conformity (DoC). • Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer. • Credentials of manufacturer abroad duly notarized from the country of origin.
70.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2999 **Evaluator**: AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Pipeline Flex Embolization Device with Shield Technology (Bare-metal intracranial vascular stent) Sterile Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: - • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate. • Valid Full Quality Assurance certificate or equivalent. • Valid Declaration of Conformity (DoC). • Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer. • Credentials of manufacturer abroad duly notarized from the country of origin.
71.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi.	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:**	MARKSMAN Catheter (Vascular microcatheter) Codes & Sizes: As per FSC Class-D	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original and Valid Free Sale Certificate of the country of origin duly attested by Embassy of

	(ELI-00273) 3000 **Evaluator**: AD-II	Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Shelf Life: 3 years	Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.
72.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 3062 **Evaluator**: AD-II	Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA Manufacturing sites: Medtronic Europe Sarl. Route du Molliau 31, Case Postale, 1131Tolochenaz, Switzerland FSC Netherlands valid till 01-07-2020	Azure XT DR MRI SureScan (Dual-Chamber Implantable Pacemaker, rate responsive) Codes: W2DR01 Class-D Shelf Life: 18 months from the date of power source connection	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original and Valid Free Sale Certificate of the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Detail of manufacturing and quality control process. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.
73.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2986 **Evaluator**: AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Echelon Micro Catheter (Vascular Micro Catheter) Codes & Sizes: As per FSC Class-D Shelf Life: 2 years	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original and Valid Free Sale Certificate of the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.
74.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2514 **Evaluator**: AD-II	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing sites:** Medtronic Europe Sarl. Route du Molliau 31, Case Postale, 1131Tolochenaz, Switzerland FSC Netherlands valid till 01-07-2020	Attesta S DR MRI SureScan Dual Chamber Implantable Pace Maker, rate-responsive. Codes & Sizes as per FSC" Clasas-D Shelf Life: 18 months from the date of power source connection	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original and Valid Free Sale Certificate of the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized

				from the country of origin. • Complete stability studies data supporting the claimed shelf life.
75.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2501 **Evaluator**: AD-II	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing sites:** Medtronic Europe Sarl. Route du Molliau 31, Case Postale, 1131Tolochenaz, Switzerland Medtronic Puerto Rico Operations Co., Juncos Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777 USA FSC Netherlands valid till 01-07-2020	Percepta Quad CRT-P MRI Sure Scan Cardiac resynchronization therapy implantable Pacemaker Codes & Sizes as per FSC" Classs-D Shelf Life: 18 months from the date of power source connection	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original and Valid Free Sale Certificate of the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorizntion from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin. • Details of manufacturing and quality control processes.
76.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2759 **Evaluator**: AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA Sterigenics U.S. LLC 900 South Gifford Ave. Los Angeles, CA 90058, USA FSC USA valid till 23-07-2021	Rebar Micro Catheter Peripheral/ Coronary Vascular Micro Catheter Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.
77.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2487 **Evaluator**: AD-II	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA FSC Netherlands valid till 01-07-2020	Claria MRI Quad CRT-D SureScan Cardiac resynchronization therapy implantable defibrillator Code: (DTMA2Q1) Class-D Shelf-life: 18 months	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Details of manufacturing and quality control processes. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin. •

78.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2496 **Evaluator:** AD-II	**Legal manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432 USA **Manufacturing sites:** Medtronic Europe Sarl. Route du Molliau 31, Case Postale, 1131Tolochenaz, Switzerland FSC Switzerland valid till 06-03-2021	Astra XT DR MRI SureScan Dual Chamber Implantable Pace Maker, rate-responsive. Codes & Sizes as per FSC" Class-D Shelf-life: 18 months	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Design Exmination Certificate duly notarized from country of origin. • Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Valid DoC duly notarized from country of origin • Details of manufacturing and quality control processes. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.
79.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2760 **Evaluator:** AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Mirage Hydrophilic Guidewire (Peripheral Vascular Guidewire, manual) Codes & Sizes as per FSC" Class-D Shelf-life: 3 years	**Deferred** for provision of following documents: - • Valid Full QA certificate or equivalent. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Original & valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Valid and original agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer. • Credentials of manufacturer abroad duly notarized from the country of origin.
80.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2768 **Evaluator:** AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	Axium Detachable Coil System Neurovascular Embolization Coil Codes & Sizes as per FSC" Class-D Shelf-life: 3 years	**Deferred** for provision of following documents: - • Only Codes of one configuration (bare, nylon and PLGA) will be considered on this application. Submit separate applications for the rest. • Complete stability studies of Axium™ Detachable Coil System supporting the shelf life claim of 3 years. • Valid Full QA certificate or equivalent duly notarized from country of origin. • Valid Declaration of Conformity (DoC) duly notarized from country of origin. • Valid original Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin.

81.	M/s Medtronic Pakistan (Pvt) Ltd, Ocean tower, 21st floor, plot # G-3, Khayaban e Iqbal, Block 09, Clifton, Karachi. (ELI-00273) 2777 **Evaluator:** AD-II	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA **Manufacturing site:** Micro Therapeutics Inc d/b/a ev3Neurovascular 9775 Toledo Way, Irvine, CA92618 USA FSC USA Valid till: 23.07.2021	AXIUM PRIME Detachable Coil System (Neurovascular embolization coil) Codes & Sizes as per FSC* Class-D Shelf-life: 3 years	**Deferred** for provision of following documents: - ▪ Complete stability studies of Axium™ Prime Detachable Coil System supporting the shelf life claim of 3 years. ▪ Valid Full QA certificate or equivalent duly notarized from country of origin. ▪ Valid Declaration of Conformity (DoC) duly notarized from country of origin. ▪ Valid Free Sale Certificate of country of origin duly attested by Embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized from country of origin. ▪ Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer duly notarized by the country of origin. ▪ Credentials of manufacturer abroad duly notarized from the country of origin.
82.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -56-	**Legal Manufacturer & Mfg. site:** M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Single (250ml) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC. Reg. No. 011442 Valid Till: 09-03-2019	**Deferred** for provision of following documents: - •Valid & original FSC of country of origin and any RRA duly attested by the embassy •Design examination certificate.
83.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -57-	**Legal Manufacturer & Mfg. site:** M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Triple (500ml + 300mlx2) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC. Reg. No. 011444 Valid Till: 09-03-2019	**Deferred** for provision of following documents: - •Valid & original FSC of country of origin and any RRA duly attested by the embassy •Design examination certificate.
84.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -58-	**Legal Manufacturer & Mfg. site:** M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Quadruple (500ml + 300mlx3) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC Reg. No. 011445 Valid Till: 09-03-2019	**Deferred** for provision of following documents: - •Valid & original FSC of country of origin and any RRA duly attested by the embassy •Design examination certificate.
85.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -59-	**Legal Manufacturer & Mfg. site:** M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Double (500ml + 300ml) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC Reg. No. 011443 Valid Till: 09-03-2019.	**Deferred** for provision of following documents: - •Valid & original FSC of country of origin and any RRA duly attested by the embassy •Design examination certificate.

86.	M/s S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) -60-	**Legal Manufacturer & Mfg. site:** M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620, Singapore FSC Singapore Issuance Date (11-10-2019)	JMS Blood Collection Bag Single (500ml) Class-D Shelf Life: 03-years. Codes & Sizes as per FSC Reg. No. 01122 Valid Till: 26-02-2020.	**Deferred** for provision of following documents: - •Valid & original FSC of country of origin and any RRA duly attested by the embassy •Design examination certificate.
87.	M/s S. Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2791 **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 (Single) 500mlIBSP-BSB-NP-CLP 17G (DT) (Blood bags) Class-D Shelf life: 3 years Code: 811-5004	**Deferred** for provision of following documents: - • Credentials of manufacturer abroad. • Updated and notarized agency agreement. • FSC of reference country • Design examination certificate • Updated and notarized ISO 13485 and FQA certificate, the submitted certificates are without notarization also the reference has not been provided of notarized document. • European type Declaration of conformity, duly notarized. • Undertaking on stamp paper.
88.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 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 following documents: - • Credentials of manufacturer abroad. • Updated and notarized agency agreement. • FSC of reference country • Design examination certificate • Updated and notarized ISO 13485 and FQA certificate, the submitted certificates are without notarization also the reference has not been provided of notarized document. • European type Declaration of conformity, duly notarized. • Undertaking on stamp paper.
89.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 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 following documents: - • Credentials of manufacturer abroad. • Updated and notarized agency agreement. • FSC of reference country • Design examination certificate • Updated and notarized ISO 13485 and FQA certificate, the submitted certificates are without notarization also the reference has not been provided of notarized document. • European type Declaration of conformity, duly notarized. • Undertaking on stamp paper.
90.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi Pakistan. (ELI-00078) 2677 **Evaluator**	**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:	**Deferred** for provision of following documents: - • Credentials of manufacturer abroad. • Updated and notarized agency agreement. • FSC of reference country • Design examination certificate • Updated and notarized ISO 13485 and FQA certificate, the submitted certificates are without notarization also the reference has not been provided of notarized document.

	AD-III		811-5408	• European type Declaration of conformity, duly notarized. • Undertaking on stamp paper.
91.	M/s Elite Traders, Office 342-B, 1st Floor, B-Block Satellite Town , Rawalpindi. ELI:00193. -1540-	**Legal Manufacturer & Mfg. site:** Implantcast GmbH Luneburger Schanze 26 D- 21614 Buxtehue Germany. FSC: Germany Date of issue: 07-03-2019	MUTARS ® shoulder Implant System Class-D Shelf Life: 5 years. Codes & Sizes as per FSC	**Deferrd for** provision of following documents: - • valid ISO-13485 & Full QA certificate. • valid & original Letter of Authorization.
92.	M/s Elite Traders, Office 342-B, 1st Floor, B-Block Satellite Town , Rawalpindi. ELI:00193. -1541-	**Legal Manufacturer & Mfg. site:** Implantcast GmbH Luneburger Schanze 26 D- 21614 Buxtehue Germany. FSC: Germany Date of issue: 07-03-2019	MUTARS ® Hip Implants System. Class-D Shelf Life: 05-years. Codes & Sizes as per FSC.	**Deferred for provision of** following documents: - • valid ISO-13485 & Full QA certificate. • valid & original Letter of Authorization.
93.	M/s Elite Traders Office 342-B, 1st Floor, B-Block Satellite Town Rawalpindi ELI-00193. -2227-	**Legal Manufacturer & Mfg. site:** M/s Oasrtis GmbH Lagestr 11-15 dieburg hessen 64807 Germany. FSC: Germany Date of issue: 11.03.2020	BonOs ® R NF Genta (Bone cement, medicated) Gentamicin Sulphate. Codes & Sizes: As per FSC Class: D Shelf Life: 03-years	**Deferred for provision of** following documents: - • valid ISO-13485 & Full QA certificate. • valid & original Letter of Authorization.
94.	M/s Elite Traders,Office 342-B, 1st Floor, B-Block Satellite Town , Rawalpindi. ELI:00193 [1532-P] **Evaluator**: AD-II	**Legal Manufacturer and manufacturing site** Implantcast GmbH Luneburger Schanze 26 D- 21614 Buxtehue Germany FSC: Germany **Date of Issue:** March 07, 2019	MUTARS® KNEE SYSTEM (MUTARS ® Knee Implants Code: As per FSC Class-D Shelf Life: 5 years	**Deferred** for provision of Valid and Original Agency Agreement or Letter of Authorization, Credentials of manufacturer abroad duly notarized from the country of origin, Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate, and Full Quality Assurance certificate.
95.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer & Mfg. site**: Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden Germany. FSC: Germany. issued on **01-12-2020**	ALERE HIV Combo Set. Class-D Shelf life: 18-months. Codes & Sizes as per FSC.	**Deferred for provision of; -** The firm asked to provide Declaration of Conformity and Design examination certificate. Clarification is required in regard of manufacturer name, Alere or Abbott, Japan.
96.	M/s Cardiac Care 848-C, Shadman-1, Lahore Eli-00070 {2060}	**Legal Manufacturer**: Edwards Life sciences, LLC One Edwards Way Irvine, CA 92614, USA) **Mfg. site**: Edwards Life sciences, 12050 Lone Peak Parkway Draper UT 84020 USA	**Physio II** Mitral Ring 5200 Mxx. Class-D Shelf Life: 05-years. Codes & Sizes: As per FSC.	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details.

		FSC: USA Valid till: 13.07.2022.		
97.	M/s Cardiac Care 848-C, Shadman-1, Lahore Eli-00070 (1432)	**Legal Manufacturer & Mfg. site:** PROUSE MEDICAL, Route du Manoir-60173 Ivry Le Temple-France FSC: Frane Date of Issue:23-10-2017.	POLYTHESIS IC/ICT Class-D Shelf Life: 5 years. Codes & Sizes: As per FSC.	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details.
98.	M/s Cardiac Care, 848-C, Shadman-1, Lahore ELI: 00070. -1992-	**Legal Manufacturer:** Edwards Life sciences, LLC One Edwards Way Irvine, CA 92614, USA) www.edwards.com **Mfg. site:** Edwards lifesciences, (Singapore) Pte. Ltd., 35 Changi, North Cresent-Singapore 499641, Singapore FSC: USA Valid till: 13.07.2022	CARPENTIER-EDWARDS ® Perimount ® **(Biological Heart Valve) 3300 TFX** Class-D Shelf Life: 04-years. Codes & Sizes: As per FSC.	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization. • Provide the technical documents like stability studies and QC-details.
99.	M/s Cardiac Care 848-C, Shadman-1, Lahore Eli-00070 2733-P **Evaluator** AD-III	**Legal Manufacturer:** M/s Edwards Lifesciences, LLC One Edwards Way Irvine, CA 92614 USA FSC: USA Valid till: 14.05.2022	Edwards bovine pericardial patch (Pericardial Patch) Class-D Shelf Life: 4 years Model: 4700	**Deferred** for provision for following documents:- • Valid Letter of Authorizzation. • Embassy attested FSC mentioning the subject device. • Readable copy of IFU.
100.	M/s Cardiac Care, 848-C, Shadman-1, Lahore ELI: 00070 2235-P **Evaluator** AD-III	**Legal Manufacturer:** Vygon GmbH Co., KG Prager Ring 100-52070 Aachen- Germany FSC: Germany Date of issue: 29.03.2019	Multicath 2 (Central Venous Catheter) Class: B Shelf Life: 5 years Codes as per DoC	**Deferrered** for provision of following documents:- Valid Letter of Authorization. Valid ISO 13485. Noturized copy of Declaration of Conformity. Differential Fee of Rs.25,000/- as the product fall in class-D.
101.	M/s. Cardiac Care, 848-C Shadman-I Lahore. ELI-00070 Evaluator: [AD-VIII] 1466	**Legal manufacturer:** PROUSE MEDICAL, Route du Manoir-60173 Ivry Le Temple-France FSC: France Date of Issue: 13-02-2018	**Dolphin** **(Inflation device)** Code: As per FSC Class-B Shelf Life: 5 years	**Deferred for the provisions of following deficiencies/documents:** i. Name of responsible person is different on form-7A than Establishment License. ii. Provide valid ISO 13485. The provided one is expired now but found valid upon submission. iii. Provided FSC is scanned copy (Date of Issue: Feb 13, 2018) but embassy attestation is original. Therefore, provide Original FSC. iv. The form-7A need revision regarding mentioning codes, sizes, grouping & brief descriptions of the applied medical device to be registered etc. Furthermore, the documents provided are peculiar in explaining the intended medical device product (name, codes, sizes, grouping etc.) to be registered.

102.	M/s Cardiac Care, 848-C, Shadman-1, Lahore 54610, Pakistan ELI: 00070 Evaluator: [AD-VIII] 2869	**Legal Manufacturer:** KIMAL PLc Anrundel Road, Uxbridge, Middlesex, UBB 2SA United Kingdom **Manufacturing site:** KIMAL Plc, 34 Sherwood Rd, Bromsgrove Worcestershire B60 3DR United Kingdom FSC: UK Date of issue: 16.03.20200	Altius Classic Central Venous Catheter- 5 Lumen Set (Central Venous Catheter adult and paediatric) Codes & sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for the provisions of following deficiencies/documents:** i. Form-7A shall be revised regarding mentioning of "complete list of various configurations/codes/sizes to be registered. ii. Proposed MRP not given on application form, therefore revise form. iii. Rizwan hasan mentioned as responsible person however the same not mentioned on establishment license. iv. Provide labels as approved in country of origin for all codes and sizes as per FSC. Since the provided one doesn't mention the name of manufacturer. v. Provide Original FSC.
103.	M/s Cardiac Care, 848-C, Shadman-1, Lahore 54610, Pakistan (ELI: 00070) **Evaluator** AD-VII	Legal Manufacturer: KIMAL Plc Arundel Road, Uxbridge, Middlesex, UB8 2SA United Kingdom Manufacturing site: KIMAL Plc, 34 Sherwood Rd, Bromsgrove Worcestershire B60 3DR United Kingdom	Altius Classic Central Venous Catheters-3 Lumen Codes & sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of :- I. Valid Original, valid and embassy attested FSC. Only photocopy provided. II. Provide notarized and valid ISO 13485 Certificate, Full Quality Assurance and Design Examination certificate. Also provide original and notarized LOA. The already submitted are copies. III. Form-7A shall be revised regarding mentioning of "complete list of various configurations/codes/sizes to be registered.Proposed MRP not given on application form, therefore revise form 7A. IV. Provide labels as approved in country of origin for all codes and sizes as per FSC. Since the provided one doesn't mention the name of manufacturer.
104.	M/s Cardiac Care, 848-C, Shadman- 1 Lahore. ELI: 00070 **170-R&I** **03.01.2022** **Evaluator** AD-IX	**Legal Manufacturer:** M/s Kimal PLC, 34 Sherwood Road, Bromsgrove, Worcestershire B60 3DR, United Kingdom FSC: UK Date of Issue: 16.02.2020	Altius Classic Central Venous Cathetrs-1 Lumen (Central Venous Catheter) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for the following:** • Provide stability testing of the applied product along with the protocol of the stability studies from the finished product manufacturer since the submitted data is from MT Catheters technology which is not approved for manufacturing of Altius Classic Catheters-1 Lumen as per the submitted full quality assurance certificate. • Full quality assurance and Design examination certificate are issued for M/s Kimal Plc Arundel road, Uxbridge, Middlesex, UB8 2SA, United Kingdom while the manufacturing facility as per Free Sale Certificate is M/s M/s Kimal PLC, 34 Sherwood road, Bromsgrove, Worcestershire B60 3DR, United Kingdom, please clarify and provide original, legalized and valid free sale certificate mentioning the correct name and address of finished product manufacturer since the submitted certificate is a copy. • Provide Instruction for Use for the applied product. • Detail of quality control procedures along with the testing method and specifications are required. • Submission of notarized ISO-13485, full quality assurance certificate, design examination certificate and credentials of manufacturer. • Please submit notarized and valid letter of authorization from legal manufacturer.

