



No.F.4-6/2023-MD (M-57)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 2nd May, 2023

Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT – SUBMISSION OF DEFICIENT INFORMATION /DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 57th meeting held on 12th April, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
I	II	III	IV	V
1.	M/s Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 Evaluator DD-II	Legal Manufacturer: Vygon 5 rue Adeline-95440 Ecouen-France Copy of Free Sale Certificate (FSC) date 29/10/2021	CPAP+ (Continuous positive airway pressure device) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred the case for submission of clarification regarding the issuing authority of Free Sale Certificate And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC)• Notarized copy of ISO13485• Notarized LOA
2.	M/s Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 Evaluator DD-II	Legal Manufacturer: Vygon 5 rue Adeline-95440 Ecouen-France FSC: France Date of issue: 29/10/2021	Locoplex (Needle for plexus and peripheral nerve blocks with electrical stimulation) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred the case for submission of clarification regarding the issuing authority of Free Sale Certificate And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC)• Notarized copy of ISO13485• Notarized LOA
3.	M/s Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 Evaluator DD-II	Legal Manufacturer: Vygon 5 rue Adeline-95440 Ecouen-France FSC: France Date of issue: 29/10/2021	Octopus () Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred the case for submission of clarification regarding the issuing authority of Free Sale Certificate. And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC)• Notarized copy of ISO13485• Notarized LOA

4.	M/s Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade-2, Phase -7 Bahria Town, Rawalpindi. ELI: 00086 Evaluator DD-II	Legal Manufacturer: I-SENS, Inc, 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea Manufacturing Site: 27-36, Gwangun-ro, Nowon-gu, Seoul 01891, Korea (as per FSC) 27-34, Gwangun-ro, Nowon-gu, Seoul 01891, Korea Original Legalized Free Sale Certificate (FSC) dated 11.08.2020	i-Smart 300 Blood Gas Analyzer (Blood Gas Analyzer) Accessories: Power adapter, Power cord, Barcode scanner, Printer paper. Codes & Size: As per FSC Class-B Shelf Life(warranty): 01 years	Deferred the case for submission of clarification regarding the difference in Address of importer (as per the submitted application) from that mentioned on their Establishment License to import. And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC) of reference country or notarized copy CE marking• Notarized copy of ISO13485• Notarized valid LOA
5.	M/s Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade-2, Phase -7 Bahria Town, Rawalpindi. ELI: 00086 Evaluator DD-II	Legal Manufacturer: I-SENS, Inc, 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea Manufacturing Site: 27-36, Gwangun-ro, Nowon-gu, Seoul 01891, Korea (as per FSC) 27-34, Gwangun-ro, Nowon-gu, Seoul 01891, Korea Original Legalized Free Sale Certificate (FSC) dated 11.08.2020	i.Smart 300 Cartridge (6520-6521-6522-6523-6524-6525-6526) (Blood Gas and electrolyte analyzer reagent) Class-B Shelf Life: 7 months (15 °C -25°C) & 36 months (2 °C -8 °C)	Deferred the case for submission of clarification regarding the difference in Address of importer (as per the submitted application) from that mentioned on their Establishment License to import. And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC) of reference country or notarized copy CE marking• Notarized copy of ISO13485• Notarized valid LOA
6.	M/s Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI: 00086 Evaluator DD-II	Legal Manufacturer: I-SENS, Inc, 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea Manufacturing Site: 27-36, Gwangun-ro, Nowon-gu, Seoul 01891, Korea (as per FSC) 27-34, Gwangun-ro, Nowon-gu, Seoul 01891, Korea Original Legalized Free Sale Certificate (FSC) dated 11.08.2020	i-Smart 30 PRO Electrolyte Analyzer Accessories: Power adapter, Power cord, Barcode scanner, Printer paper. Class-B Shelf Life (warranty): 1 year	Deferred the case for submission of clarification regarding the difference in Address of importer (as per the submitted application) from that mentioned on their Establishment License to import. And submission of following: <ul style="list-style-type: none">• Valid Embassy attested Free Sale Certificate (FSC) of reference country or notarized copy CE marking• Notarized copy of ISO13485• Notarized valid LOA 