105.	M/s Cardiac Care, 848-C, Shadman- 1 Lahore ELI: 00070 **169-R&I** **03.01.2022** **Evaluator** AD-IX	Legal Manufacturer: M/s Kimal PLC, 34 Sherwood Road, Bromsgrove, Worcestershire B60 3DR, United Kingdom FSC: UK Date of Issue: 16.02.2020	Altius Classic Central Venous Catheters-4 lumen (Central Venous Catheter) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for:** • Provide stability testing of the applied product along with the protocol of the stability studies from the finished product manufacturer. • Full quality assurance and Design examination certificate is issued for M/s Kimal Plc Arundel road, Uxbridge, Middlesex, UB8 2SA, United Kingdom while the manufacturing facility as per Free Sale Certificate is M/s M/s Kimal PLC, 34 Sherwood road, Bromsgrove, Worcestershire B60 3DR, United Kingdom, please clarify and provide original, legalized and valid free sale certificate mentioning the correct name and address of finished product manufacturer since the submitted certificate is a copy. • Provide Instruction for Use for the applied product. • Detail of quality control procedures along with the testing method and specifications are required. • Submission of notarized copy of ISO-13485, full quality assurance certificate, design examination certificate and credentials of manufacturer. • Please submit notarized and valid letter of authorization from legal manufacturer.
106.	M/s Cardiac Care, 848-C, Shadman- 1 Lahore ELI: 00070 **3526-R&I** **07.02.2022** **Evaluator** AD-IX	Legal Manufacturer: M/s Kimal Plc Arundel road, Uxbridge, Middlesex, UB8 2SA, United Kingdom. Manufacturing facility: M/s Kimal PLC, 34 Sherwood road, Bromsgrove, Worcestershire B60 3DR, United Kingdom. FSC: MHRA, UK Date of Issue: 16.02.2020	Altius Classic Central Venous Catheters-2 Lumen (Central Venous Catheter adult and paediatric) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for:** • The protocol for conducting the aging stability studies is submitted whereas the results of the studies are not provided with the registration application. Furthermore, refer the guideline according to which the criterion/protocol for the said study is selected. • Full quality assurance and Design examination certificate is issued for M/s Kimal Plc Arundel road, Uxbridge, Middlesex, UB8 2SA, United Kingdom while the manufacturing facility as per Free Sale Certificate is M/s M/s Kimal PLC, 34 Sherwood road, Bromsgrove, Worcestershire B60 3DR, United Kingdom, please clarify and provide original, legalized and valid free sale certificate mentioning the correct name and address of finished product manufacturer since the submitted certificate is a copy. • Provide Instruction for Use for the applied product. • Detail of quality control procedures along with the testing method and specifications are required. • Submission of notarized copy of ISO-13485, full quality assurance certificate, design examination certificate and credentials of manufacturer. • Please submit notarized and valid letter of authorization from legal manufacturer.
107.	M/s Cardiac Care, 848-C, Shadman- 1 Lahore ELI: 00070 **32910-R&I** **Evaluator** AD-IX	Legal Manufacturer: M/s On-X Life Technologies, Inc. (Susidiary of cryolife, Inc.)1300 East Anderson Lane, Bldg. B, Austin TX 78752 USA. FSC: MHRA, UK	Chord-X suture (Polyolefin suture, monofilament) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years Grouping: SMD	**Deferred for:** • Provide Instruction for Use for the applied product. • Submission of following notarized and valid documents is required: ➢ ISO-13485 ➢ Full quality assurance certificate ➢ Design examination certificate ➢ Declaration of conformity ➢ Credentials of manufacturer.

		Date of Issue: 16.02.2020		• Please submit original, notarized and valid letter of authorization from legal manufacturer. • Provide original, legalized and valid Free Sale Certificate.
108.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) -2540-	**Legal Manufacturer:** Ethicon, LLC Guaynabo USA	**PROLENE (W8434)** Polypropylene Sterile Synthetic Absorbable Surgical Suture. Class-D. Shelf Life:03-years. Codes & Sizes: As per FSC.	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization and Design examination certificate. • Provide the technical documents like stability studies and QC-details.
109.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) -2596-	**Legal Manufacturer & Mfg. site:** Biosense Webster, Inc. 33-Technology Driver Irvine, CA USA 92618. **FSC; USA Valid till 21-02-2021.**	AVAIL Fixed Curve Catheters. Class-D. Shelf Life:03-years. Codes & Sizes as per FSC	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization and Design examination certificate. • Provide the technical documents like stability studies and QC-details.
110.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) -2599-	**Legal Manufacturer & Mfg. site** Biosense Webster, Inc. 15715 Arrow HWY, Irwindale CA, USA 91706	LASSO 2515 NAV Eco-Variable Catheter. Class-D. Shelf Life:..... Codes & Sizes as per FSC	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization and Design examination certificate. • Provide the technical documents like stability studies and QC-details.
111.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) -2498-	**Legal Manufacturer & Mfg. site** Biosense Webster, Inc. 15715 Arrow HWY, Irwindale CA, USA 91706	SURGICEL Fibrillar Absorbable Hemostate Class-D. Shelf Life; 03-years Codes & Sizes as per FSC	**Deferred for provision of; -** • Provide the valid & original FSC. • Valid ISO-13485/ latest GMP report of all manufacturing sites. • Original Letter of Authorization and Design examination certificate. • Provide the technical documents like stability studies and QC-details.
112.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi. (ELI-00154) 3198 **Evaluator** AD-III	**Legal Manufacturer:** DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA. FSC US FDA validity 04-04-2021 FSC US FDA validity 21-05-2021	PFC Sigma total knee replacement (total knee replacement) Class-D Shelf life: Codes as per FSC	**Deferred** for provision of vaid Free Sale Certificate, ISO 13485, Manufacturing and QC details.
113.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive, Irvine, CA USA 92618.	Celsius Thermocool Catheter	**Deferred** for provision of following documents: 1. Applied product and product class not clear. Applied as class B medical device, the codes and description provided for Celsius Thermocouple

	Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator:** AD-IV [497(6A)]	**Manufacturer:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico, 32574 (FSC USFDA valid till 21-2-2021)	Class B (class to be confirmed) Codes: As per FSC Shelf Life: 3 years	Catheter which indicates it is class D medical device. Some documents are provided for **Celsius Thermocouple RD** including unsigned DOC and that too from different manufacturer and EPSP. Clearly state the product required on this application, its manufacturer, sites, its codes, its relevant DOC, its IFU, all labels and product description and other relevant documents and if the product is class D medical device then submit differential fee of Rs. 25,000/- Highlight the codes on all legal documents 2. FSC, Full QA, ISO13485 expired now. Provide valid certificates.
114.	M/s. Chemical House, 6-C Sikander Malhi Road, Canal park Gulberg II, Lahoer: ELI:00156. -1655-	**Legal Manufacturer & mfg. site:** Bio RAD; 3-Boulevard Raymond Poincare, 92430 Marnes-la, Coquette, France FSC: France Date of issue: 15-03-2018	Monolisa HBs Ag Ultra (Catalogue # 72346, 72348,72408). (EIA Microplate Formate-HBV antigen antibody detection) Class-D Shelf Life:.....	**Deferred for provision of; -** • Provided original free sale certificate (FSC) of France. • The letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describes the subject site, clarification is required.
115.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156. -2553-	**Legal Manufacturer & Mfg. site:** M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la- Conquette, France FSC: France Date of Issue: 15.03.2019	Genscreen Ultra HIV Ag-Ab assay (EIA Microplate Format) Codes & Sizes: As per FSC Class-D Shelf Life: 18 months	**Deferred for provision of; -** • Provided original free sale certificate (FSC) of France. • The letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describes the subject site, clarification is required.
116.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156. -2554-	**Legal Manufacturer & Mfg. site:** M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la- Conquette, France FSC: France Date of Issue: 15.03.2019	Geenius HIV (EIA Microplate Format) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	**Deferred for provision of; -** • Provided original free sale certificate (FSC) of France. • The letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describes the subject site, clarification is required.
117.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156. -2550-	**Legal Manufacturer & Mfg. site:** M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la- Conquette, France FSC: France Date of Issue: 15.03.2019	Geenius HCV Supplement Assay & Control Kit (Immunochromatographic test) Codes & Sizes: As per FSC Class-D Shelf Life: 12 months	**Deferred for provision of; -** • Provided original free sale certificate (FSC) of France. • The letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describes the subject site, clarification is required.
118.	M/s. Universal Enterprises 29 Block 3, Overseas	**Legal Manufacturer & Mfg. site:** Sanyo Chemical Industries, Ltd	AQUABIRD Surgical Sealant. Class-D Shelf Life:	**Deferred for provision of; -** • Provide the Original Letter of Authorization, that shows the relation/ legal link of Owner of the product and actual manufacturer and importer.

	Cooperative Housing Society, Stadium Road, Karachi (ELI-00079) -3664-	11-1, IkkyoNomoto-cho, Higashiyama-ku, kyoto-shi, Kyoto 605-0995, Japan.	24-months. Codes and sizes as per FSC	• Provide the valid & original FSC of country of origin and/or RRA duly attested by the embassy. • Provide the technical documents like stability studies, QC-details.
119.	M/s. Oriental Sales Corporation, 327, DMCHS, Clock-3, Haider Ali Road Karachi (ELI-00025) -3648-	**Legal Manufacturer & Mfg. site:** Cochealer Limited, 1 University Avenue, Macquarie University NSW 2109, Australia. Scanned copy of ARTGA provided.	Cochealer Nucleus C1500 Series. Class-D Shelf Life: 24-months. Codes and sizes as per FSC.	**Deferred for provision of; -** • Provided original free sale certificate (FSC). • Provide the **original & valid** agency agreement. • Provide the valid ISO-13485 certificate/ latest GMP report.
120.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi (ELI-00091) -2924-	**Owner & mfg. Site:** Polysuture Industria E Comercio Ltda (a MEDTRONIC Company) located at Avendia Vereador Gabriel Ramos da Silva, 1245 Sao Sebastio do parasio MG 37950 Brazil.	MAXSORB Surgical Suture. Codes & Sizes: As per FSC Class-D Shelf Life: 05-years.	**Deferred for provision of; -** • Provided the original free sale certificate (FSC) of Ireland, original letter of authorization, QC-details & Certificate of Analysis, valid Full QA and Design Examination certificates. • Provide valid ISO-13485 certificate/ latest GMP report of all manufacturing sites involved in the production of the subject products. • Provide the clarification regarding the Legal manufacturer, manufacturing sites and any other MAH/ PAH involved in the exportation of the subject product on revised Form-7A alongwith miscellaneous fee, if applicable.
121.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi (ELI-00091) -3065-	**Legal Manufacturer & mfg. Site:** Polysuture Industria E Comercio Ltda (a MEDTRONIC Company) located at Avendia Vereador Gabriel Ramos da Silva, 1245 Sao Sebastio do parasio MG 37950 Brazil. Evidence of Reg. of Brazil. FSC: HPRA Ireland. Valid till 05-11-2024.	MIDSORB Surgical Suture. Codes & Sizes: As per FSC Class-D Shelf Life: 05-years.	**Deferred for provision of; -** • Provided the original free sale certificate (FSC) of Ireland, original letter of authorization, QC-details & Certificate of Analysis, valid Full QA and Design Examination certificates. • Provide valid ISO-13485 certificate/ latest GMP report of all manufacturing sites involved in the production of the subject products. • Provide the clarification regarding the Legal manufacturer, manufacturing sites and any other MAH/ PAH involved in the exportation of the subject product on revised Form-7A alongwith miscellaneous fee, if applicable.
122.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi (ELI-00091)	**mfg. Site:** Polysuture Industria E Comercio Ltda (a MEDTRONIC Company) located at Avendia Vereador Gabriel Ramos da Silva, 1245 Sao Sebastio do parasio MG 37950 Brazil. Evidence of Reg. of Brazil. FSC: HPRA Ireland. Valid till 05-11-2024.	DEXON TM Surgical Suture. Codes & Sizes: As per FSC Class-D Shelf Life: 05-years.	**Deferred for provision of; -** • Provided the original free sale certificate (FSC) of Ireland, original letter of authorization, QC-details & Certificate of Analysis, valid Full QA and Design Examination certificates. • Provide valid ISO-13485 certificate/ latest GMP report of all manufacturing sites involved in the production of the subject products. • Provide the clarification regarding the Legal manufacturer, manufacturing sites and any other MAH/ PAH involved in the exportation of the subject product on revised Form-7A alongwith miscellaneous fee, if applicable.

123.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi (ELI-00091) -3074-	**mfg. Site:** Polysuture Industria E Comercio Ltda (a MEDTRONIC Company) located at Avendia Vereador Gabriel Ramos da Silva, 1245 Sao Sebastio do parasio MG 37950 Brazil. Evidence of Reg. of Brazil. FSC: HPRA Ireland. Valid till 05-11-2024.	POLYGLACTIN-910 Surgical Suture. Codes & Sizes: As per FSC Class-D Shelf Life: 05-years.	**Deferred for provision of; -** • Provided the original free sale certificate (FSC) of Ireland, original letter of authorization, QC-details & Certificate of Analysis, valid Full QA and Design Examination certificates. • Provide valid ISO-13485 certificate/ latest GMP report of all manufacturing sites involved in the production of the subject products. • Provide the clarification regarding the Legal manufacturer, manufacturing sites and any other MAH/ PAH involved in the exportation of the subject product on revised Form-7A alongwith miscellaneous fee, if applicable.
124.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4306 **Evaluator** AD-III	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432. **Manufacturing site:** Medtronic Neuromodulation 7000 central Ave., N.E Minneapolis, MN USA 55432 FSC: USA Valid Till: 5-5-2023	Activa DBS Platform (Deep Brain Electrical stimulation system) Class-D Shelf life: 4 years Codes as per FSC	**Deferred** for provision of following documents:- • Complete description of all the components included in the system. • Clarification regarding the grouping of device in a system. • Shelf life of all the applied components/ accessories used within a system.
125.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 2558-KP **Evaluator** AD-III	**Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Sites:** Boston Scientific Ecublens (ECU) Site (Symetis SA) 11 Chemin de la venoge, 1024 Ecublens, Switzerland FSC: Switzerland Valid till: 24.09.2023	Acurate neo2 Aortic Valve System (Cardiac valves, biological with support for percutaneous implantation) Class-D Shelf Life: 12 months Codes & Sizes: as per FSC	**Deferred** for provision of following documents: - • Valid LOA and ISO 13485. • All legal documents provided are copies without notarization and attestation.
126.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 2657-KP Renewal **Evaluator** AD-III	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Availmed S.A. De C.V C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A Col. Cd. Mexico C.P 22444 FSC US FDA Valid till: 06.08.2022	Expo Angiographic Catheter (Catheter, Angiographic) Class-D Shelf Life: 2 years Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Valid Letter of Authorization. • All the legal documents provided are copies without notarization and attestation. • Differential fee of 25.000/-.
127.	M/s Ferozsons Laboratories Limited P.O	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston	Mach 1 ™ Guide Catheters (Intravascular guiding catheter, single-use)	**Deferred** for provision of following documents:- • Valid Letter of Authorization.

	Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 2658-KP Renewal **Evaluator** AD-III	Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Availmed S.A. De C.V C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A Col. Cd. Mexico C.P 22444 FSC US FDA Valid till: 06.08.2022	Class-D Shelf Life: 3 years Codes & Sizes as per FSC	• All the legal documents provided are copies without notarization and attestation. • Differential fee of 25.000/-.
128.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 2656-KP Renewal **Evaluator** AD-III	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Availmed S.A. De C.V C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A Col. Cd. Mexico C.P 22444 FSC US FDA Valid till: 06.08.2022	Impulse Angiographic Catheter (Catheter, Angiographic) Class-D Shelf Life: 2 years Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Valid Letter of Authorization. • All the legal documents provided are copies without notarization and attestation. • Differential fee of 25.000/-.
129.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 Evaluator: [AD-VIII] 2774-KPK	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland FSC: Ireland Valid till: 20.01.2025	SYNERGY MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System (Drug- Eluting Coronary artery stent, bioabsorbable-polymer-coated) Class-D Shelf Life: 24 months	**Deferred for the provisions of following deficiencies/documents:** i. That M/S Ferozsons Laboratories has already registered "PROMUS ELITE ***Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System***" Having Reg. No. MDIR-0001809 (Validity of Registration Date is 09/22/2025), Now the M/S Ferozsons Laboratories has applied with brand name "SYNERGY MEGATRON ***Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System***", it appears to be same medical devices, which NEED CLARIFICATION/ JUSTIFICATION. ii. Provided the stability studies of "Project Name: Synergy II", However applied "SYNERGY MEGATRON ***Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System***" as per form-7A. iii. Provide valid Original Agency agreement or letter of authorization since attached on is expired now (valid upon submission). iv. Provide the Free sale certificate in the country of origin duly attested by Embassy of Pakistan. v. The Provided ISO 13485, Full QA certificate & Design Examination certificate are not duly notarized by the country of origin.
130.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK)	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA	JUDO 6 Guidewire (Ballon Dilation Catheter Guidewire) Codes & Sizes: UPN:	**Deferred for the provisions of following deficiencies/ documents:** i. Provide written agreement/ evidence to establish a link between the Legal Manufacturer and the manufacturing site:

	ELI-00120 Evaluator: [AD-VIII] 2775	Manufacturing Site: FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan FSC: USA Valid Till: 10.06.2022	H749393781902 H749393783002 Class-D Shelf Life: 3 years	Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA **Manufacturing Site:** FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan ii. Provided the photocopy of Agency agreement also the same was found expired (valid upon submission), therefore provide original and valid agency agreement duly notarized by the country of origin. iii. Provide the Free sale certificate in the country of origin duly attested by Embassy of Pakistan. Provided one is unattested photocopy. iv. Provide the Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin for the manufacturing site i.e. FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan or otherwise justify.
131.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 Evaluator: [AD-VIII] 2776	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA Manufacturing Site: FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan FSC: USA Valid Till: 10.06.2022	JUDO 3 Guidewire (Catheter Guidewire) Codes & Sizes: UPN: H749393771902 H749393773002 Class-D Shelf Life: 3 years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide written agreement/ evidence to establish a link between the Legal Manufacturer and the manufacturing site: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA **Manufacturing Site:** FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan ii. Provided the photocopy of Agency agreement also the same was found expired (valid upon submission), therefore provide original and valid agency agreement duly notarized by the country of origin. iii. Provide the Free sale certificate in the country of origin duly attested by Embassy of Pakistan. Provided one is unattested photocopy. iv. Provide the Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin for the manufacturing site i.e. FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan or otherwise justify.
132.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 Evaluator: [AD-VIII] 2777	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA Manufacturing Site: FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan FSC: USA Valid Till: 10.06.2022	JUDO 1 Guidewire (Catheter Guidewire) Codes & Sizes: UPN: H749394151902 H749394153002 Class-D Shelf Life: 3 years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide written agreement/ evidence to establish a link between the Legal Manufacturer and the manufacturing site: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA **Manufacturing Site:** FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan ii. Provided the photocopy of Agency agreement also the same was found expired (valid upon submission), therefore provide original and valid agency agreement duly notarized by the country of origin. iii. Provide the Free sale certificate in the country of

				origin duly attested by Embassy of Pakistan. Provided one is unattested photocopy. iv. Provide the Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin for the manufacturing site i.e. FMD. CO., Ltd. 1-166 Shimoobari Nakashima Komaki, Aichi, Japan or otherwise justify.
133.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2809-KP] Renewal Case	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Medical Device (Malaysia) SDN BHD, PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian, Batu Kawan, 14110 Bandar Cassia, Pulau Pinang, Malaysia FSC Ireland valid till 11.09.2025	Maverick 2 Monorail PTCA Dilatation Catheter Codes & Sizes: As per FSC Class D Shelf Life: 3 years Fee submitted: Rs 25,000/-	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. ISO13485 of manufacturing site i.e Malaysia as evident from the documents 4. Original valid notarized Letter of Authorization 5. Notarized Design Examination Certificate
134.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2810-KP] Renewal Case	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA FSC US FDA valid till 22-2-2023.	Sterling Monorail PTA Balloon Dilatation Catheter Codes & Sizes: As per FSC Class D Shelf Life: 3 years Fee submitted: Rs 25,000/-	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. Original valid notarized Letter of Authorization 4. Notarized Design Examination Certificate
135.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2808-KP] Renewal Case	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific limited Ballyhrit Business Park, Galway, Ireland FSC IRELAND valid till: 20.01.2025	Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System Codes & Sizes: As per FSC Class-D Shelf Life: 24 months Fee submitted: Rs 25,000/-	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. Original valid notarized Letter of Authorization 4. Notarized Design Examination Certificate 5. Signed and stamped EU Declaration of conformity (DOC) from the manufacturer

136.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2806-KP] Renewal Case	**Legal Manufacturer**: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site**: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC IRELAND valid till: 01.05.2025 FSC USFDA not provided.	Emerge Monorail PTCA Dilatation Catheter Codes & Sizes: As per FSC Class-D Shelf Life: 3 years Fee submitted: Rs 25,000/-	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. Original valid notarized Letter of Authorization 4. Notarized Design Examination Certificate
137.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2807-KP] Renewal Case	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site**: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC IRELAND valid till: 01.05.2025 FSC USFDA not provided.	Emerge Over-the-wire PTCA Dilatation Catheter Codes & Sizes: As per FSC Class-D Shelf Life: 2 years Fee submitted: Rs 25,000/-	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. Original valid notarized Letter of Authorization 4. Notarized Design Examination Certificate.
138.	M/s Ferozsons Laboratories Limited. P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 **Evaluator:** AD-IV [2805-KP] Renewal Case	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC US FDA valid till 22-02-2023.	NC QUANTUM Apex ™ Monorail PTCA Dilatation Catheter Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Original, valid Embassy attested Free Sale Certificate 3. Original valid notarized Letter of Authorization 4. Notarized Design Examination Certificate.
139.	M/s Ferozsons Laboratories Limited, P.O Ferozsons Amangarh,	Leagal manufacturer Boston Scientific Neuromodulation 25155 Rye Canyon Loop Valencia, CA 91355, USA	Vercise ™ Deep Brain Stimulation (DBS) System Active implantable medical Device Class D Claimed Shelf life 2 years	**Deferred** for provision of :- I. Valid Original and embassy attested FSC, since the submitted FSC is a copy. Also provide model of the product to be registered. II. Provide notarized and valid ISO 13485 Certificate, Full Quality Assurance and Design Examination

	Nowshera (KPK)-Pakistan (ELI-00120) **Evaluator** AD-VII			certificate. Also provide original and notarized LOA. The already submitted are copies. III. Provide stability/ aging studies since the submitted does not specify shelf life neither mentioned on Form7A.
140.	M/s Ferozsons Laboratories Limited, P.O Ferozsons Amangarh, Nowshera (KPK)-Pakistan (ELI-00120) **Evaluator** AD-VII	Boston Scientific Neuromodulation 25155 Rye Canyon Loop Valencia, CA 91355, USA	Vercise™ PC System Active implantable medical Device Class D Shelf life 2 years FSC USA	**Deferred** for provision of :- I. Valid Original and embassy attested FSC, since the submitted FSC is a copy. Also provide model of the product to be registered. II. Provide notarized and valid ISO 13485 Certificate, Full Quality Assurance and Design Examination certificate. Also provide original and notarized LOA. The already submitted are copies.
141.	M/s Ferozsons Laboratories Limited, P.O Ferozsons Amangarh, Nowshera (KPK)-Pakistan (ELI-00120) **Evaluator** AD-VII	Legal Manufacturer Lake Region Medical 340 Lake Hazeltine Dr. CHASKA, MN USA 55318 Distributor Boston Scientific Corporation marina bay cust shea boulevard quincy MA USA	Safari 2™ Guidewires Codes As Per FSC Class D Shelf life 3 years FSC USA valid till April 13,2022	**Deferred** for provision of valid ISO 13485 Certificate, Full Quality Assurance and Design Examination certificate. Also provide original and notarized LOA. The submitted are expired.
142.	M/s Ferozsons Laboratories Limited, P.O Ferozsons Amangarh, Nowshera (KPK)-Pakistan (ELI-00120) **Evaluator** AD-VII	Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland	Watchman Flx ™ Left Atrial Appendage Closure Device with Delivery System Class D Shelf life 3 years FSC Irland valid till 12th November 2024 Codes as pe Fsc	**Deferred** for Provision of valid notarized ISO 13485 Certificate. The submitted has been expired. Also provide notarized Full Quality Assurance and Design Examination certificate. The submitted are copies
143.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK) Pakistan ELI-00120 2759 **Evaluator**: AD-II	**Legal Manufacturer and Manufacturing Site**: Boston Scientific Neuromodulation 25155 Rye Canyon Loop Valencia, CA 91355, USA FSC: U.S.A Valid till: 25.08.2022	Vercise Gevia ™ Deep Brain Stimulation System (Active Implantable Medical Devices) Codes & Sizes: As per FSC Class-D Shelf Life: 2 years	**Deferred** for provision of following documents: - • Notarized and Embassy attested Legal documents • Valid Agency agreement • Clarification regarding shelf-life and storage conditions of each component of the system
144.	M/s Al Farman Trading, 74-C Satellite Town Sargodha, Pakistan	**Manufactured by:** M/s Brivant Ltd Parkmore West Business Park Galway,	ITRAC Guidewire (Guidewire) Class-D	**Deferred** for provision of following documents:- • Manufacturing process and QC testing in details.

	ELI: 00588 2336-P **Evaluator** AD-III	Country Galway Ireland. **Distributed by:** amg international GmbH Boschstrabe 16 21423 Winsen-Luhe. FSC Ireland Date of Issue: 24.11.2020	Shelf Life: 4 years Codes & Sizes As per FSC	• stability studies of claimed shelf life. • ISO 13485 certificate of amg International, gmbh, Germany. • FSC of Ireland provided is notarized, the FSC should be attested. • Declaration of Conformity provided is without notarization,
145.	M/s 3M Surgicals, Plot 5/172 Street 172, Sarwar Road, Rawalpindi. ELI: 00122 2507-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: 01.05.2024	Cardiac Tape (Cotton Tape/ Heart Tape) Class-D Shelf Life: 5 years Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Manufacturing process and QC testing in details. • Stability studies of claimed shelf life. • Reference country FSC. • Design examination certificate • Essential principle checklist. • Information on validation for medical device with sterile function.
146.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4068 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China FSC China Valid Till: 21-2-2013	Star Chromic Catgut Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification. • Original and valid agency agreement. • Design examination certificate. • valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
147.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4069 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China FSC China Valid Till: 21-2-2013	Star Polypropylene Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification. • Original and valid agency agreement. • Design examination certificate. • valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
148.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4070	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China	Star Silk Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification • Original and valid agency agreement. • Design examination certificate.

	Evaluator AD-III	FSC China Valid Till: 21-2-2013		• valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
149.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4071 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China FSC China Valid Till: 21-2-2013	Star PGLA Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification • Original and valid agency agreement. • Design examination certificate. • Valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
150.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4072 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China FSC China Valid Till: 21-2-2013	Star Polyester Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification • Original and valid agency agreement. • Design examination certificate. • Valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
151.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4073 **Evaluator** AD-III	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China FSC China Valid Till: 21-2-2013	Star Nylon Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification • Original and valid agency agreement. • Design examination certificate. • Valid and notarized ISO 13485 and FQA certificates. • European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
152.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi. (ELI-00066) 4074 **Evaluator**	**Legal Manufacturer:** Shanghai Pudong Jinhuan Medical Products Co., Ltd 25 LianZhen Road, Pudong New Area, Shanghai China	Star Polyglycolic Acid Suture with needle Class-D Shelf Life: 3 years Codes/ sizes as per FSC	**Deferred** for provision of following documents: - • Original and valid FSC of the country of origin. • FSC of reference country duly attested or provide CE marked document or WHO prequalification • Original and valid agency agreement. • Design examination certificate. • Valid and notarized ISO 13485 and FQA certificates.

	AD-III	FSC China Valid Till: 21-2-2013		• European Type Declaration of conformity. • EPSPs and labels of all applied sizes. • Fee clarification is required in written from the B&A division. • MRP.
153.	M/s Vertex Medical Pvt LTd, 70-B-1, Gul berg -II Lahore ELI: 00150 1608-P **Evaluator** AD-III	**Legal Manufacturer** Sorin Group Italia S.r.L Via Benigno Crespi 17, 20159, Milano, Italy FSC: Italy Date of issue: 02-03-2018	**Carbomedics Reduce Aortic (Heart valves)** **Class-D** **Shelf Life: 5 years** **Codes as per FSC**	**Deferred** for provision of following documents: - • Original and updated Letter of Authorization, duly notarized, • Stability studies for the claimed shelf life. • Valid and notarizaed ISO 13485 certificate. • The submitted FQA and design examination certificates are without notarization. • Essential Principle checklist. • Clarification as the application applied on letter head is for Optiform valve whereas in Form-7A the applied device and its information is of Reduced aortic valve.
154.	M/s Health Tec, House No. 10-B, Street 24, Valley, Road Westridge-1, Lahore ELI: 000046 Renewal 603 **Evaluator** AD-III	**Legal Manufacturer:** M/s Blue Medical Devices B.V Located at Panovenweg 7, 5708 HR, Helmond The Netherlands FSC Netherlands validity 14-03-2022	EVEREST (PTCA Dilatation Catheter) Class-D Shelf Life: 3 years Codes as per Design Examination certificate.	**Deferred** for provision of valid Free Sale Certificate, Full Quality Assurance, Design Examination Certificate and differential Fee of Rs.25,000/-
155.	M/s Health Tec, House No. 10-B, Street 24, Valley, Road Westridge-1, Lahore ELI: 000046 Renewal 603 **Evaluator** AD-III	**Legal Manufacturer:** M/s Blue Medical Devices B.V Located at Panovenweg 7, 5708 HR, Helmond The Netherlands FSC Netherlands validity 14-03-2022	FORCE NC (PTCA Dilatation Catheter Non-complaint) Class-D Shelf Life: 3 years Codes as per Design Examination certificate	**Deferred** for provision of valid Free Sale Certificate, Full Quality Assurance, Design Examination Certificate and differential Fee of Rs.25,000/-
156.	M/s Health Tec, House No. 10-B, Street 24, Valley, Road Westridge-1, Lahore ELI: 000046 Renewal 603 **Evaluator** AD-III	**Legal Manufacturer:** M/s Blue Medical Devices B.V Located at Panovenweg 7, 5708 HR, Helmond The Netherlands FSC Netherlands validity 14-03-2022	SUMMIT CTO (PTCA DILATATION CATHETER Class-D Shelf Life: 3 years Codes as per Design Examination certificate	**Deferred** for provision of valid Free Sale Certificate, Full Quality Assurance, Design Examination Certificate and differential Fee of Rs.25,000/-
157.	M/s Health Tec, House No. 10-B, Street 24, Valley, Road Westridge-1, Lahore	**Legal Manufacturer:** M/s Blue Medical Devices B.V Located at Panovenweg 7, 5708 HR, Helmond The	PROTÉGÉ Drug Eluting Balloon Catheter (Paclitaxel Elution Balloon Dilatation Catheter)	**Deferred** for provision of valid Free Sale Certificate, Full Quality Assurance, Design Examination Certificate, Labels and differential Fee of Rs.25,000/-

	ELI: 000046 Renewal 2845-P **Evaluator** AD-III	Netherlands FSC Netherlands validity 14-03-2022	Class-D Shelf Life: 3 years Codes as per Design Examination certificate	
158.	M/s Bionta Pharma Suite # A10, Plot B-10 Block 13-A Gulshan-e-Iqbal Karachi, Pakistan. (ELI-00367) 3212 **Evaluator** AD-III	**Legal Manufacturer:** Scivision Biotech Inc. 9, South 6th Road, KEPZ Kaohsiung City 806, Taiwan. **FSC Taiwan validity 25-04-2019**	Hya Joint Plus Synovial Fluid Joint Supplement (Hyaluronic acid) Class-D Shelf life: Not provided Code: 3mL Syringe	**Deferred** as the product is from Taiwan.
159.	M/s Mian Scientific Corporation (Pvt) Ltd 534- Jinnah Colony Faisalabad, 38030 Pakistan ELI: 00442 2858-P **Evaluator** AD-III	**Legal Manufacturer:** M/s CTK Biotech Inc. 13855 Stowe Dr. Poway, California USA FSC California validity 23-01-2021 FSC USA FDA Validity 07-10-2020 to 06-10-2022	RecombiLISA- HIV 1+2 Ab ELISA Test Kit (HIV 1+2 Ab ELISA Test Kit) Class-D Shelf Life: 12 months Code: E0410	**Deferred** for provision of following documetns: - FSC of US FDA as the provided FSc missing the subject device. Apply separately for HIV 1+2 Ag-Ab ELISA Test Kit
160.	M/s Hope Pharma, 1/B, Guldasht Town, Zarar Shaheed Road, Lahore ELI: 00178 2871-P **Evaluator** AD-III	**Legal Manufacturer:** M/s Medas Inc. 12550 Biscayne Blvd # 405, North Miami, Florida 33181, USA FSC US FDA Valid till: 24.03.2023	Encourage PTCA Balloon Dilatation Catheter (PTCA Balloon Dilatation Catheter) Class-D Shelf Life: 2 years Codes as per FSC	**Deferred for provision of** original Ambassy attested Free Sale Certificate.
161.	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 provision of following documents:- • Credentials of Legal Manufacturer of Canada, as the Legal Manufacturer mentioned on Form-7A is of Canada whereas the submitted LOA and FSC mentioning the Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada, submit the relevant document. • FSC of Germany missing the applied device i.e HIV Rapid Cassette, submit the FSC of HIV ½ Rapid test cassette, duly attested. • FSC of country of origin, duly attested. • The manufacturing and quality control details. • Valid and Notarized ISO 13485 and FQA certificates of Legal manufacturer.

				• Design examination certificate as the device falls in Class-D, duly notarized. • Declaration of conformity to be printed on manufacturer's letter head duly filled and signed. • Label of applied model as per FSC approved in the country of origin, the provided label missing the required information. • Linkup letter or any relevant document between the legal manufacturer Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada and the site Zhejiang Orient Gene Biotech Co., Ltd 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China.
162.	M/s Alfa Scientific Store, Store-24-Maclogen Road, Lahore ELI: 00148 2860-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 (HCV RAPID TEST Cassette) Class-D Shelf Life: 24 months	**Deferred** for provision of following documents: - • Credentials of Legal Manufacturer of Canada, as the Legal Manufacturer mentioned on Form-7A is of Canada whereas the submitted LOA and FSC mentioning the Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada, submit the relevant document. • FSC of Germany missing the applied device i.e HIV Rapid Cassette, submit the FSC of HIV ½ Rapid test cassette, duly attested. • FSC of country of origin, duly attested. • The manufacturing and quality control details. • Valid and Notarized ISO 13485 and FQA certificates of Legal manufacturer. • Design examination certificate as the device falls in Class-D, duly notarized. • Declaration of conformity to be printed on manufacturer's letter head duly filled and signed. • Label of applied model as per FSC approved in the country of origin, the provided label missing the required information. • Linkup letter or any relevant document between the legal manufacturer Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada and the site Zhejiang Orient Gene Biotech Co., Ltd 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China.
163.	M/s Alfa Scientific Store, Store-24-Maclogen Road, Lahore ELI: 00148 2861-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	HEALSTONE (HbsAg Rapid Test Cassette) Class-D Shelf Life: 24 months	**Deferred** for provision of following documents: - • Credentials of Legal Manufacturer of Canada, as the Legal Manufacturer mentioned on Form-7A is of Canada whereas the submitted LOA and FSC mentioning the Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada, submit the relevant document.

		Anji 313300 Huzhou, Zhejiang, China FSC Germany Date of Issue:13.05.2021		• FSC of Germany missing the applied device i.e HIV Rapid Cassette, submit the FSC of HIV ½ Rapid test cassette, duly attested. • FSC of country of origin, duly attested. • The manufacturing and quality control details. • Valid and Notarized ISO 13485 and FQA certificates of Legal manufacturer. • Design examination certificate as the device falls in Class-D, duly notarized. • Declaration of conformity to be printed on manufacturer's letter head duly filled and signed. • Label of applied model as per FSC approved in the country of origin, the provided label missing the required information. • Linkup letter or any relevant document between the legal manufacturer Healstone Biotech Inc. 655 W Kent North, Unit 650 Vancouver BC V6P 6T7 Canada and the site Zhejiang Orient Gene Biotech Co., Ltd 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China.
164.	M/s Briogene Pvt Ltd., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi. (ELI-00015) 4315 **Evaluator** AD-III	**Legal Manufacturer:** ISLAB Bioteknoloji Tibbi Malzeme Saglik Hiz.San.ve Tic.A.S. Kayanarca Mah.Kadirli Sok.Dblok No:10/B Pendik Istanbul Turkey FSC Turkey Issued: 4-1-2021 valid for 36 Months	OBG AHG GEL Anti-erythrocytic Antibodies Gel Class-D Shelf life: 13 Months Code: (OBGAHG-50)	**Deferred** for provision of following documents:- • Credential of manufacturer abroad as per format approved in 3rd meeting of MDB. • Manufacturing details and QC testing related to the applied device. • FSC of reference country, duly attested. • Design examination certificate missing the applied device, submit the design examination certificate of applied device, duly notarized..
165.	M/s Briogene (Pvt) Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) **Evaluator:** AD-IV [4253]	Manufacturer: Xiamen Zeesun Pvt. Ltd Building 1#, 4F and A area 3F of Building 11#, No. 3701 North Xiang'an Road, (Xiang An) Industrial area, Torch High-Tech Zone, Xiamen City, Fujian Province, 361101, P.R China Export only certificate of China Copy of Netherlands FSC issued for Thailand	SARS-COV-2 Test Kit Code: 801302 Class C Shelf life: 12 months	**Deferred** for provision of following documents: 1. What is the brand name of the device? 2. Free Sale Certificate (FSC) of Netherlands is copy, not original and issued for Thailand. Provide original, valid and Pakistani Embassy attested FSC issued for Pakistan for the applied product and it should also contain the code of the product i.e 801302 as only the name SARS-COV-2 Test Kit does not establish that it is the applied product that's on free sale. 3. Front page of the Notary public for all notarized documents is torn. Clarify why is it so? The notarized documents should be provided in original form for the authenticity to stay intact 4. Full QA certificate and Design-Examination not provided for the applied product. Either provide valid and notarized certificates or provide justification from manufacturer abroad as to why Full QA certificate and Design-Examination certificates are not available for the applied product.

				5. Provide pictures of actual product label for the applied product 6. Provide Essential principles of safety and performance for the applied device as per the relevant EU directive.
166.	M/s Global Marketing Services, 111, Hali Road Westridge, 1, Rawalpidni ELI: 00109 Evaluator: [AD-VIII] 2865	**Legal Manufacturer:** M/s Laboratories Grifols, S.A located at Parets del Valles (Barcelona) Spain) **Manufacturing site:** C/ Marte, 4. Poligono Industrial Los Llanos. 30565. Las Torres de Cotillas. Murcia. Spain. FSC: Spain Validity: (Unable to comprehend)	**CPD-SAG -MANNITOL Grifols Quadruple S.K (Blood bags)** Composition per 100ml: Citric acid (monohydrate) … 0.327g (eq. to 0.299g citric acid anhydrous) Trisodium citrate (dihydrate) … 2.63g Monobasic sodium phosphate (monohydrate) … 0.222g Dextrose (monohydrate) … 2.55g Water for injection q.s. … 100ml **Codes & sizes: As per FSC** **Class-D** **Shelf Life: 3 years**	**Deferred for the provisions of following deficiencies/ documents:** i. Provide notarized credentials of manufacturer. ii. Provide original and valid free sale certificate duly attested by embassy of Pakistan, along with English translation specifically highlighting the validity period. iii. Provide labels as approved in country of origin applied medical device. Since the provided one doesn't mention the name of manufacturer. iv. Provide English translated LOA, FSC, Full quality Assurance and design examination to further process the application.
167.	M/s SES Associates, 148 Ejaz Park Model Town Extension, Lahore ELI: 00041 Evaluator: [AD-VIII] 2811-P	Legal Manufacturer: M/s Venus Medtech (Hangzhou) Inc. Room 311, 3/F, Block 2, No. 88, Jiangling Road, Binjing District, Hangzhou, PRC FSC: China Valid till: 24.04.2022	VenusA-Valve ™ System (Transcatheter Aortic Valve System) **Model:** L23, L26, L29, L32 Class-D Shelf Life: 2 years	**Deferred for the provisions of following deficiencies/ documents:** i. Since many fields are left blank in application form, therefore provide revised form-7A completely filled with relevant information. ii. The firm is required to submit a differential fee of rupees 25000/- to process the application. iii. The firm submitted FSC of China which is not given in Rule 67 of MDR, 2017. Therefore, the firm may be asked for any FSC of any RRA or CE certification or WHO pre-qualification in the light of Rule 15(2) of rules ibid. iv. Provide Stability Studies Reports showing conclusive results to justify the proposed shelf life. v. The submitted FSC in the country of origin doesn't cover the applied model/codes of medical product. vi. Provide valid Full quality assurance and Design examination of applied medical device as per law. vii. Provide the details in English of manufacturing and quality control processes of applied product. viii. Provide labels approved in the country of origin since the provided one doesn't cover applied model/ codes.
168.	M/s Med Art Pakistan A175, Block 13-C, KDA Scheme 24, Gulshan E Iqbal Karachi, Karachi East Gulshan Town (ELI-00024)	Hangzhou kangji Medical instrument Co., Ltd No. 1668 Chungjinag East Road, Tonglu, Hanzhou, Zhejiang, P.R.C.	**Disposable Titanium Ligation Clips** **Codes and Sizes** **103Y.501** **103Y.401** **103Y.301** **as per FSC of MHRA**	**Deferred for the provisions of following deficiencies/ documents:** i. The covering letter of the Form-7A bears subject regarding registration of "Disposable Titanium ligation clips", which is contrary to the name mentioned in form-7A i.e. "Polymer Ligation Clips", clarification is required. ii. Provide original LOA duly notarized.