7.	M/s Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI: 00086 Evaluator DD-II	Legal Manufacturer: I-SENS, Inc 43 Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea. FSC: Korea	i-Smart 30 PRO Cartridge Reagent for Electrolyte Analyzer Class-B Shelf Life: 18 months	Deferred the case for submission of clarification regarding the difference in Address of importer (as per the submitted application) from that mentioned on their Establishment License to import. And submission of following: <ul style="list-style-type: none"> Valid Embassy attested Free Sale Certificate (FSC) of reference country or notarized copy CE marking Notarized copy of ISO13485 Notarized valid LOA
8.	M/s Trans-Continental Pharma (Pvt) Ltd, House # 1, Street # 4. Near Iqra School Abshar Colony, Warsak Road, Peshawar, KPK. ELI: 000524 Evaluator: DD-III	Legal Manufacturer: Albomed GmbH Hildebrandstrasse 11 D-90592 Schwarzenbruck Original FSC: Germany Date of Issue: 30/08/2021	KD Intra-Articular Gel 1.0%, 1.6%, 2.2 %, 2.5% & KD Intra-Articular Gel Ultra One 2.5 % (Hyaluronic acid) Codes & Sizes: As per FSC Class-D Shelf Life: 42 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> Declaration as per form-7 A must be on stamp paper duly notarized & signed & stamped by importer. Separate notarized Doc for KD Intra-Articular Gel Ultra One 2.5 % Notarized DOC for KD Intra-Articular Gel Justification, that FSC is issued from regulatory body from country of origin. Label for KD Intra-Articular Gel 2.5%, 2ml Agency agreement validity Clarification of how under MDMC rules 2017 that how KD Intra-Articular Gel and KD Intra-Articular Gel Ultra One can be combined under family. Full QA certificate Stability studies of all product strengths Complete product description including manufacturing process. MRP of the applied device
9.	M/s Trans-Continental Pharma (Pvt) Ltd, House # 1, Street # 4. Near Iqra School Abshar Colony, Warsak Road, Peshawar ELI: 000524 Evaluator: DD-III	Legal Manufacturer: Parcus Medical LLC, 6423 Parkland Dr. Sarasota, FL 34243 Florida USA FSC: U.S.A Valid till: 04.03.2023	Parcus Threaded Suture Anchors (Suture Anchors) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> Declaration as per form-7 A must be on stamp paper duly notarized & signed & stamped by importer. Form-7A without stamp MRP of the applied device Product broacher Product label Clarify & highlight the device with name and proper codes on FSC Justify the classification as system under MDMC rules 2017 Clarify the Doc regarding the brand name applied

				<ul style="list-style-type: none"> • Proper stability studies for claimed shelf life • Manufacturer credentials
10.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat. ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Yasee Bio Medical Inc., No-9 Xiuyuan Rd, High-tech Development Zone, Qingdao City, Shandong 266000 China FSC: China 2023/05/16	Smart Gluco-Blood Glucose Meter (AC-303) (Blood Glucose Meters) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original notarized DOC • original embassy attested FSC • Incomplete stability studies (i.e., without conclusion & final results etc • FSC issued by MHRA for export of medical products to Australia is submitted • The submitted FSC issued by MHRA for export to Australia attested by Chinese council not from country of origin • FSC issued by MHRA for export to Pakistan.
11.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Yasee Bio Medical Inc., No-9 Xiuyuan Rd, High-tech Development Zone, Qingdao City, Shandong 266000 China FSC: China 2023/05/16	Smart Gluco-Blood Glucose Test Strips (AC-303) (Blood Glucose Test Strips) Class-B Shelf Life: 2 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • ORIGINAL NOTARIZED DOC • Original embassy attested FSC • Updated Full QA • FSC of reference country.
12.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Haiyan Kangyuan Medical Instrument, Songpodong Rd. Shendang Town, Haiyan Zhejiang 314311, China FSC: Valid till: 2022/02/05	Haiyan-Urinary Catheters for Single Use (Foley) (Urinary Catheters for single use (Foley) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • FSC of country of origin expired but valid at the time of submission • Updated Full QA certificate • Certificate of FDA registration is expired. Provide the valid registration certificate • Valid & original Doc • Original & valid FSC of reference country duly attested by embassy • MRP of the applied device • Stability data of relevant medical device.
13.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat. ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Haiyan Kangyuan Medical Instrument, Songpodong Rd. Shendang Town, Haiyan Zhejiang 314311, China FSC: Valid till: 2022/02/05	Haiyan-Suction Catheters for Single Use (Suction Catheters for Singe Use) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Updated FSC of country of origin • Updated Full QA certificate • Certificate of FDA registration is expired. Provide the valid registration certificate • Valid & original Doc • Original & valid FSC of reference country duly attested by embassy • MRP of the applied device