	Evaluator: [AD-VIII] 3350	**FSC:** MHRA **Date of issue:** June 24, 2019	**Class: C** **Shlef life: 3Years**	iii. The models of applied product are different in FSC of MHRA and country of origin (China), need clarifi-cation. iv. Provide valid original embassy attested FSC by the country of origin. v. Provide original FSC issued by MHRA. vi. Provide valid Full QA certificate or equivalent, duly notarized by the country of origin. vii. The provided DoC is devoid of list of medical device/products.
169.	M/s Gene-Tech Laboratories 246/B, PECHS Block 6, karachi-75400 Pakistan (ELI-00089) Evaluator: [AD-VIII] 3351	**Legal Manufacturer:** SHIN POONG PHARM. CO. LTD 161, Yeoksam-ro, Gangnam-gu, Seoul, 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**	**MEDICURTAIN 5ml "Hyaluronic acid (non-animal source)...10mg/ml"** **Codes & Sizes:** **As per FSC** **Class D** **Shelf Life: 3Year**	**Deferred for the provisions of following deficiencies/ documents:** i. Sterilization site "The Standard Co., Ltd. 120, Gunpocheonmdansaneop 2-ro, Gunpo-si, Gyeonggi-do, Republic of Korea" as mentioned in credentials doesn't cover under ISO 13485. ii. The firm submitted FSC of Korea which is not given in Rule 67 of MDR, 2017. Therefore, the firm may be asked for any FSC of any RRA or CE certification or WHO pre-qualification in the light of Rule 71 of rules ibid. iii. The firm applied "MEDICURTAIN 5ml" which is not mentioned on FSC Korea. iv. The verification test on the term of HA-Care (claimed similar to Medicurtain) is applied by M/s SHIN POONG PHARM. CO. LTD 434-4, Monknae-dong, Danwon-gu, Ansan-si Kyunggi-do, Korea, which is different than manufacturing site and conducted by Korea Conformity Laboratories, need clarification. v. Full Quality assurance and Production Quality Assurance is not provided with the application. Provide as per law. vi. The DECLARATION (on stamp paper) as per Form-7A is not provided with application. Provide as per law. vii. Provide valid ISO 13485 of all manufacturing site involved in manufacturing of the applied medical device. viii. Provide original FSC as the provided one is Scanned copy.
170.	M/s Gene-Tech Laboratories 246/B, PECHS Block 6, karachi-75400 Pakistan (ELI-00089) 3244 **Evaluator**: AD-II	Syntacoll GmbH Donaustr. 24 93342 Saal / Donau Germany FSC: Germany Date of Issue: 07.10.2020	Collatamp G Gentamicin Sulfate-Collagen implant Sterile Class-D Shelf life: 48 months (Real time stability studies data for 24 months provided) Codes and Sizes as per FSC	**Deferred** for provision of following documents: - • Duly notarized copy of Credential of manufacturer abroad. • Stability study data for claimed shelf life. • Original and valid agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer. • Free sale certificate in the country of origin duly attested by Embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485). • Full Quality Assurance certificate or equivalent Design examination certificate (if applicable) duly notarized by country of origin. • Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.

171.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Evaluator: [AD-VIII] 3576	Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaxing, Zhejiang, Peoples Republic of China **EU representative:** Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, 20537, Hamburg, Germany. FSC: Germany Date of Issue: April 24, 2024	Venous Disposable Anesthesia Kit (Epidural Kit) Codes and sizes as per FSC **Class D** **Shelf Life: 5 YEARS**	**Deferred for the provisions of following deficiencies/ documents:** i. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" **hold godown** at **"Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi"**, However no such godown is mentioned on Establishment license, need clarification. ii. Since the documents attached with application covers full range of product being manufactured by manufacturer therefore it is required to highlight the applied products (BRAND name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturing & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application. iii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure iv. Provide the DECLARATION (on stamp paper) as per Form-7A.
172.	Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Evaluator: [AD-VIII] 3577	Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaxing, Zhejiang, Peoples Republic of China **EU representative:** Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, 20537, Hamburg, Germany. FSC: Germany Date of Issue: April 24, 2024	SPINAL NEEDLE (PENCIL POINT BEVEL TYPE) Codes and sizes as per FSC **Class D** **Shelf Life: 5 Years**	**Deferred for the provisions of following deficiencies/ documents:** i. The firm submitted 25000/- as registration fee for Class D medical device, therefore the firm is required to submit a differential fee of rupees 25000/- to proceed the application. ii. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" **hold godown** at **"Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi"**, However no such godown is mentioned on Establishment license, need clarification. iii. Since the documents attached with application covers full range of product being manufactured by manufacturer therefore it is required to highlight the applied products (name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturing & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application.
173.	Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Evaluator: [AD-VIII] 3581	Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaxing, Zhejiang, Peoples Republic of China **EU representative:** Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse,	**VENOUS SPINAL NEEDLE (QUINCKE BEVEL TYPE)** **Codes and sizes:** **G-18; G-20; G-21; G-22; G-23; G-24; G-25; G-26; G-27 & G-29** **Class D** **Shelf Life: 5 Years**	**Deferred for the provisions of following deficiencies/ documents:** i. The firm submitted 25000/- as registration fee for Class D medical device, therefore the firm is required to submit a differential fee of rupees 25000/- to proceed the application. ii. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" **hold godown** at **"Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi"**, However no such godown is mentioned on Establishment license, need clarification. iii. Since the documents attached with application covers full range of product being manufactured

		80, 20537, Hamburg, Germany. FSC: Germany Date of Issue: April 24, 2024		by manufacturer therefore it is required to highlight the applied products (name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturing & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application. iv. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure v. Provide the DECLARATION (on stamp paper) as per Form-7A.
174.	Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Evaluator: [AD-VIII] 3583	Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaxing, Zhejiang, Peoples Republic of China **EU representative:** Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, 20537, Hamburg, Germany. FSC: Germany Date of Issue: April 24, 2024	VENOUS COMBINED SPINAL & EPIDURAL KIT (CSE), DISPOSABLE ANESTHESIA KIT Codes and sizes as per FSC **Codes and sizes: G-16; G-18; G-20 & G-22** **Class D** **Shelf Life: 5 Years**	**Deferred for the provisions of following deficiencies/ documents:** i. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" **hold godown** at **"Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi"**, However no such godown is mentioned on Establishment license, need clarification. ii. Since the documents attached with application covers full range of product being manufactured by manufacturer therefore it is required to highlight the applied products (BRAND name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturing & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application. iii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure iv. Provide the DECLARATION (on stamp paper) as per Form-7A.
175.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Evaluator: [AD-VIII] 3580	Zhejiang Runqiang Medical Instruments Co., Ltd, 618#, Dade Road, Xiuzhou District, Jiaxing, Zhejiang, Peoples Republic of China **EU representative:** Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80, 20537, Hamburg, Germany. FSC: Germany Date of Issue: April 24, 2024	VENOUS DISPOSABLE HEAT MOISTURE EXCHANGE FILTER HME / BACTERIAL / VIRAL HEAT MOISTURE EXCHANGE FILTER **Codes and sizes: Not clear** **Class B** **Shelf Life: Not specified in application**	**Deferred for the provisions of following deficiencies/ documents:** i. The credentials of firm shows that "M/s Safe Health Pakistan Bizcon" **hold godown** at **"Office No. 18 & 19, 1st Floor, Dilkusha Chamber, Marston Road, Karachi"**, However no such godown is mentioned on Establishment license, need clarification. ii. Since the documents attached with application covers full range of product being manufactured by manufacturer therefore it is required to highlight the applied products (BRAND name, model, codes and sizes) on all the documents including shelf-life certificate, manufacturing & Quality control procedures, Free sale certificates (Country of Origin & Germany), ISO 13485, Full Quality Assurance and Production Quality Assurance System Certificates, Design Examination, DoC etc. Accordingly submit revise form-7A for further processing of application. iii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure iv. Provide the DECLARATION (on stamp paper) as

				per Form-7A.
176.	M/s Meher Traders, Office A21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi (ELI-00128) Evaluator: [AD-VIII]	**Legal Manufacturer** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China FSC China Valid Till 10-04-2021	**PASORB** **(Synthetic Absorbable Surgical Suture Violet Polyglycolic Acid Braided Coated)** **Codes & Sizes:** **As per FSC** **Class-D** **Shelf Life: 03 Years**	**Deferred for the provisions of following deficiencies/ documents:** i. Provide the credentials of manufacturer abroad duly notarized from the country of origin. ii. Highlight the applied medical device "PASORB Polyglycolic Acid Sutures" on the provided details of manufacturing and quality control processes. iii. Provided the shelf-life & storage conditions, i.e., justified with stability studies: iv. Provide original LOA mentioning validity of agreement, duly notarized by the country of origin. Provided one is un-notarized photocopy. v. The firm provided photocopy of Chinese FSC which is not embassy attested. Therefore, provide Original, valid FSC duly attested by embassy of Pakistan in the country of origin. vi. The provided FSC states that "This is to certify the above products have been registered to be manufactured and exported in China." Furthermore, brand name is not mentioned on FSC. vii. Provided the Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. viii. The submitted ISO 13485 is un-notarized & expired. Therefore, Provide the Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. Furthermore, provide reference/link of certifying body. ix. Provide notarized ISO 13485, design examination certificate and Full Quality Assurance Certificate. The firm has provided copy of these documents. x. Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. xi. Provided the label (as approved in the country of origin) and its packaging, promotion material and brochure.
177.	M/s K.M Enterprises, K.M Mansion, 605 D, Block MA, Johar Town, Lahore ELI: 00054 Evaluator: [AD-VIII] 2864	Legal Manufacturer: Eurolatex Sdn. Bhd. Plot 33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia **FSC:** Malaysia Valid till: 12.10.2023	KINGSTER (Male Latex Condom) Codes & sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred for the provisions of following deficiencies/ documents:** i. Provide the credentials of manufacturer abroad duly notarized from the country of origin. ii. Provide the DECLARATION (on stamp paper) as per form-7A. iii. Provide the 5 year shelf-life & storage conditions of applied, i.e., justified with stability studies since the provided real time stability studies are of 3 years hence incomplete. iv. Provided the Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. v. It is claimed that applied product is UNFPA/WHO prequalified however the same could not be verified from provided link https://www.unfpa.org/sites/default/files/resource-pdf/Prequalification%20List%20for%20Male%20Condoms_Feb%202022.pdf. vi. The provide DoC classify the applied product class IIb equivalent to Class C, however the

				product is classified as Class D on Application form (form-7A), clarify or submit revised application form. vii. Provide valid Full quality assurance or equivalent, duly notarized by the country of origin since the provided one is expired upon submission (18-02-2021). viii. The provided configurations of the medical devices to be registered are not mentioned on provided Free Sale Certificate, clarification is required. ix. Provided the label (as approved in the country of origin) and its packaging, promotion material and brochure for all the configurations to be registered. x. Provide notarized ISO 13485 and Full Quality Assurance Certificate. The firm has provided copy of these documents.
178.	M/s Optisurg, 17/C-1, Valencia Town, Lahore ELI: 00305 Evaluator: [AD-VIII] 2151	Legal Manufacturer: Medicontur Medical Engineering Ltd, Herceghalmi Road 1, 2071 Zsambek, Hungary FSC: Hungary Date of issue: 24.09.20	Medicontur 677ADY Bi-Flex (Aspheric hydrophilic acrylic IOL with blue light filter for implantation into the capsular bag) odes & Sizes: As per FSC Class- C Shelf Life:5 years	**Deferred for the provisions of following deficiencies/ documents:** i. The firm submitted FSC of Hungary which is not given in Rule 67 of MDR, 2017. Therefore, the firm may be asked for any FSC of any RRA or CE certification or WHO pre-qualification in the light of Rule 71 of rules ibid. ii. The provided photocopy of free sale is not embassy attested. Therefore, provide valid, original Embassy attested copy of free sale certificate by the country of origin. iii. Provide the Original Agency agreement or letter of authorization duly notarized by the country of origin. iv. Provide the **complete** Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin. As the provided one is incomplete. v. The firm submitted Declaration letter stating that *"Medicontur's EC Certificate Full Quality Assurance System conform to Directive 93/42/EEC on Medical Devices, Annex II excluding (4).* *Annex II (4) only applies to Class III medical devices. As sterile intraocular lenses fall into Class IIb in the EU, Annex II (4) is not applicable and therefore it is not required to issue a CE Design Certificate."*
179.	M/s UDL Distribution Pvt Ltd. I-D-13, Sector 30, Korangi Industrial Area Karachi (ELI-00073) Evaluator: [AD-VIII] 4321	**Legal manufacturer:** Arrow International LLC, (Subsidary of Teleflex Incorporated) 3015 Carrington Mill Blvd, Morrisville, NC USA 27560 **Manufacturing Sites:** Arrow International, De Chihuahua S.A. De C.V. Ave. Washinton 3701, Interior Circuito Industrial Alta Technologia, Edificio	**Arrow Single Lumen Infusion Catheter (SLIC®)** **Codes & Sizes:** SS-14701 SC-14701 Class: D Shelf Life: 3 Years	**Deferred for the provisions of following deficiencies/ documents:** i. Provided endorsed challan of fee submission bears the date 03-10-2018 however the R&I date is 15-03-2022, that requires clarification. ii. Registration Application covering letter & Fee challan states that the application & fee is submitted on 03-10-2018 however the applicant has been authorized on October 26, 2021 by M/s Teleflex medical, Ireland (3 years later than fee submission), need clarification. iii. Highlight the applied medical device "Arrow Single Lumen Infusion Catheter" on the provided details of manufacturing and quality control processes. iv. Provide Original LOA as photocopy is attached with application.

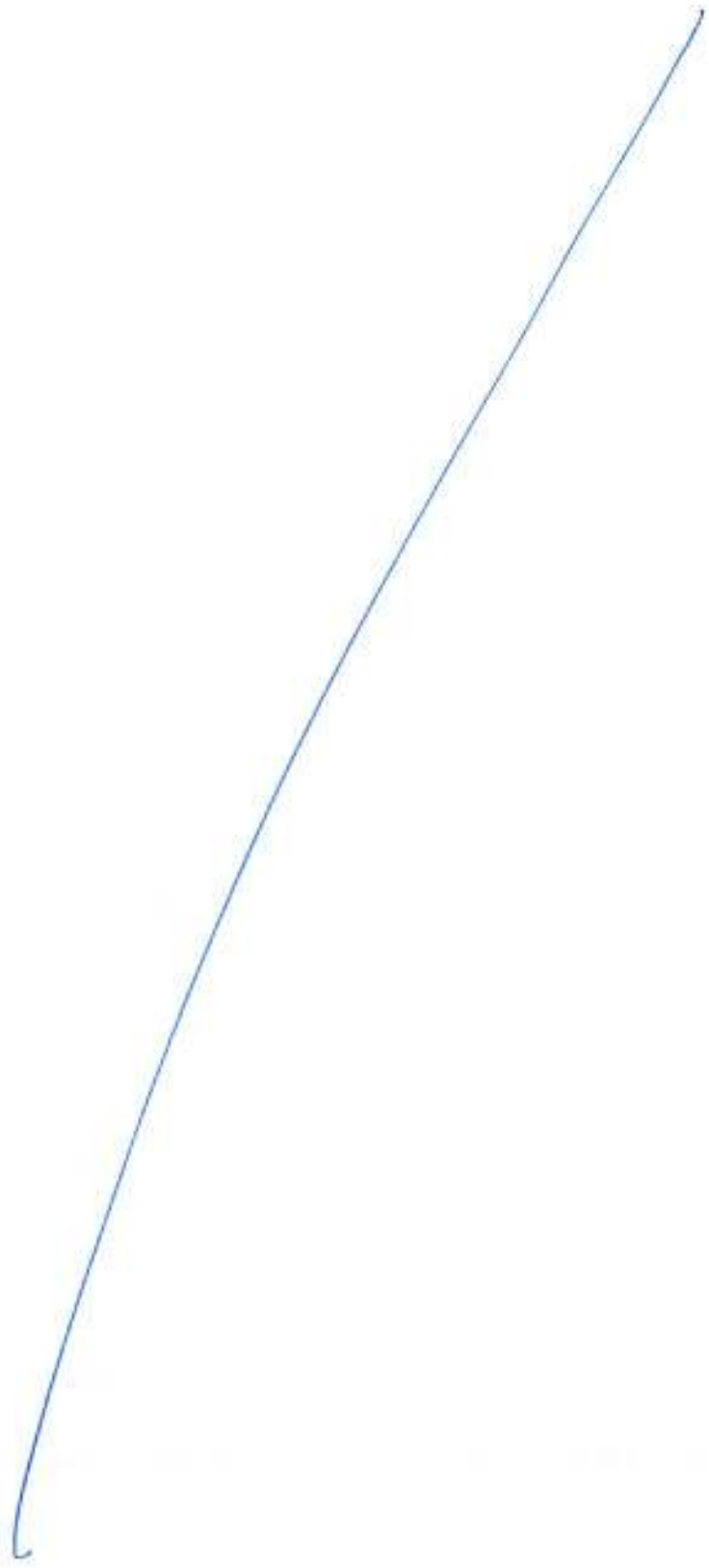
		40 Colonia Chihuahua CP 31200, Mexico. Arrow International C.R. A.S. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic. FSC:USA Valid Till: 25-10-2023		v. Clearly state the difference between Arrow SLIC SS-14701 & Arrow CVC SC-14701 applied as family for registration in Class-D, support the same with documentary evidence like labels, brochures, technical documents etc. vi. Provide the Original free sale certificate. vii. Highlight the relevant scope in ISO 13485:2016 regarding manufacturing of applied product i.e. Arrow Single Lumen Infusion Catheter. Similarly Highlight the product covering applied medical device in Full quality assurance. viii. Provide notarized ISO 13485 and Full Quality Assurance Certificate. The firm has provided copy of these documents. ix. Provide the label (as approved in the country of origin) and its packaging, promotion material and brochure for SC-14701 or clarify. x. Name of manufacturer is "Arrow International, Inc. 2400 Bernville Road, Reading, PA 19605 USA" as per provided label of Arrow SLIC SS-14701. However, FSC, ISO 13485 & Full Quality Assurance mentions "Arrow International LLC, (Subsidiary of Teleflex Incorporated) 3015 Carrington Mill Blvd, Morrisville, NC USA 27560" as legal manufacturer, this require clarification. **Similar is the case with provided DoC.** xi. Provide the Design examination certificate, duly notarized by the country of origin. Firm did not provide the DEC.
180.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2750-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trucryl (Polyglycolic acid absorbable suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 3 years	**Deferred** for the provision of following documents: (i) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (ii) Is the name Trucryl brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trucryl. Provide relevant labels of all the codes required on this application alongwith product brochure (iii) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (iv) 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 (v) Stability studies data provided is only of 82 days for three years shelf life claim. Provide real-time stability studies from manufacturer abroad for the applied product supporting the claimed shelf life of 3 years (vi) Original documents not found in this dossier and reference of their submission is also not provided. Provide original legal documents (vii) Provide Undertaking from the manufacturer abroad that same product with same specifications

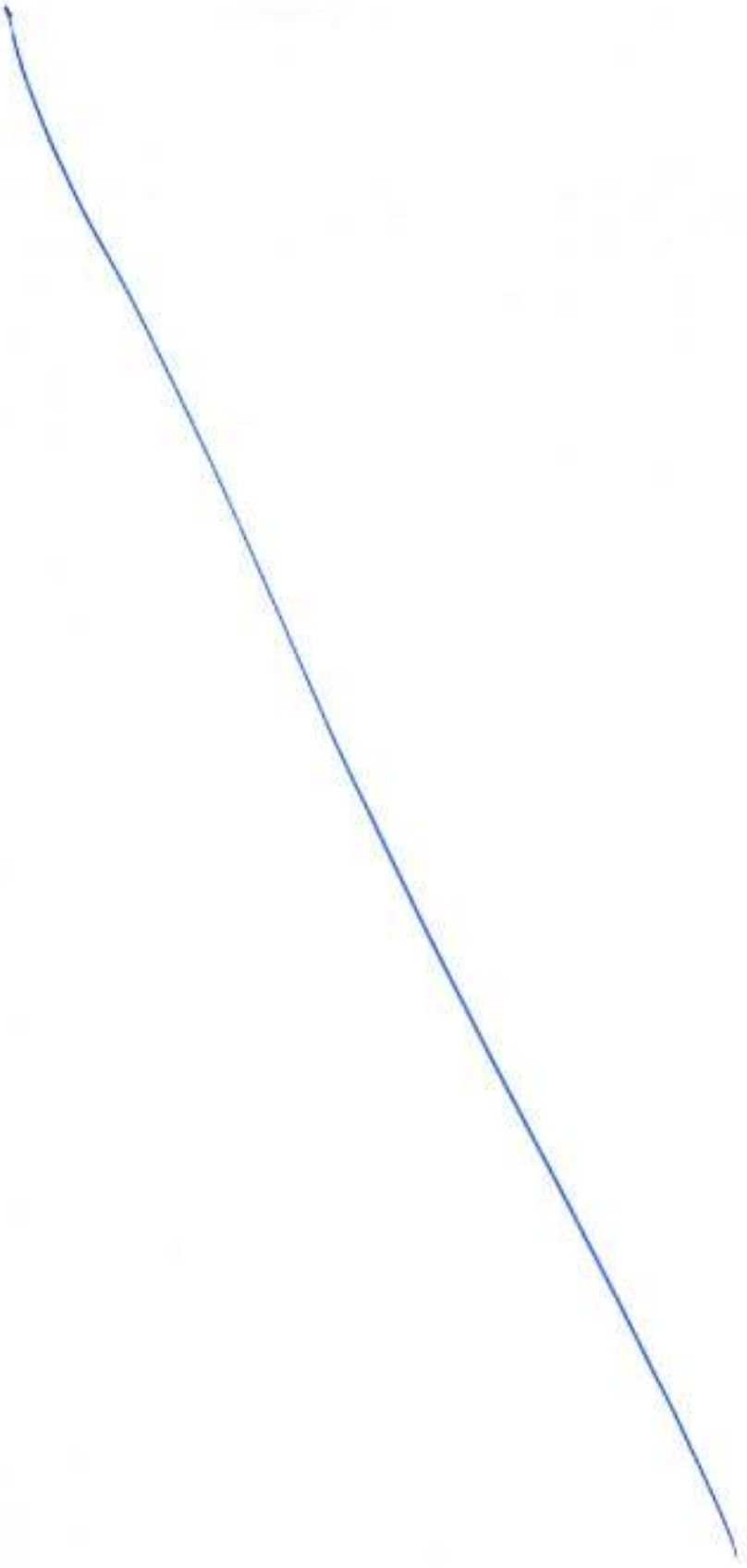
				will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
181.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2751-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Truprone (Poliglecaprone Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 3 years	**Deferred** for the provision of following documents: (i) This product is not mentioned in the Agency agreement between manufacturer and importer. Provide authorization from manufacturer for this product (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) Is the name Trupone brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trupone. Provide relevant labels of all the codes required on this application alongwith product brochure (iv) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (v) 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 (vi) Stability studies data provided is only of 82 days for three years shelf life claim. Provide real-time stability studies from manufacturer abroad for the applied product supporting the claimed shelf life of 3 years (vii) Original documents not found in this dossier and reference of their submission is also not provided. Provide original legal documents (viii) Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel
182.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2748-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Truglactin-910 (Polyglactin 910 Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 3 years	**Deferred** for the provision of following documents: (i) This product is not mentioned in the Agency agreement between manufacturer and importer. Provide authorization from manufacturer for this product (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) Is the name Truglactin-910 brand name made

				for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Truglactin-910. Provide relevant labels of all the codes required on this application along with product brochure (iv) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (v) 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 (vi) Stability studies data provided is only of 82 days for three years shelf life claim. Provide real-time stability studies from manufacturer abroad for the applied product supporting the claimed shelf life of 3 years (vii) Original documents not found in this dossier (viii) Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
183.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2749-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Truxanon (Polydioxanone Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 3 years	**Deferred** for the provision of following documents: (i) This product is not mentioned in the Agency agreement between manufacturer and importer. Provide authorization from manufacturer for this product (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) Is the name Truxanon brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Truxanon. Provide relevant labels of all the codes required on this application alongwith product brochure (iv) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (v) 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 (vi) Stability studies data provided is only of 82 days for three years shelf life claim. Provide real-time stability studies from manufacturer abroad for the applied product supporting the claimed shelf life of 3 years (vii) Original documents not found in this dossier (viii) Provide Undertaking from the manufacturer

				abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
184.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2747-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trucryl Rapid (Polyglycolic Acid Rapid Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 5 years (studies not provided)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it. This shortcoming is also applicable to dossier of Trucryl (Polyglycolic acid Absorbable Suture) (ii) All the legal and technical documents provided in this dossier are of PGA, PDO, PGLA and PGCL sutures and does NOT cover PGA Rapid. (iii) Provide all the technical documents including details of manufacturing, QC, composition, intended use, contraindication, instructions for use (IFU), stability studies supporting claimed shelf life of 5 years, EPSP, sterilization validation report etc. (iv) CE marking documents, Declaration of conformity not provided for this product. Is the product not CE marked? Provide valid, relevant notarized documents and highlight the product in it. In case it is CE marked then alongwith CE mark documents, provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel (v) This product is not mentioned in the Agency agreement between manufacturer and importer. Provide authorization from manufacturer for this product (vi) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (vii) Is the name Trucryl rapid brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trucryl rapid. Provide relevant labels of all the codes required on this application alongwith product brochure (viii) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (ix) 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 (x) Original documents not found in this dossier
185.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13	Manufacaturer: M/s Yancheng Huida	Trugut (Plain) (Catgut Plain Absorbable suture)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it.

	Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2752-P]	Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 5 years (studies not provided)	(ii)	All the legal and most of technical documents provided in this dossier are of PGA, PDO, PGLA and PGCL sutures and does NOT cover Catgut Plain Absorbable suture.
				(iii)	Provide all the technical documents including details of manufacturing, QC, composition, stability studies supporting claimed shelf life of 5 years, EPSP, etc.
				(iv)	Provide list of all materials of animal, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin;
				(v)	Provide detailed information concerning the selection of sources or donors
				(vi)	Provide detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;
				(vii)	Process full description of the system for record keeping allowing traceability from sources to the finished medical device.
				(viii)	Report or certificate containing information on the objectives, methodology, results, discussion and conclusions of the biocompatibility tests conducted on materials used in the medical device
				(ix)	Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical physical tests conducted on the medical device
				(x)	CE marking documents not provided for this product. Is the product not CE marked? Provide valid, relevant notarized documents and highlight the product in it. In case it is CE marked then alongwith CE mark documents, provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel
				(xi)	Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes
				(xii)	Is the name Trugut Plain brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Provide labels of all the codes required on this application alongwith product brochure
				(xiii)	Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017
				(xiv)	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 (xv) Original documents not found in this dossier
186.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2753-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trugut Chromic (Catgut Chromic Absorbable suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 5 years (studies not provided)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it. (ii) All the legal and most of technical documents provided in this dossier are of PGA, PDO, PGLA and PGCL sutures and does NOT cover Catgut Chromic Absorbable suture. (iii) Provide all the technical documents including details of manufacturing, QC, composition, stability studies supporting claimed shelf life of 5 years, EPSP, etc. (iv) Provide list of all materials of animal, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin; (v) Provide detailed information concerning the selection of sources or donors (vi) Provide detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances; (vii) Process full description of the system for record keeping allowing traceability from sources to the finished medical device. (viii) Report or certificate containing information on the objectives, methodology, results, discussion and conclusions of the biocompatibility tests conducted on materials used in the medical device (ix) Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical physical tests conducted on the medical device (x) CE marking documents not provided for this product. Is the product not CE marked? Provide valid, relevant notarized documents and highlight the product in it. In case it is CE marked then alongwith CE mark documents, provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel (xi) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (xii) Is the name Trugut Chromic brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Provide

				labels of all the codes required on this application alongwith product brochure (xiii) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (xiv) 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. (xv) Original documents not found in this dossier.
187.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2754-P]	Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trulon Nylon (Non-Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class C Shelf Life: 5 years (studies not provided)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it. (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) EC Full QA certificate does not specify the name and type of sutures covered by it. Provide valid notarized Full QA certificate covering Nylon sutures (iv) In case product is CE marked then alongwith CE mark documents also provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel (v) ISO13485 does not cover non-absorbable sutures under its scope. Provide valid notarized certificate having non-absorbable sutures under its scope (vi) Declaration of conformity provided states that the declaration is valid in connection with the "final inspection report" of the device. Provide that report (vii) Provide stability studies supporting claimed shelf life of 5 years and Essential principles of safety and performance (EPSP) for nylon sutures (viii) Is the name Trulon brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trulon. Provide relevant labels of all the codes required on this application alongwith product brochure (ix) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (x) 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 (xi) Original documents not found in this dossier and reference of their submission is also not provided. Provide original legal documents

188.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2755-P]	Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trulene Polypropylene (Non-Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class C Shelf Life: 5 years (studies not provided)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it. (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) EC Full QA certificate does not specify the name and type of sutures covered by it. Provide valid notarized Full QA certificate covering Polypropylene sutures (iv) In case product is CE marked then alongwith CE mark documents also provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel (v) ISO13485 does not cover non-absorbable sutures under its scope. Provide valid notarized certificate having non-absorbable sutures under its scope (vi) Declaration of conformity provided states that the declaration is valid in connection with the "final inspection report" of the device. Provide that report (vii) Provide stability studies supporting claimed shelf life of 5 years and Essential principles of safety and performance (EPSP) for nylon sutures (viii) Is the name Trulene brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trulen. Provide relevant labels of all the codes required on this application alongwith product brochure (ix) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (x) 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 (xi) Original documents not found in this dossier and reference of their submission is also not provided. Provide original legal documents
189.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2756-P]	Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trusilk (Silk Braided Non-Absorbable Suture) Codes & Sizes: Not mentioned in FSC Class C Shelf Life: 5 years (studies not provided)	**Deferred** for the provision of following documents: (i) DRAP copy of fee challan is not provided. Provide it. (ii) Free Sale Certificate (FSC) China does not have the name, sizes/codes of the applied product and only general term "surgical needle with suture" is mentioned. Provide original valid Embassy attested FSC issued by Chinese FDA having the name of the applied product along with sizes/specs/codes (iii) EC Full QA certificate does not specify the name and type of sutures covered by it. Provide valid notarized Full QA certificate covering Silk sutures (iv) In case product is CE marked then alongwith CE mark documents also provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel (v) ISO13485 does not cover non-absorbable sutures under its scope. Provide valid notarized certificate

				having non-absorbable sutures under its scope (vi) Declaration of conformity provided states that the declaration is valid in connection with the "final inspection report" of the device. Provide that report (vii) Provide stability studies supporting claimed shelf life of 5 years and Essential principles of safety and performance (EPSP) for nylon sutures (viii) Is the name Trusilk brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Also label does not have the applied name Trusilk. Provide relevant labels of all the codes required on this application alongwith product brochure (ix) Provide original, valid, Embassy attested FSC from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017 (x) 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 (xi) Original documents not found in this dossier and reference of their submission is also not provided. Provide original legal documents.
190.	M/s La-Vie (Pvt) Ltd, Behind PSO Petrol Pump, Peco Road, Kot Lakhpat, Lahore (ELI-00113) Evaluator: AD-IV [2618-P]	Manufacturer: M/s AILEE CO., LTD 28, Gaya-daero 196 beon-gil, Sasang-gu, Busan Korea FSC Korea Date of issue: 08-05-2020	MONOFIT-S (Polyglecaprone suture) Codes: As per FSC Class D Shelf Life: 5 years	**Deferred** for the provision of following documents: (i) The technical details provided are of Surgifit suture and not of applied product i.e MONOFIT-S (Polyglecaprone suture). Provide applied product details (ii) Credentials of manufacturer abroad not provided (iii) MRP not provided (iv) Instructions for use and Essential principles of safety and performance not provided (v) Declaration of conformity is not of applied product. Provide relevant document (vi) CE mark documents not provided. The applied product is Class D medical device and Full QA certificate and Design-Examination is not provided. Provide valid and notarized certificates (vii) Sizes and codes required on this application are not mentioned on Form. Clearly state the sizes and codes required on this application, highlight them on FSC and since registration is applied on basis of CE mark documents so all those codes should be CE marked and highlight on CE marking documents. Provide product brochure and labels of all codes required on this application. (viii) Stability studies supporting claimed shelf life of 5 years not provided (ix) Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
191.	M/s La-Vie (Pvt) Ltd, Behind PSO Petrol Pump, Peco Road, Kot Lakhpat, Lahore (ELI-00113) Evaluator: AD-IV	Manufacturer: M/s AILEE CO., LTD 28, Gaya-daero 196 beon-gil, Sasang-gu, Busan Korea FSC Korea Date of issue: 08-05-2020	AILEE Blue Nylon Suture Polyamide Codes: As per FSC Class D Shelf Life: 5 years	**Deferred** for the provision of following documents: (i) Declaration of conformity provided states that product is class IIa in Europe whereas the class applied on form is class D. Clarification is required from manufacturer abroad that how and under what rule is the product classified as class IIa in Europe? And under what rule of Medical Devices Rules, 2017 is the product classified as class D? Provide relevant documents to support

	[2621-P]			the claim (ii) The technical details provided are of Surgifit suture and not of applied product i.e Blue Nylon Suture Polyamide. Provide applied product details (iii) Credentials of manufacturer abroad not provided (iv) MRP not provided (v) Provide Instructions for use (IFU) clearly stating the intended use of the product and Essential principles of safety and performance (vi) CE mark documents not provided Provide valid and notarized Full QA certificate and Design-Examination having applied product (vii) Sizes and codes required on this application are not mentioned on Form. Clearly state the sizes and codes required on this application, highlight them on FSC and since registration is applied on basis of CE mark documents so all those codes should be CE marked and highlight on CE marking documents. Provide product brochure and labels of all codes required on this application. (viii) Stability studies supporting claimed shelf life of 5 years not provided (ix) Provide Undertaking from the manufacturer abroad that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
192.	M/s La-Vie (Pvt) Ltd, Behind PSO Petrol Pump, Peco Road, Kot Lakhpat, Lahore (ELI-00113) Evaluator: AD-IV [2620-P]	Manufacturer: M/s AILEE CO., LTD 28, Gaya-daero 196 beon-gil, Sasang-gu, Busan Korea FSC Korea Date of issue: 08-05-2020	AILEE Black silk suture Codes: As per FSC Class D Shelf Life: 5 years	**Deferred** for the provision of following documents: (i) Declaration of conformity provided states that product is class IIa in Europe whereas the class applied on form is class D. Clarification is required from manufacturer abroad that how and under what rule is the product classified as class IIa in Europe? And under what rule of Medical Devices Rules, 2017 is the product classified as class D? Provide relevant documents to support the claim (ii) The technical details provided are of Surgifit suture and not of applied product i.e Blue Nylon Suture Polyamide. Provide applied product details (iii) Credentials of manufacturer abroad not provided (iv) MRP not provided (v) Provide Instructions for use (IFU) clearly stating the intended use of the product and Essential principles of safety and performance (vi) CE mark documents not provided. Provide valid and notarized Full QA certificate and Design-Examination having applied product (vii) Sizes and codes required on this application are not mentioned on Form. Clearly state the sizes and codes required on this application, highlight them on FSC and since registration is applied on basis of CE mark documents so all those codes should be CE marked and highlight on CE marking documents. Provide product brochure and labels of all codes required on this application. (viii) Stability studies supporting claimed shelf life of 5 years not provided (ix) Provide Undertaking from the manufacturer abroad that same product with same specifications

				will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
193.	M/s Physiomed (Pvt) Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI-00199 Evaluator AD-IV [2783-P]	Manufacturer: M/s Greatbatch Medical 2300 Berkshire Lane North, Minneapolis, MN 55441 USA FSC USFDA valid till 21-05-2021	Myopore Bipolar Suture less Myocardial Pacing Lead Codes: As per FSC Class D Shelf Life: 36 months	**Deferred** for provision of following documents: 1. Letter of Authorization not provided 2. Provide valid FSC, ISO13485 3. MRP not provided
194.	M/s Physiomed (Pvt) Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI-00199 Evaluator AD-IV [2782-P]	Manufacturer: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA Manufacturing Site: St. Jude Medical, Costa Rica Ltda. Edificio # 44, Calle 0, Avenida 2, Zona Franca Coyol, El Coyol, Alajuela, Costa Rica FSC not provided	TactiCath Contact Force Ablation Catheter, Sensor Enabled (Cardiac radio-frequency ablation system catheter) Codes & Sizes: As per FSC Class D Shelf Life: 18 months	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its manufacturing site, sizes/codes for all the applied products of this manufacturer. 2. Letter of Authorization 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 sole/exclusive authorization is given to importer 3. ISO expired now. Provide valid certificate 4. Full QA not provided. Provide valid and notarized certificate 5. Design Examination is not notarized. Provide notarized certificate 6. MRP not provided.
195.	M/s Physiomed Pvt Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI: 00199 Evaluator: [AD-VIII] 2812-P	Legal Manufacturer: M/s St. Jude Medical 14901 DeVeau Place. Minetonka, Mn 55345, USA **Sterilization Site (Contract):** Steris Isomedix 380 90th Ave,NW, USA. Sterigenics: 57725 Harold Gatty Dr. Salt Lake City, USA. Midwest Sterilization Corporation 1204 Lenco Ave. Jackson, MO 63755 USA. FSC: USA Valid till: 18.02.2023	**Response Electrophysiology Catheter with Lumen** Codes & Sizes: 401132; 401130; 401133; 401134; 401142; 401144; D401147; 401137 Class-D Shelf Life: As per stability study	**Deferred for the provisions of following deficiencies/ documents:** i. Since many fields are left blank in application form, therefore provide revised form-7A completely filled with relevant information. ii. Provide Original and valid FSC. The firm provided photocopy having validity till 18.02.2023 (Valid upon submission). iii. Provide label (as approved in the country of origin) for all the codes & sized applied on form-7A. the firm provided labels for **401130 & 401144.** iv. Provide valid ISO 13485 certificates of all manufacturing sites involved in design, manufacturing, sterilization etc. of applied product. v. Provide Stability studies Reports showing conclusive results to justify the proposed shelf life. vi. Provide Essential Requirement for safety and performance. vii. Provide the details of manufacturing and quality control processes. viii. Provide Original, valid LOA notarized by the country of origin.

196.	M /s Physiomed Pvt Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI: 00199 2762 **Evaluator:** AD-II	**Legal Manufacturer:** Lake Region Medical Ltd Butlersland , New Ross, Co. Wexford International Ireland **Manufacturing Site:** Abbott Medical 5050 Nathan Lane North, Plymouth, Minnesota 55442, USA **Contract Sterilizer:** Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore, CO. Offlay, Ireland **Original FSC: Ireland** Valid Till: 27.05.2025	GuideRight Guidewire Codes & Sizes: As per FSC Class-D Shelf Life: As per stability study.	**Deferred** for provision of following documents :- • Form-7A completely filled and duly signed. • Copy of valid establishment license. • Name & particulars of responsible persons. • Credentials of manufacturer abroad duly notarized from the country of origin. • HS code/ GMDN code. • Shelf-life & storage conditions, i.e., justified with stability studies: • Proposed MRP of medical device • 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: • Grouping of medical devices • List of MD, constituents-components that are grouped together: • Description of accessories, other medical devices or products that are not MD, are intended to be used in combination with: • Complete list of various configurations to be registered; • Complete description with intended use, Key functional elements, formulation & composition with functionality. • DECLARATION (on stamp paper) as per Form-7A.
197.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3264]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL Guiding Catheter Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC for the applied product. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and from which the guiding catheter of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site of the product. 2. Accelerated studies provided are of only 127 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product. 3. Original documents i.e Letter of Authorization, ISO, Full QA, credentials original notarization certificates are not found in this dosser. Provide them.
198.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3269]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL Peripheral Guidewire Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Classification not clear. The intended use of product states it is for peripheral use whereas the EU DOC states it is class III medical device and applied as class D on Form. Explanation is required for manufacturer abroad as to how and for which indication (with supporting evidence) it is classified as class D medical device and also provide relevant rule provision of Schedule A of Medical Devices Rules 2017 2. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC for the applied product. Also on Form the manufacturing site mentioned is China and label states Made in Germany. The label also states the name to be

				Advancer peripheral guidewire whereas the word "advancer" is not found in any other document. Provide relevant labels of all codes required on this application. Clarify the manufacturing site of this product. Is it made in China or Germany and the Peripheral Guidewire of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site of the product 3. Accelerated studies provided are of only 137 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product 4. Original documents i.e Letter of Authorization, ISO, Full QA, credentials original notarization certificates are not found in this dosser. Provide them.
199.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3270]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL PTFE Coated Guidewire Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Classification not clear. The intended use of product states it is for peripheral use whereas the EU DOC states it is class III medical device and applied as class D on Form. Explanation is required for manufacturer abroad as to how and for which indication (with supporting evidence) it is classified as class D medical device and also provide relevant rule provision of Schedule A of Medical Devices Rules 2017 2. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC for the applied product. Also on Form the manufacturing site mentioned is China and label states Made in Germany. The label also states the name to be Advancer peripheral guidewire whereas the word "advancer" is not found in any other document. Provide relevant labels of all codes required on this application. Clarify the manufacturing site of this product. Is it made in China or Germany and the Peripheral Guidewire of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site of the product 3. Accelerated studies provided are of only 137 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product 4. Original documents i.e Letter of Authorization, ISO, Full QA, credentials original notarization certificates are not found in this dosser. Provide them.
200.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3123]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL Angiographic Catheter Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its sizes/codes for all the applied products of this manufacturer. Also on Form, the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the Angiographic Catheter of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site of the product.

201.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3124]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL PTCA Guidewire Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC for the applied product. Also on Form the manufacturing site mentioned is China and label states Made in Germany. The label also states the name to be Origin PTCA guidewire whereas the word "origin" is not found in any other document. Provide relevant labels of all codes required on this application. Clarify the manufacturing site of this product. Is it made in China or Germany and the PTCA Guidewire of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site, sizes/codes of the product 2. Accelerated studies provided are of only 137 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product.
202.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3263]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL Introducer Set Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Classification not clear. EU DOC states it is class III medical device and applied as class D on Form. Explanation is required for manufacturer abroad as to how and for which indication (with supporting evidence) it is classified as class D medical device and also provide relevant rule provision of Schedule A of Medical Devices Rules 2017 2. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its sizes/codes for all the applied products of this manufacturer. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the Introducer Set of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site, sizes/code of the product 3. Accelerated studies provided are of only 28 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product.
203.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3262]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL PTCA Balloon Dilatation Catheter Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its sizes/codes for all the applied products of this manufacturer. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the PTCA Balloon Dilatation Catheter of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site, sizes/code of the product 2. Attached stability document is protocol and not test report. Provide complete real-time stability studies clearly supporting claimed shelf life of 3 years for this product.
204.	M/s Melamine Emporium 814, Star City Mall,	Manufacturer: SWL Medizin GmbH Havelstr.16 64295	SWL Microcatheter	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including

	Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3267]	Darmstadt Germany FSC not provided	Codes and Sizes: FSC not provided Class D Shelf life: 3 years	its types, sizes/codes for all the applied products of this manufacturer. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the Microcatheter of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site, types, sizes/code of the product. The label also states the name to be Pioneer Microcatheter whereas the word "pioneer" is not found in any other document. Provide relevant labels of all codes required on this application. 3. Clarify the product required on this application is peripheral microcatheter or coronary microcatheter or neural microcatheter? 2. Accelerated studies provided are of only 137 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product 3. Declaration of conformity, Full QA, Design-Examination for all applied products namely Microcatheter, PTCA Balloon Dilatation Catheter, Introducer Set, PTCA Guidewire, Angiographic Catheter, PTFE Coated Guidewire, Peripheral Guidewire, Guiding Catheter do not have sizes/codes in it. Justify and provide evidence for all products that which sizes and codes are CE marked?
205.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3266]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL Hydrophilic Coated Guidewire Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its types, sizes/codes for all the applied products of this manufacturer. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the Hydrophilic Coated Guidewire of which site will be supplied to Pakistan? The above mentioned FSC should include the manufacturing site, types, sizes/code of the product. 2. Accelerated studies provided are of only 137 days. Provide real-time stability studies clearly supporting claimed shelf life of 3 years for this product 3. Declaration of conformity, Full QA, Design-Examination for Hydrophilic Coated Guidewire do not have sizes/codes in it. Justify and provide evidence that which sizes and codes are CE marked?
206.	M/s Melamine Emporium 814, Star City Mall, Saddar Karachi (ELI-00414) **Evaluator:** AD-IV [3265]	Manufacturer: SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany FSC not provided	SWL NC Coronary Dilatation Catheter Codes and Sizes: FSC not provided Class D Shelf life: 3 years	**Deferred** for provision of following documents: 1. Free Sale Certificate (FSC) is not provided. Provide original valid and Embassy attested FSC including its sizes/codes for all the applied products of this manufacturer. Also on Form the manufacturing site mentioned is China and label states Made in Germany. Clarify the manufacturing site of this product. Is it made in China or Germany and the NC Coronary Dilatation Catheter of which site will be supplied to Pakistan? The above mentioned FSC

				should include the manufacturing site, sizes/code of the product 2. Attached stability document is protocol and not test report. Provide complete real-time stability studies clearly supporting claimed shelf life of 3 years for this product 3. Declaration of conformity, Full QA, Design-Examination for NC Coronary Dilatation Catheter do not have sizes/codes in it. Justify and provide evidence that which sizes and codes are CE marked? 4. Design-Examination not notarized. Provide notarized certificate.
207.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator:** AD-IV [107(Renewal)]	**Manufacturer:** B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany FSC Germany issued on 15-3-2021	Certofix Trio (Triple-Lumen Central Venous Catheter) Codes: As per FSC Class D Shelf life 5 years	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Valid ISO13485, Design Examination certificate and labels
208.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator:** AD-IV [108(Renewal)]	**Manufacturer:** B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany FSC Germany issued on 18-5-2021	Intrafix Primeline IV administration sets with air vent for pressure and gravity infusions Codes: As per FSC Class D Shelf life: 5 years	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Manufacturing site not clear. The codes applied have different manufacturing sites i.e some codes are manufactured in Germany, some in Vietnam, one in Hungary etc whereas on Free Sale Certificate the production facility mentioned is Germany only. Clarify this ambiguity and clearly state the manufacturing sites of each code applied, provide label of each code and state from which site the codes will be supplied to Pakistan? and accordingly provide the relevant valid, original, Embassy attested Free Sale Certificate (FSC) is not provided. 3. Difference amongst the codes applied is not clear. Explain and also provide pictures of these codes to clarify the difference 4. ISO expired now. Provide valid certificate.
209.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator:** AD-IV [106(Renewal)]	Manufacturer: B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany FSC Germany issued on 15-3-2021	Certofix Trio Peads (Triple-Lumen Central Venous Catheter for pediatrics) Codes: As per FSC Class D Shelf life 5 years	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Valid ISO13485, Design Examination certificate and labels.
210.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9,	Manufacturer: B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany	Certofix Mono (Single-Lumen Central Venous Catheter) Codes: As per FSC	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Valid ISO13485, Design Examination certificate and labels.

	Clifton, Karachi (ELI-00006) **Evaluator:** AD-IV [105(Renewal)]	FSC Germany issued on 15-3-2021	Class D Shelf life 5 years	
211.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator:** AD-IV [104(Renewal)]	Manufacturer: B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany FSC Germany issued on 15-3-2021	Certofix Duo (Double-Lumen Central Venous Catheter) Codes: As per FSC Class D Shelf life 5 years	**Deferred** for provision of following: 1. Differential fee of Rs. 25,000 to be submitted as the product will be considered as new application 2. Valid ISO13485, Design Examination certificate and labels.
212.	B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) Evaluator: [AD-VIII] 4320	B.Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany **Manufacturing site:** M/s B.Braun Melsungen AG Vascular Systems Sieversufer 8 12359 berlin Germany. FSC: Germany Issued: 18-10-2016	**SeQuent Please Neo PTCA Catheter (Coated with Paclitexal) Class-D Shelf life: 2 Year**	**Deferred for the provisions of following deficiencies/ documents:** i. Provide the Original Agency agreement or letter of authorization regarding applied product or category of medical device(s) mentioning the validity of agreement, duly notarized by the country of origin. Provided one is for "SeQuent Neo". ii. The provided photocopy of FSC in the country of origin/RRA is expired upon submission therefore provide Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. iii. Clarify that provided document including "ISO 13485, Full Quality Assurance, Design Examination" the scope is to design, manufacture PTCA Catheter rather than "Drug Coated PTCA Catheters" as mentioned on Form-7A. iv. Provide notarized documents, as the provided documents are not notarized like Credentials, LOA, ISO 13485, Full Quality Assurance, Design Examination. v. Provide role of "Aesculap AG AM Aesculap-Platz, 78532 Melsungen Germany" or "B.Braun Melsungen AG, D-34209 Melsungen Germany" as the same is not given on FSC but mentioned on label, promotion material and brochure. vi. Provide labels as approved in country of origin for all codes and sizes as per FSC. vii. Provide stability studies covering all sizes to justify the shelf life of applied product having special focus on Paclitaxel release. viii. Clarify the status of "M/s B.Braun Melsungen AG Vascular Systems Sieversufer 8 12359 berlin Germany" as manufacturer as per FSC or distributor as per promotion material/label.
213.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (Ext). Opposite National Stadium, Karachi (ELI-00029)	Manufacturer: Elekta Instrument AB, Kungstensgatan 18 P.O.Box 7593 SE-103 93, Stockholm, Sweden	Elekta Disposable Biopsy Needle Kit for Leksell Stereotactic System Code: 911933 Class D	**Deferred** for provision of following documents: 1. Multiple products applied on one application. The name Disposable Biopsy Needle Kit for Leksell Stereotactic System (911933) will be considered on this application. Submit separate application for other types

	Evaluator: AD-IV [3374]	FSC Sweden valid till 26-5-2024	Shelf life: 2 years (studies not provided)	2. Stability studies for Disposable Biopsy Needle Kit not provided. Provide shelf life studies supporting claimed shelf life of 2 years 3. Letter of Authorization and ISO 13485 expired now. Provide valid certificate 4. Provide MRP for Disposable Biopsy Needle Kit.
214.	M/s Kokab Enterprises No. G-56, Billys Shoppers Galleria, Gulistan-e-jauhar, Block 18, Karachi (ELI-00544) **Evaluator:** AD-IV [3599]	**Manufacturer:** Preservation Solutions Inc. 1099 Proctor Drive, Elkhorn, WI 53121 USA	Belzer UW Cold Storage Solution Class D Shelf life 24 months	**Deferred** as Product is already registered in name of M/s. Healthline Pharmaceutical Pvt Ltd. Office No.402, Al-Hafeez Heights, Gulberg-3, Lahore. Reg No. MDIR-0000606.
215.	M/s Amin Agencies CB-6349/B, Amar Pak Plaza, Jhelum Road, Rawalpindi. ELI-00610 **Evaluator:** AD-IV [1646-P]	Legal Manufacturer: ACCURA MEDIZINTECHNIK GMBH Max-Planck-str.33 61184 Karben, Germany FSC Germany issued on 13.08.2019	Introducer Set (femoral and radial) Codes: as per FSC Class-B Shelf Life: 5 years	**Deferred** for provision of following documents: 1. The product applied is not clear. On cover letter it is mentioned transradial introducer set whereas on form the name mentioned is Introducer Set (femoral and radial). Clearly state the name of the product required on this application, its brand name, its sizes/codes required on this application which should also be mentioned on Free Sale Certificate(FSC) and highlight the product codes on FSC and DOC. Also provide pictures of actual product labels of all the codes required on this application and clearly state the difference amongst these codes. Provide supporting evidence and product brochure 2. Manufacturing site not clear. On Form-7A SCW, China is mentioned. What is the link of SCW china with Accura Gmbh Germany? What is the manufacturing site of the applied product? And from which site the applied product will be supplied to Pakistan? And this manufacturing site should be mentioned on FSC. The relevant FSC should be original, valid and Embassy attested 3. Stability studies supporting the claimed shelf life of 5 years is not provided. Provide it 4. Provide details of product, its manufacturing and QC tests performed on the product
216.	M/s Amin Agencies CB-6349/B, Amar Pak Plaza, Jhelum Road, Rawalpindi. ELI-00610 **Evaluator:** AD-IV [1643-P]	Legal Manufacturer: ACCURA MEDIZINTECHNIK GMBH Max-Planck-str.33 61184 Karben, Germany FSC Germany issued on 13.08.2019	Balloon In-Deflation Device Class B Shelf life: not provided Codes: as per FSC	**Deferred** for provision of following documents: 1. Multiple products applied on this application. The product namely Balloon In-Deflation device will be considered on this application. Submit separate application for Push Click Y Connector 2. Clearly state the brand name and sizes/codes of Balloon In-Deflation device required on this application, these codes should also be mentioned on Free Sale Certificate (FSC). Also explain the difference between the two codes of Balloon In-Deflation device mentioned on FSC and provide pictures and labels of both codes 3. Manufacturing site not clear. On Form-7A Demax Beijing, China is mentioned. What is the link of Demax Beijing, China with Accura Gmbh Germany? What is the manufacturing site of the applied product? And from which site the applied product will be supplied to Pakistan? And this

				manufacturing site should be mentioned on FSC. The relevant FSC should be original, valid and Embassy attested 4. Stability studies supporting the claimed shelf life of 5 years is not provided. Provide it 5. Provide details of product, its manufacturing and QC tests performed on the product 6. Declaration of conformity (DOC) is incomplete. Provide complete document 7. Notarized ISO provided was expired even upon submission and the valid one is not notarized. Provide valid and notarized ISO13485 certificate.
217.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077) Evaluator: AD-IV [4317]	Manufacturer: Phenox GmbH, Lise-Meitner Allee 31, D-44801 Bochum Germany FSC Germany issued on 30-8-2021	Portal Steerable Hydrophillic Guidewire Class D Shelf life: not mentioned Codes: as per FSC	**Deferred** for provision of following documents: 1. Copy of Establishment License to import medical devices is not attached in dossier. Provide it 2. 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 3. Details of manufacturing and QC not provided 4. Shelf life not mentioned on Form and stability studies not provided. Clearly state the shelf life and provide stability studies supporting claimed shelf life 5. Letter of Authorization is not original. Provide original notarized letter 6. Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation 7. Sizes/codes of applied product not mentioned on Form. Clearly state the codes required on this application, these codes should also be mentioned on Free Sale Certificate (FSC) and also provide labels of all codes 8. 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 9. ISO, Full QA and Design-Examination certificates not notarized. Provide notarized certificates 10. Provide Essential Principles of safety and performance for the applied product.
218.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077) Evaluator: AD-IV [4318]	Manufacturer: Phenox GmbH, Lise-Meitner Allee 31, D-44801 Bochum Germany FSC Germany issued on 30-8-2021	pCONUS-Birfurcation Aneurysm Implant Class D Shelf life: not mentioned Codes: as per FSC	**Deferred** for provision of following documents: 1. Copy of Establishment License to import medical devices is not attached in dossier. Provide it 2. 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 3. Details of manufacturing and QC not provided 4. Shelf life not mentioned on Form and stability studies not provided. Clearly state the shelf life and provide stability studies supporting claimed shelf life 5. Letter of Authorization is not original. Provide original notarized letter 6. Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation 7. Sizes/codes of applied product not mentioned on Form. Clearly state the codes required on this application, these codes should also be mentioned

				on Free Sale Certificate (FSC) and also provide labels of all codes 8. 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 9. ISO, Full QA and Design-Examination certificates not notarized. Provide notarized certificates 10. Provide Essential Principles of safety and performance for the applied product 11. Declaration of Conformity of applied product not provide. Provide it.
219.	M/s Life Cares M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077) Evaluator: AD-IV [4319]	Manufacturer: Not clear FSC not provided	Avenir Coil System Class D Shelf life: not mentioned Codes: not provided	**Deferred** for provision of following documents: 1. Manufacturer not clear. On Form Phenox GmbH, Lise-Meitner Allee 31, D-44801 Bochum Germany is mentioned whereas on Declaration of Conformity and Design-Examination Certificate it is mentioned Wallaby Medical, Inc. Who is the manufacturer of the product? What is the manufacturing site of the product? Provide documents from relevant manufacturer 2. Copy of Establishment License to import medical devices is not attached in dossier. Provide it 2. 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 3. Details of manufacturing and QC not provided 4. Shelf life not mentioned on Form and stability studies not provided. Clearly state the shelf life and provide stability studies supporting claimed shelf life 5. Letter of Authorization 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 sole/exclusive authorization is given to importer 6. Free Sale Certificate not provided. Provide valid, original document with Embassy attestation having the applied product along with codes 7. Sizes/codes of applied product not mentioned on Form. Clearly state the codes required on this application, these codes should also be mentioned on Free Sale Certificate (FSC) and also provide labels of all codes 8. 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 9. Provide relevant, valid and notarized ISO, Full QA and Design-Examination certificates for the applied product 10. Provide Essential Principles of safety and performance for the applied product 11. Declaration of Conformity of applied product not provide. Provide it.
220.	M/s Life Cares, M-20, Mezzanine Floor Falaknaz Plaza	**Legal Manufacturer:** Rontis Coorporation S.A. Bahnhofstrasse 7,	InRo Semi-Compliant Coronary Balloon Catheter Balloon Catheter	**Deferred** for provision of following documents:-

	Natha Khan Bridge, Shahra-e-Faisal, Karachi. (ELI-00077) 4316 **Evaluator** AD-III	CH 6300, Zug, Switzerland. **Manufacturing site:** Rontis Hellas S.A., Industrial Area of Larisa, 45100 Larisa, Greece. FSC: Switzerland Valid Till: 27-8-2024	Class-D Shelf life: 4 years Codes as per FSC	• Embassy attested and notarized all legal documents. • MRP of the device. • Full Quality Assurance Certificate duly notarized.
221.	M/s Interex Company 195, 2nd floor, KMCHS, Near Hill Park Karachi (ELI-00249) Evaluator: AD-IV [4314]	Manufacturer: MicroPort CRM S.r.l Via Crescentino s.n. 13040 Saluggia (VC) Italy FSC France issued on 28-10-2020	KORA 250 SR Pacemaker (MR Conditional) Class D Code: TPM013C Shelf life: 24 months	**Deferred** for provision of following documents: 1. Manufacturer and manufacturing site not clear. On Form, MicroPort CRM S.r.l Via Crescentino s.n.13040 Saluggia (VC) Italy is mentioned whereas on Free Sale Certificate, production site mentioned is France and label states *made in France*. Clarification is required from manufacturer abroad to address this ambiguity that who is the legal manufacturer of the product? And what is the manufacturing site of the product. 2. DRAP copy of fee challan is not provided, only scan is attached. Provide it 3. 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 4. Letter of Authorization is not original. Provide original notarized letter 5. Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation 6. ISO, Full QA and Design-Examination certificates not notarized. Provide notarized certificates 7. Declaration of Conformity of KORA 250 SR Pacemaker not provided. Provide it.
222.	M/s Interex Company 195, 2nd floor, KMCHS, Near Hill Park Karachi (ELI-00249) Evaluator: AD-IV [4313]	Manufacturer: MicroPort CRM S.r.l Via Crescentino s.n. 13040 Saluggia (VC) Italy FSC France issued on 28-10-2020	KORA 250 DR Pacemaker (MR Conditional) Class D Code: TPM010C Shelf life: 24 months	**Deferred** for provision of following documents: 1. Manufacturer and manufacturing site not clear. On Form, MicroPort CRM S.r.l Via Crescentino s.n.13040 Saluggia (VC) Italy is mentioned whereas on Free Sale Certificate, production site mentioned is France and label states *made in France*. Clarification is required from manufacturer abroad to address this ambiguity that who is the legal manufacturer of the product? And what is the manufacturing site of the product 2. DRAP copy of fee challan is not provided, only scan is attached. Provide it 3. 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 4. Letter of Authorization is not original. Provide original notarized letter 5. Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation 6. ISO, Full QA and Design-Examination certificates not notarized. Provide notarized certificates 7. Declaration of Conformity of KORA 250 DR Pacemaker and the relevant Full QA certificate with scope of pacemakers not provided. Provide it.

223.	M/s Interex Company 195, 2nd floor, KMCHS, Near Hill Park Karachi (ELI-00249) Evaluator: AD-IV [4313]	Manufacturer: MicroPort CRM S.r.l Via Crescentino s.n. 13040 Saluggia (VC) Italy FSC France issued on 28-10-2020	KORA 250 DR Pacemaker (MR Conditional) Class D Code: TPM010C Shelf life: 24 months	**Deferred** for provision of following documents: 1. Manufacturer and manufacturing site not clear. On Form, MicroPort CRM S.r.l Via Crescentino s.n.13040 Saluggia (VC) Italy is mentioned whereas on Free Sale Certificate, production site mentioned is France and label states *made in France*. Clarification is required from manufacturer abroad to address this ambiguity that who is the legal manufacturer of the product? And what is the manufacturing site of the product 2. DRAP copy of fee challan is not provided, only scan is attached. Provide it 3. 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 4. Letter of Authorization is not original. Provide original notarized letter 5. Free Sale Certificate is copy and not Embassy attested. Provide original document with Embassy attestation 6. ISO, Full QA and Design-Examination certificates not notarized. Provide notarized certificates 7. Declaration of Conformity of KORA 250 DR Pacemaker and the relevant Full QA certificate with scope of pacemakers not provided. Provide it.
224.	M/s MH Pharma, Flat No. 1118, 11th Floor, Eden Heights, 6-Main Gulberg, Jail Road, Lahore ELI-00720 Evaluator: AD-IV [2855-P]	Legal Manufacturer: M/s SMB Corporation of India, 13, 33-36, Prem Industrial Estate Subhash Road, Jogeshwari (E) Mumbai 400 060 India. Manufacturing sites: M/s SMB Corporation of India, 13, 33-36, Prem Industrial Estate Subhash Road, Jogeshwari (E) Mumbai 400 060 India. Plot No. 156, GIDC, Umbergaon, Dist: Valsad, Gujarat, India, 396170 FSC India date of Issue: 05.01.2021	SMB IUCD (IUCD Cooper-T) Codes & Sizes: As per FSC Class D Shelf Life: 7 years	**Deferred.** The Board referred the case to Authority for directions regarding registration of medical devices from India The Board also observed the following shortcomings in the case: 1. Name not clear. Applied name is IUCD. Which type of IUCD is required on this application? Highlight the product on Free Sale Certificate (FSC). Full QA certificate and Design Examination certificate and the brand name applied SMB should be present in these CE marking documents for the device to be considered as CE marked. The provided Design Examination Certificate do not have the brand name SMB 2. Credentials of manufacturer abroad not provided 3. Details of manufacturing and QC not provided 4. MRP for Pakistan not provided 5. Letter of Authorization is not original and not notarized 6. FSC is copy and not Embassy attested 6. ISO13485 now expired and not notarized 7. Full QA certificate not provided 8. Reference country FSC not provided 9. WHO prequalification document/certificate/report not provided 10. Sterilization validation report of the applied product not provided 11. Undertaking on stamp paper not provided.
225.	DKT Pakistan (Pvt) Ltd, RJ Building, 4th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area,	Manufacturer: Pregna International Ltd. Plot No. 219, Survey # 168, Dabhel Industrial Co-operative Soc. Ltd.	Heer IUCD TCu 380A Plus (Copper T 380 A) Class D Shelf Life: 7 years	**Deferred.** The Board referred the case to Authority for directions regarding registration of medical devices from India

	Phase V. DHA Karachi (ELI-00515) Evaluator: AD-IV [4300]	Dabhel Damam (U.T) India 396210 FSC India date of Issue: 09-9-2020		The Board also observed the following shortcomings in the case: 1.Stability studies supporting claimed shelf life of 7 years not provided 2. MRP not provided 3. FSC is copy and not Embassy attested 4. ISO13485 expired upon submission 5. WHO prequalification document/certificate/report not provided 6. Sterilization validation report of the applied product not provided 7. Undertaking on stamp paper not provided.
226.	M/s FM Health Care, 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road, Karachi (ELI-00082) Evaluator: AD-IV [2013]	**Manufacturer:** M/s Well Lead Medical Co., Ltd., C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, PR China FSC China valid till 09-02-2020	Well Lead Heat and Moisture Exchange Filter Codes: As per FSC Class B Shelf Life: 5 years	**Deferred** for provision of reference country Free Sale Certificate or CE mark documents as well valid FSC from China.
227.	M/s National Enterprises, Office No.409, 4th Floor, Al-Sehat Center, Annexe Regent Plaza, Shahra-e-Faisal, Karachi, Pakistan (ELI-00043) **Evaluator** AD-VII	Wellong Instruments Co. Ltd. 2F , 63 Linsen North Road Taipei, **Taiwan R.O.C**	BMI Peritoneal Catheter (Low, Medium, High, W/O Pressure) CLASS D	**Deferred since the product is from Taiwan and** has not provided the following documents. I. Copy of Free sale provided reveals that it has been issued by Ministry of Health and Welfare, Republic of China (Taiwan).Need clarification. Furthermore, a valid, original and embassy attested Free sale in the country of origin shall be submitted for the said product. Brand name written on Form-7 A is BMI Peritoneal Catheter. However, on the copy of Free Sale Certificate brand name BMI Shunting System is mentioned. This need Clarification. II. In Stability studies conducted by third party and given for shunting system and Catheter given, need clarification. III. Provide original Agency agreement from Market authorization Holder duly notarized from the country of origin. IV. Provide valid notarized, QMS 13485 certificate, Full Quality Assurance and EC Design Examination Certificate from CAB present in Nando data base. V. DOC and Essential principle for safety and performance not provide. VI. The firm has submitted 25000/ fee and has written that it is a class D medical device. Therefore need to submit differential fee. VII.
228.	M/s Medimen (Pakistan), House # 199, Phase-2, GECHS, Link Road Model Town Lahore, Pakistan. **Evaluator** AD-VII	Ackermann Instrumente GmbH Eisenbahnstrasse 65-67, 78604, Ritheim-Weilheim, Germany	Ackermann Europclip Class D	Deferred for provison of :- I. valid, original and embassy attested Free sale in the country of origin. II. Provide Stability studies reflecting claimed shelf life (for Accelerated and Real time) III. Provide valid and original Agency agreement from Market authorization Holder duly notarized from the country of origin.

				IV. Provide valid notarized, QMS 13485 certificate, Full Quality Assurance and EC Design Examination Certificate from CAB present in Nando data base. V. DOC and Essential principle for safety and performance not provide VI. The firm has submitted 25000/ fee and has written that it is a class D medical device. Therefore, need to submit differential feeof RS 25000/-or clarify
229.	M/s Anwar & Sons, Apartment-10, Safari Viollas-2 Commercial Complex, Bahria Town, Phase-7, Rawalpindi ELI: 00017 **Evaluator** AD-VII	Legal Manufacturer: M/s SMI AG located at Steinerberg 8. 4780-St. Vith Belgium Original FSC: Belgium Date of Issue: 25.11.2021	CatGutChrom Codes & Sizes: As per FSC Class-D Shelf Life: 5 years	**Deferred** for provision of :- I. Original, valid and embassy attested FSC,duly issued by the regulatory authority of the country of origin. since the FSC provided is issued by the Chamber of Commerce. II. The Medical device as per DOC falls in class D. However, the firm has submitted fee of Rs 25000/-. Therefore, a differential fee of Rs 25000/- shall be submitted. III. Provide notarized design examination certificate and Full Quality Assurance Certificate. IV. Provide Notarized Declaration of conformity (DOC) and credential, the firm has provided photocopy of these documents. V. The brand name on the Form-7A is written as catgut Chromic, However on FSC and other documents Catgut chrom is written. Clarify.
230.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Diagnostic Kit For Hepatitis B Virus Surface Antigen (ELISA) CAT. NO. ITP21001 96 Tests/Kit Class D Shelf life 12 months FSC: China Valid Till: 25-10-2022	**Deferred** for provision of the following documents:- i. The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory Authority or notarized Evidence of the CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. ii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC). The firm has provided photocopy of these documents.
231.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi. **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advance Quality One Step Malaria (p.f / p.v) Tri-Line Test CAT. NO. ITP11003, 25 Tests/Kit & 40 Tests/Kit" Class to be confirmed Shelf Life 24 months Class to be cinfirned FSC: China Valid Till: 2-7-2021	**Deferred** for provision of the following documents:- i. Provide Valid, originaland embassy attested Free Sale Certificate in The Country of Origin. Since the provided FSC is for export purpose only and as per FSC the product is not registered in China. ii.The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory Authority or notarized Evidence of the CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017 iii.Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC), since the copy of DOC provided does not clarify about the Class of the IVD. Therefore clarify.
232.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	Manufacturer InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Diagnostic Kit For Antibody to Hepatitis C Virus (ELISA) CAT. NO. ITP23001 96 Tests/Kit Shelf life 12 months FSC:. China	**Deferred** for provison of the following documents :- i. The brand name applied on Form-7A does not match the name on the FSC submitted. Need clarification. ii.The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory

			Valid Till: 25-10-2022 Class D	Authority or notarized Evidence of the CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. iii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC). The firm has provided photocopy of these documents.
233.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality Rapid Anti HCV Test/ Diagnostic kit for antibody to hepatitis C Virus Collodial Gold CAT. NO. ITP01102,40 Test/kit Shelf life 24 months Class D FSC: China Valid Till: 25-10-2022	**Deferred** for provision of clarification / following documents :- i. The firm has submitted two application with the same brand name but different codes i.e, ITP01102 and ITPW01152, one of which is WHO prequalified. However, on the Free Sale Certificate only one name mentioned and don't have code with it. Therefore, need clarification/ provide embassy attested FSC having codes on it. ii. The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory Authority or notarized Evidence of The CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. iii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC) and Credential of the manufacturer. The firm has provided photocopy of these documents .
234.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality Rapid Anti HCV Test/ Diagnostic kit for antibody to hepatitis C Virus Collodial Gold CAT. NO. ITPW01152,40 Test/kit FSC: China Valid Till: 25-10-2022 Class D Claimed Shelf Life 24months	**Deferred** for provision of clarification / following documents:- i. The firm has submitted two applications with the same brand name but different codes i.e, ITP01102 and ITPW01152, one of which is WHO prequalified. However, on the Free Sale Certificate only one name mentioned and don't have code with it. Therefore, need clarification/ provide Embassy Attested FSC having codes on it. ii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC) and Credential of the manufacturer. The firm has provided photocopy of these documents. iii. Provide complete stability studies to justify shelf life since the provided study is incomplete.
235.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality ONE STEP HBsAg Test / Diagnostic Kit For Hepatitis B Virus Surface Antigen, Colloidal Gold (Whole Blood / Serum / Plasma) CAT. NO. ITP01003-Test Card 40 Shelf life 24 months Class D FSC: China Valid Till: 25-10-2022	**Deferred** for provision of clarification / following documents :- i. The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory Authority or notarized Evidence of The CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. ii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC). The firm has provided photocopy of these documents.

236.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality Rapid Anti HIV (1&2) Test / Diagnostic kit for Antibody to Human Immunodeficiency Virus (Collodial Gold) CAT. NO. ITP02002, 40Tests/Kit FSC: China Valid Till: 25-10-2022 Class D Shelf life 12 months	**Deferred** for provision of clarification / following documents: - i. The product is from non-reference country. Therefore, Provide FSC of any reference Regulatory Authority or notarized Evidence of The CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. ii. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC). The firm has provided photocopy of these documents. iii. The firm has submitted two applications with the same brand name but different codes i.e., ITP02002 and ITP02152 one of which is WHO prequalified as per Form-7A. However, on the Free Sale Certificate only one name mentioned and don't have code with it Therefore, need clarification/ provide free sale certificate with codes mentioned on it.
237.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality One step Anti HIV (1&2) Test / Diagnostic kit for Antibody to Human Immunodeficiency Virus (Collodial Gold) CAT. NO. ITPW02152, 40Tests/Kit Class D Shelf Life 12 months FSC: China Valid Till: 25-10-2022 WHO PRE	**Deferred** for provision of clarification / following documents:- i.The firm has submitted two applications with the same brand name but different codes i.e., ITP02002 and ITPW02152 one of which is WHO prequalified as per Form-7A. However, on the Free Sale Certificate only one name mentioned and don't have code with it. Therefore, need clarification/ provide Embassy Attested Free Sale Certificate with codes mentioned on it. ii.Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC). The firm has provided photocopy of these documents.
238.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China	Advanced Quality One Step Anti TP (Treponema pallidum / Syphilis) Test / Diagnostic kit for Antibody to Treponema pallidum (Collodial Gold) CAT. NO. ITP03004, 40 Tests/Kit" Class C FSC: China Valid Till: 25-10-2022 Shelf life 24 months	**Deferred** for provision of:- I. Valid and embassy attested FSC of any reference Regulatory Authority or notarized Evidence of The CE-Certification or WHO prequalification in accordance to rule 15(2) of the MDR 2017. II. Provide valid ISO 13485 certificate, as the submitted has been expired also provide Notarized Declaration of conformity (DOC).The firm has provided photocopy of these documents.
239.	M/s Ophthalmo-Tec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi. **Evaluator** AD-VII	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYSORB Dyed Class D Shelf Life 5 year	**Deferred** for provision of :- I. Valid, original and embassy attested Free Sale Certificate of the Belgium since the copy of the Free trade certificate provided was issued in 2017 and is expired. Furthermore, Free Trade Certificate does not clearly mention that the device is available in Belgium. II. Provide valid authorization letter since the letter provided is expired after submission. III. Provide Valid ISO 13485 Certificate or GMP certificate. Since the submitted certificate are expired. IV. The name of the Principle manufacturer present

				on FORM-7A is different then as mentioned on FSC and other documents. Submit revised Form-7A.
240.	M/s Ophthalmo-Tec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi **Evaluator** AD-VII	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYSILK (Black braided silk) Class D Shelf life 05 years File no 3568	**Deferred** for provision of :- I. Valid, original and embassy attested Free Sale Certificate of the Belgium since the copy of the Free trade certificate provided was issued in 2017 and is expired. Furthermore, Free Trade Certificate does not clearly mention that the device is available in Belgium. II. Provide valid authorization letter since the letter provided is expired after submission. III. Provide Valid ISO 13485 Certificate or GMP certificate. Since the submitted certificate are expired. IV. The name of the Principle manufacturer present on FORM-7A is different then as mentioned on FSC and other documents. Submit revised Form-7A.
241.	M/s Ophthalmo-Tec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi **Evaluator** AD-VII	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYCRYLIC FAST' Class D Shelf Life 5 year 3570	**Deferred** for provision of :- I. Valid, original and embassy attested Free Sale Certificate of the Belgium since the copy of the Free trade certificate provided (Belgium) was issued in 2017 and is expired. Furthermore, Free Trade Certificate does not clearly mention that the device is available in Belgium. II. Clarification of The fee slip (2036881) attached with this application posses the name of 'Egycrylic fast'. However, the application is submitted for 'Egycryl Fast'. III. valid authorization letter since the letter provided is expired after submission. IV. Valid ISO 13485 Certificate or GMP certificate. Since the submitted certificate are expired. The name of the Principle manufacturer present on FORM-7A is different then as mentioned on FSC and other documents. Submit revised Form-7A.
242.	M/s Ophthalmo-Tec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi **Evaluator** AD-VII	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYCRYLIC Dyed and undyed Class D Shelf Life 5 years	**Deferred** for provision of :- I. Valid, original and embassy attested Free Sale Certificate of the Belgium since the copy of the Free trade certificate provided was issued in 2017 and is expired. Furthermore, Free Trade Certificate does not clearly mention that the device is available in Belgium. II. The application and Fee submitted is with the brand name (Form-7A) EGYCRYLIC Dyed and undyed, which does not match with the brand name EGYCRYL (Dyed and undyed) present on FSC and letter of authorization. Need clarification and submit revise Form-7A. III. Provide valid authorization letter since the letter provided is expired after submission. IV. Provide Valid ISO 13485 Certificate or GMP certificate. Since the submitted certificate are expired. V. The name of the Principle manufacturer present on FORM-7A is different then as mentioned on FSC and other documents. Submit revised Form-7A.

243.	M/s Ophthalmo-Tec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi **Evaluator** AD-VII	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYPROLENE (Polypropylene monofilament) Class D Shelf life 05years	**Deferred** for provision of :- I. Valid, original and embassy attested Free Sale Certificate of the Belgium since the copy of the Free trade certificate provided was issued in 2017 and is expired. Furthermore, Free Trade Certificate does not clearly mention that the device is available in Belgium. II. Provide valid authorization letter since the letter provided is expired after submission. III. Provide Valid ISO 13485 Certificate or GMP certificate. Since the submitted certificate are expired. IV. The name of the Principle manufacturer present on FORM-7A is different then as mentioned on FSC and other documents. Submit revised Form-7A.
244.	M/s Meritorious Business Solutions (Pvt) Ltd., House No. 39, College Road, Safari Villas 1, Bahria Town, Rawalpindi. **Evaluator** AD-VII	M/s AccuBioTech Co., Ltd Building 10, No. 28 Yuhua Road, Beijing 101300 China	ACCU-TELL ® HEV IgM Cassette Class D Shel life 12 months	**Deferred** for provision of:- I. Valid, Original and embassy attested Free sale certificate in the country of origin and also in Germany, since only copy of FSC of Germany is provided. II. Provide valid notarized ISO 13485 Certificate. Also provide valid and notarized CE certification issued by the CABs present in the Nando data base. The certificate provided have been issued by the company itself. III. Provide valid, notarized Authorization letter and Credential of the manufacturer.
245.	M/s Meritorious Business Solutions (Pvt) Ltd., House No. 39, College Road, Safari Villas 1, Bahria Town, Rawalpindi **Evaluator** AD-VII	M/s AccuBioTech Co., Ltd Building 10, No. 28 Yuhua Road, Beijing 101300 China	ACCU- TELL ® HAV IgM Test Cassette Class D Shel life 24 months FSC China and Germany	**Deferred** for provision of :- I. Valid, Original and embassy attested Free sale certificate in the country of origin and also in Germany, since only expired copy of FSC of Germany is provided. II. Provide valid notarized ISO 13485 Certificate. Also provide valid and notarized CE certification issued by the CABs present in the Nando data base. The certificate provided have been issued by the company itself. III. Provide valid, notarized Authorization letter and Credential of the manufacturer.
246.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) **Evaluator** AD-VII	**Legal Manufacturer:** Lohmann & Rauscher International GmbH Co.KG, Westerwalds traße 4, 56579 Rengsdorf, GERMANY **Physical manufacturer** Lohmann & Rauscher GmbH Co.KG, Irlicher StraBe 55 56567 Neuwied GERMANY	Suprasorb® C Collagen Wound Dressing 20483 (8X12) FSC: Germany Issued: 28-1-2021 3 years Class D	**Deferred** for provision of :_ I. Original valid and embassy attested Free sale certificate. II. Notarised ISO 13485, Full Quality Assurance, LOA, credential and III. Design Examination certificate, the submitted is copy
247.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi	**Legal Manufacturer:** Lohmann & Rauscher International GmbH Co.KG, Westerwaldstraße 4,	Suprasorb A + AG Antimicrobial Calcium Alginate Wound Dressing and Rope 20571 (10X10)	**Deferred** for provision of :- I. Original valid and embassy attested Free sale certificate.

	(ELI-00030) **Evaluator** AD-VII	56579 Rengsdorf, GERMANY Lohmann & Rauscher kirchengasse 17 2525, sochonau a.d triesting austria	20572 (10X20) 20573 (2g rope) FSC: Germany Issued: 28-1-2021 5years	II. Notarised ISO 13485, Full Quality Assurance, LOA, credential and Design Examination certificate, the submitted is copy
248.	M/s Ham International, Mezzenine floor plot No. LS-2, St. 9, Block-15, KDA Scheme, 36 Gulistan e Johar, Karachi. ELI: 00008 **5070-R&I** **22.02.2022** **Evaluator** AD-IX	**Legal Manufacturer:** M/s Shunmei Medical Co., Ltd., R401 of building B No. 8 Jinlong Yifa 3rd road, Yifa Industrial Zone Dushi village, Pingtan town, Huiyang District, Huizhou, Guangdong, China.	Shunmei Peripheral Guidewire (Peripheral Guidewire) Codes/sizes: As per FSC Class D Shelf Life: 3 years	**Deferred for:** • Provide notarized and valid Declaration of conformity by the manufacturer, ISO 13485, full quality assurance certificate and design examination certificate. • Please submit notarized credential of manufacturer and letter of authorization. • Submit original, legalized and valid free sale certificate. • Provide information on validation for medical device with respect to sterility of the applied product. • Provide instruction for use. • Since the country of origin is China, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Please provide evidence of submission of applicable fee by submitting the original receipt is not submitted with the dossier.
249.	M/s Ham International, Mezzenine floor plot No. LS-2, St. 9, Block-15, KDA Scheme, 36 Gulistan e Johar, Karachi. ELI: 00008 **5069-R&I** **22.02.2022** **Evaluator** AD-IX	**Legal Manufacturer:** M/s Shunmei Medical Co., Ltd., R401 of building B No. 8 Jinlong 1st road, baolong industrial zone, long gang district Shenzhen, China **Manufacturing facility:** M/s Shunmei Medical Co., Ltd., R401 of building B No. 8 Jinlong Yifa 3rd road, Yifa Industrial Zone Dushi village, Pingtan town, Huiyang District, Huizhou, Guangdong, China.	Shunmei micro Guidewire (Micro Guide wire) Codes/sizes: As per FSC Class D Shelf Life: 3 years	**Deferred for:** • Provide notarized and valid Declaration of conformity by the manufacturer, ISO 13485, full quality assurance certificate and design examination certificate. • Please submit notarized credential of manufacturer and letter of authorization. • Submit original, legalized and valid free sale certificate. • Provide information on validation for medical device with respect to sterility of the applied product. • Provide instruction for use. • Since the country of origin is China, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Please provide evidence of submission of applicable fee by submitting the original receipt is not submitted with the dossier.
250.	M/s Ham International, Mezzenine floor plot No. LS-2, St. 9, Block-15, KDA Scheme, 36 Gulistan e Johar, Karachi. ELI: 00008	**Legal Manufacturer:** M/s Shunmei Medical Co., Ltd., R401 of building B No. 8 Jinlong 1st road, baolong industrial zone, long gang district Shenzhen, China **Manufacturing facility:**	Shunmei micro catheter (Micro Catheter) Codes/sizes: As per FSC Class D Shelf Life: 137 days	**Deferred for:** • Provide notarized and valid Declaration of conformity by the manufacturer, ISO 13485, full quality assurance certificate and design examination certificate. • Please submit notarized credential of manufacturer and letter of authorization. • Submit original, legalized and valid free sale certificate.

	5068-R&I **Evaluator** AD-IX	M/s Shunmei Medical Co., Ltd., R401 of building B No. 8 Jinlong Yifa 3rd road, Yifa Industrial Zone Dushi village, Pingtan town, Huiyang District, Huizhou, Guangdong, China.		• Provide information on validation for medical device with respect to sterility of the applied product. • Provide instruction for use. • Since the country of origin is China, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Please provide evidence of submission of applicable fee by submitting the original receipt is not submitted with the dossier.
251.	M/s K.S. Agencies, Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) **18009-R&I** **23.07.2020** **Evaluator** AD-IX	**Legal Manufacturer:** Shandong Haidike Medical Products Company Limited Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China	SuperGut Sutures (Catgut Chromic) Codes & Sizes: As per FSC Class D Shelf life: 5years Grouping: SMD	**Deferred for provision of:** • Notarized letter of authorization and credentials of manufacturer shall be submitted. • The submitted copy of Full Quality Assurance certificate does include Chromic catgut sutures in its scope. Therefore, provide notarized and valid certificate mentioning the applied product in its scope. • The submitted copy of ISO-13485 is expired, submit notarized and valid ISO-13485 for further processing of your case, please. • Original, legalized and valid Free Sale Certificate is required. • Notarized and valid design examination certificate and Declaration of conformity by the manufacturer are required since these certificates are not provided with the submitted dossier. • Provide information on validation for medical device with sterile or with measuring function, please. • Provide instruction for use. • Provide stability studies of the applied product supporting the claimed shelf life. • Since the country of origin is China, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Provide label (as approved in country of origin) and its packaging, promotion material and brochure.
252.	M/s K.S. Agencies, Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) **29832-R&I** **Evaluator** AD-IX	**Legal manufacturer:** Betatech Medikal Cihazler sanyai, Mumessillik, Ic ve, Dis, Tic, Ltd. Sti. Iki Telli Organize Sanayi Bolgesi, Ataturk Oto Sanayi Sitesi, 22 Sok Unal, Is Merkezi No. 9 / Basaksehir, Istra Nbul, Turkey	OXICEL suture (Oxidized Regenerated Cellulose - Absorbable Hemostat) Codes and Sizes as per FSC: Class: D Shelf Life: 3 years	**Deferred for:** • Notarized letter of authorization and credentials of manufacturer shall be submitted. • Provide notarized and valid full quality assurance certificate. • Submit notarized and valid ISO-13485 for further processing of your case, please. • Original, legalized and valid Free Sale Certificate is required. • Notarized and valid design examination certificate and Declaration of conformity by the manufacturer are required since copies of these certificates are submitted. • Provide information on validation for medical device with sterile or with measuring function, please. • Provide instruction for use. • Provide stability studies of the applied product supporting the claimed shelf life.

				• Since the country of origin is Turkey, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Provide label (as approved in country of origin) and its packaging, promotion material and brochure.
253.	M/s K.S. Agencies, Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi (ELI-00382) **18009-R&I** **Evaluator** AD-IX	**Legal Manufacturer:** Shandong Haidike Medical Products Company Limited Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China	SuperCryl Sutures (Polyglycolic Acid) Codes & Sizes: As per FSC Class D Shelf life: 5years Grouping: SMD	**Deferred for:** • Notarized letter of authorization and credentials of manufacturer shall be submitted. • Provide notarized and valid full quality assurance certificate. • The submitted copy of ISO-13485 is expired, submit notarized and valid ISO-13485 for further processing of your case, please. • Original, legalized and valid Free Sale Certificate is required. • Notarized and valid design examination certificate and Declaration of conformity by the manufacturer are required since these certificates are not provided with the submitted dossier. • Provide information on validation for medical device with sterile or with measuring function, please. • Provide instruction for use. • Provide stability studies of the applied product supporting the claimed shelf life. • Since the country of origin is China, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Provide label (as approved in country of origin) and its packaging, promotion material and brochure.
254.	M/ s Lucky Lab International, F-6 Usmania Center, Muhammad Ali Housing Society Commercial Market, Karachi ELI: 00448 **4056-R&I** **Evaluator** AD-IX	Legal Manufacturer: M/s Ergon Sutramed S.R.L Zone Industrial SNC-67062 Magliano dei marsi (AO) Italy FSC: ITALY Date of Issue: 06.08.2019	Selene Non- Abosrobable Surigical Suture (Non-Absorbable Surgical Suture) Code: BT445-BL458-DE516-BD979 Sizes: 0, 1, 2, 2.0, 3.0, 4.0 Class D Shelf Life: 5 years	**Deferred for:** • Please submit original and valid letter of authorization from legal manufacturer. • Detail of manufacturing method, quality control procedures, specifications and analytical method is not provided in the submitted dossier. Please provide the required data along with the testing method used for the routine analysis of the applied product. • The submitted copy of ISO-13485 is expired, therefore, you are required to submit valid copy of the certificate. • Submission of declaration of conformity printed on the letter head of manufacturer filled and duly signed by the responsible persons as per the format of European Directives is required. • Label of the applied product as approved in the country of origin along with the detail of packaging, promotional material and brochure is required. • Submit stability studies of the applied product till claimed shelf life. • Since the submitted FSC does not contain the configuration/sizes, therefore, submit original, legalized and valid FSC mentioning all the sizes/configurations of sutures. The submitted copy of Design examination certificate does not specify

				the configuration/sizes of the Selene sutures, therefore. Submission of design examination certificate mentioning the configuration/sizes of sutures is required. • The applied product is categorized under Class D of medical devices as per Medical Devices Rules 2017, therefore, you are required to submit differential fee of Rs. 25,000/-.
255.	M/ s Lucky Lab International, F-6 Usmania Center, Muhammad Ali Housing Society Commercial Market, Karachi ELI: 00448 **4057-R&I** **Evaluator** AD-IX	Legal Manufacturer: M/s Ergon Sutramed S.R.L Zone Industrial SNC-67062 Magliano dei marsi (AO) Italy FSC: ITALY Date of Issue: 06.08.2019	Seta Non-absorbable Surgical Suture (Non- absorbable Surgical suture) (ST423-SL424-SM466-SH246-SE382-SD375 Sizes: 0, 1, 2, 2.0, 3.0, 4.0 Class D Shelf Life: 5 years	**Deferred for:** • Please submit original and valid letter of authorization from legal manufacturer. • Detail of manufacturing method, quality control procedures, specifications and analytical method is not provided in the submitted dossier. Please provide the required data along with the testing method used for the routine analysis of the applied product. • The submitted copy of ISO-13485 is expired, therefore, you are required to submit valid copy of the certificate. • Submission of declaration of conformity printed on the letter head of manufacturer filled and duly signed by the responsible persons as per the format of European Directives is required. • Label of the applied product as approved in the country of origin along with the detail of packaging, promotional material and brochure is required. • Submit stability studies of the applied product till claimed shelf life. • Since the submitted FSC does not contain the configuration/sizes, therefore, submit original, legalized and valid FSC mentioning all the sizes/configurations of sutures. • The submitted copy of Design examination certificate does not specify the configuration/sizes of the Selene sutures, therefore. Submission of design examination certificate mentioning the configuration/sizes of sutures is required. • The applied product is categorized under Class D of medical devices as per Medical Devices Rules 2017, therefore, you are required to submit differential fee of Rs. 25,000/-.
256.	M/s Lucky Lab International, F-6 Usmania Center, Muhammad Ali Housing Society Commercial Market, Karachi ELI: 00448 **4057-R&I** **Evaluator** AD-IX	Legal Manufacturer: M/s Ergon Sutramed S.R.L Zona Industriale SNC-67062 Magliano dei marsi (AO) Italy FSC: ITALY Date of Issue: 16.01.2019	Coralene Non-Absorbable Surgical Suture (Non-absorbable Surgical Suture) (BT445-BL458-BE516-BD979) Sizes: 0, 1, 2, 2.0, 3.0, 4.0 Class D Shelf Life: 5 years	**Deferred for:** • Please submit original and valid letter of authorization from legal manufacturer. • Detail of manufacturing method, quality control procedures, specifications and analytical method is not provided in the submitted dossier. Please provide the required data along with the testing method used for the routine analysis of the applied product. • The submitted copy of ISO-13485 is expired, therefore, you are required to submit valid copy of the certificate. • Submission of declaration of conformity printed on the letter head of manufacturer filled and duly signed by the responsible persons as per the format of European Directives is required. • Label of the applied product as approved in the country of origin along with the detail of packaging, promotional material and brochure is required.

				• Submit stability studies of the applied product till claimed shelf life. • Since the submitted FSC does not contain the configuration/sizes, therefore, submit original, legalized and valid FSC mentioning all the sizes/configurations of sutures. • The submitted copy of Design examination certificate does not specify the configuration/sizes of the Selene sutures, therefore. Submission of design examination certificate mentioning the configuration/sizes of sutures is required. • The applied product is categorized under Class D of medical devices as per Medical Devices Rules 2017, therefore, you are required to submit differential fee of Rs. 25,000/-.
257.	M/s SM Impex, Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah-e-Liaquat, Karachi, Pakistan (ELI-00473) 8569-R&I 16.03.2020 **Evaluator** AD-IX	Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey FSC: Turkey, valid till 3rd December, 2023.	Maxicore Biopsy Gun & Needle Codes and sizes as per FSC Biopsy Gun: GBG01 Biopsy gun Needle: GPN1410, GPN1415, GPN1420, GPN1610, GPN1810, GPN1815, GPN1820, GPN1825, GPN1830, Class D Shelf life: 5 years	**Deferred for:** • Submit notarized letter of authorization. • Provide Instructions for Use for the applied product. • Provide original, legalized and valid Free Sale certificate mentioning relevant details (codes/sizes) of the applied product. • Please provide detail of quality control procedures along with the established protocol of testing for the applied product. • Submission of notarized and valid full quality assurance certificate, ISO-13485 and Declaration of Conformity (mentioning the class of medical device) is required. • Provide stability studies for the applied product supporting claimed shelf life.
258.	M/s Iqbal & Company, Alfalah Manzil, Opp. National Police Foundation, Street#26, Sector E-11/4, Islamabad. **ELI:-00117.** 2728 **Evaluator:** AD-II	**Legal Manufacturer & Mfg. Site:** M/S Medical Components INC. USA. **Address:** DBA-Medcomp 1499 DELP DRIVE HARLEYSVILLE, PA USA 19438 **Other Manufacturing Site:** Martech Medical Products Calle Mercurio N 46 Parque Industrial Mexicali, Baja California Mexico 21210 **FSC: USFDA.** **Date of Expiry:** June. 02, 2023.	**Dignity Mid-sized CT Ports** Class:D Codes and sizes as per FSC. Shelf Life: 05-Years	**Deferred** for provision of original notarized legal documents and copy of Letter of Authorization mentioning the name of medical devices.
259.	M/s Iqbal & Company, Alfalah Manzil, Opp. National Police Foundation, Street#26, Sector E-11/4,Islamabad. **ELI:-00117.** 2731 **Evaluator:**	**Legal Manufacturer& Mfg. Site:** M/S Medical Components INC. USA. DBA-Medcomp 1499 DELP DRIVE HARLEYSVILLE, PA USA 19438 **Other Manufacturing Site:**	**Symetrex Catheter Sets** Class:D Codes and sizes as per FSC. Shelf Life: 05-Years	**Deferred** for provision of original, valid duly notarized Letter of Authorization and ISO 13485 certificate,original valid embassy attested Free Sale Certificate.

	AD-II	Martech Medical Products Calle Mercurio N 46 Parque Industrial Mexicali, Baja California Mexico 21210 **FSC: USFDA.** **Date of Expiry:** November 07, 2021.		
260.	M/s Moon Enterprises, 5/6 Rabani Road, Old Anarkali Lahore ELI: 00356 2787 **Evaluator:** AD-II	**Legal Manufacturer:** M/s Atlas Medical - Sahab Free Zone Area, King Abdullah II, Industrial City, Amman 11512, Jordan. FSC: Jordan Date of Issue: 13.12.2015	ATLAS (Blood Grouping Reagent) Codes & Sizes: As per FSC Class-D Shelf Life: 27 months	**Deferred** for provision of valid and original Free Sale Certificate of any RRA, Design Examination Certificate and Notarized and Embassy attested Legal documents
261.	M/s Medi System International, 5-A Mezzanine Floor, Sardar Begum Plaza, West Blue Area 44000, Islamabad. ELI: 00696 2821 **Evaluator:** AD-II	**Legal Manufacturer:** M/s Acrostak (Schweiz) AG-14, Stegackerstrasse, 8409 Winterthur, Switzerland. FSC Switzerland Valid till: 15.01.2024	M-CATH (Microcatheter) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred** for provision of following documents: - ▪ Details of manufacturing and quality control processes ▪ Complete description with intended use, Key functional elements, formulation & composition with functionality. ▪ Full QA certificate or equivalent, duly notarized by the country of origin. ▪ Design examination certificate duly notarized by the country of origin.
262.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4292 **Evaluator:** AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trabzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**DAYLON (Polyamide) Surgical Suture** Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - ▪ Stability studies data upto claimed shelf life. ▪ Proposed MRP of medical device. ▪ Whether the medical device is for export or to be placed only in local market? ▪ Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. ▪ Information on validation for medical devices with sterile or with measuring function.
263.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4290 **Evaluator:** AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trabzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**Politer (Polyethylene Polyester) Surgical Suture** Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - ▪ Stability studies data upto claimed shelf life. ▪ Proposed MRP of medical device. ▪ Whether the medical device is for export or to be placed only in local market? ▪ Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. ▪ Information on validation for medical devices with sterile or with measuring function.
264.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476)	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trabzon -	**PEDESENTE (Polydioxanone PDO 100%) Surgical Suture** Codes & Sizes as per FSC"	**Deferred** for provision of following documents: - ▪ Stability studies data upto claimed shelf life. ▪ Proposed MRP of medical device. ▪ Whether the medical device is for export or to be

	4291 **Evaluator**: AD-II	TURKEY FSC: Turkey Valid Till: 20-06-2024	Class-D Shelf-life: 5 years	placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
265.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4294 **Evaluator**: AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trahzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**KANSTAT ORJ Absorbable Hemostat (Oxidized Regenerated Cellulose)** Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - • Stability studies data upto claimed shelf life. • Proposed MRP of medical device. • Whether the medical device is for export or to be placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
266.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4295 **Evaluator**: AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trabzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**DOPACE (Pacing Wire) Surgical suture** Temporary Pacing Wire Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - • Stability studies data upto claimed shelf life. • Proposed MRP of medical device. • Whether the medical device is for export or to be placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
267.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4297 **Evaluator**: AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trahzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**PEGELAK Poly(glycolide-co-lactide) (PLGA) (90:10) Surgical Suture** Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - • Stability studies data upto claimed shelf life. • Proposed MRP of medical device. • Whether the medical device is for export or to be placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
268.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) 4299 **Evaluator**: AD-II	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A Ortahisar Trabzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	**TEKMON (Polyglocolide (%75) -Co- Caprolactone (%25) PGCL) Surgical Suture** Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	**Deferred** for provision of following documents: - • Stability studies data upto claimed shelf life. • Proposed MRP of medical device. • Whether the medical device is for export or to be placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
269.	M/s Nishat Surgical, Office No. A-411-296, Jail Road,	DOGSAN TIBBI MALZEME SAN. A.S. (PRIVATE) Rize Cad, No. 91A	**PROPILEN (Polypropylene) Surgical Suture**	**Deferred** for provision of following documents: - • Details of manufacturing and quality control processes. • Stability studies data upto claimed shelf life.

	Hyderabad (ELI-00476) 4293 **Evaluator**: AD-II	Ortahisar Trabzon - TURKEY FSC: Turkey Valid Till: 20-06-2024	Codes & Sizes as per FSC" Class-D Shelf-life: 5 years	• Proposed MRP of medical device. • Whether the medical device is for export or to be placed only in local market? • Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. • Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized copy as per law. • Information on validation for medical devices with sterile or with measuring function.
270.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) **33838-R&I** **02.12.2021** **Evaluator** AD-IX	Legal Manufacturer: M/s Dogsan Tibbi Malzeme San. A.S. (Private) Located at Rize Cad. No. 91A, Ortahisar Trabzon-Turkey FSC: Turkey Valid till 20/06/2023.	Silk (natural silk black) Surgical suture (Silk, non-absorbable braided coated sterile surgical suture) Codes/sizes: As per FSC Class D Shelf Life: 5 years	**Deferred for:** • The submitted copy of ISO-13485 is expired, submit notarized and valid ISO-13485 for further processing of your case, please. • Notarized and valid Declaration of conformity by the manufacturer is required. • Provide information on validation for medical device with respect to sterility of the applied product. • Provide instruction for use. • Provide stability studies along with the protocol for the applied product supporting the claimed shelf life. • Since the country of origin is Turkey, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Provide label (as approved in country of origin) and its packaging, promotion material and brochure. • Pleased provide proposed MRP of the applied medical device as it has not been mentioned in Form 7A.
271.	M/s Nishat Surgical, Office No. A-411-296, Jail Road, Hyderabad (ELI-00476) **33834-R&I** **Evaluator** AD-IX	Legal Manufacturer: M/s Dogsan Tibbi Malzeme San. A.S. (Private) Located at Rize Cad. No. 91A, Ortahisar Trabzon-Turkey FSC: Turkey Valid till 20/06/2023.	Pegelak Poly (Glucolide-Co-Lacide) Rapid (PGLA) (90:10) Surgical Suture (Pegelak Poly (Glucolide-Co-Lacide) synthetic, multifilament absorbable sterile surgical suture) Codes/sizes: As per FSC Class D Shelf Life: 5 years	**Deferred for:** • The submitted copy of ISO-13485 is expired, submit notarized and valid ISO-13485 for further processing of your case, please. • Notarized and valid Declaration of conformity by the manufacturer is required. • Provide information on validation for medical device with respect to sterility of the applied product. • Provide instruction for use. • Provide stability studies along with the protocol for the applied product supporting the claimed shelf life. • Since the country of origin is Turkey, which is not a reference country, therefore, provide a Free Sale Certificate for the applied product from a reference country as specified in Rule 67 of Medical Devices Rules, 2017. • Provide label (as approved in country of origin) and its packaging, promotion material and brochure. • Pleased provide proposed MRP of the applied medical device as it has not been mentioned in Form 7A.

(Dr.Ghazanfar Ali Khan)
Additional Director (MDMC)/
Secretary MDB
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