14.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat. ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Haiyan Kangyuan Medical Instrument, Songpodong Rd. Shendang Town, Haiyan Zhejiang 314311, China FSC: Valid till: 2022/02/05	Haiyan-Endotracheal Tubes for Single use (Endotracheal Tubes for Single use) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> Updated FSC of country of origin Updated Full QA certificate Certificate of FDA registration is expired. Provide the valid registration certificate Valid & original Doc Original & valid FSC of reference country duly attested by embassy MRP of the applied device
15.	M/s Brother Pharmaceutical Distributor, Gulzar-e-Madina Road, Zeb Super Market, District Gujrat. ELI: 00702 Evaluator: DD-III	Legal Manufacturer: Haiyan Kangyuan Medical Instrument Co., Ltd, Songpodong Rd, Ahendang Town, Haiyan, Zhejiang 314311, China FSC: China Valid till: 2022/02/05	Haiyan-Urinary Catheters for Single Use (Nelaton) Urinary Catheters for Single Use (Nelaton) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> Updated FSC of country of origin Updated Full QA certificate Certificate of FDA registration is expired. Provide the valid registration certificate Valid & original Doc Original & valid FSC of reference country duly attested by embassy MRP of the applied device Device name i.e., Urinary Catheters for Single Use (Nelaton) is not mentioned on FSC
16.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Forest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind FT4 Elisa Kit (Total FT4 Elisa Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. Separate fee challan for device Monobind FT4 Elisa Kit Updated Product QMS certificate ISO13485 Notarized copy of ISO13485 certificate Notarized copy of full QA certificate Valid & original Doc Original & valid FSC duly attested by embassy Justify the grouping of medical device as family as per MDR 2017
17.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Forest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind Prolactine Hormone Elisa Kit (Prolactin Hormone Elisa Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. Submit separate fee challan for device Monobind Prolactine Hormone Elisa Kit Updated Product QMS certificate ISO13485 Notarized copy of ISO13485 certificate Notarized copy of full QA certificate

				<ul style="list-style-type: none"> Valid & original Doc Original & valid FSC duly attested by embassy Justify the grouping of medical device as family as per MDR 2017
18.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Porest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind EIA CA-125 Elisa Kit (Cancer Antigen 125 Elisa Immunoassay) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. Separate fee challan for device Monobind EIA CA-125 Elisa Kit Updated Product QMS certificate ISO13485 Notarized copy of ISO13485 certificate Notarized copy of full QA certificate Valid & original Doc Original & valid FSC duly attested by embassy Justify the grouping of medical device as family as per MDR 2017
19.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Porest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind AFP Elisa Kit (AFP Elisa Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. separate fee challan for device Monobind AFP Elisa Kit Updated Product QMS certificate ISO13485 Notarized copy of ISO13485 certificate Notarized copy of full QA certificate Valid & original Doc Original & valid FSC duly attested by embassy Justify the grouping of medical device as family as per MDR 2017
20.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Porest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind Testosterone Elisa Kit (Testosterone Elisa Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. Separate fee challan for device Monobind Testosterone Elisa Kit Updated Product QMS certificate ISO13485 Notarized copy of ISO13485 certificate Notarized copy of full QA certificate Valid & original Doc

				<ul style="list-style-type: none"> • Original & valid FSC duly attested by embassy • Highlight the relevant product on FSC • Justify the grouping of medical device as family as per MDR 2017
21.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Forest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Monobind T3 Elisa Kit (Total T3 Elisa Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> • The firm attached a single fee challan of rupees 25000/-(slip # 8775811874) and attached copies of that challan to its 6 dossiers. • Separate fee challan for Monobind T3 Elisa Kit • Updated Product QMS certificate ISO13485 • Notarized copy of ISO13485 certificate • Notarized copy of full QA certificate • Provide valid& original Doc • original & valid FSC duly attested by embassy • Justify the grouping of medical device as family as per MDR 2017
22.	M/s A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Evaluator: DD-III	Legal Manufacturer: Monobind Inc., 1000 North Pointe Drive Lake Forest, CA 92630, United States of America FSC: USA Valid till: 2022/02/25	Menobind hCG ELISA Kit (Chronic Gonadotropin Hormone ELISA Immunoassay Kit) Codes & Sizes: As per FSC Class-B Shelf life 24 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Updated Product QMS certificate ISO13485 • Notarized copy of ISO13485 certificate • Notarized copy of full QA certificate • Valid & original Doc • Original & valid FSC duly attested by embassy • Justify the grouping of medical device as family as per MDR 2017
23.	M/s Biliness (SMC) Private Limited, Ground Floor Hameed Building, Bakkar Mandi, Band Road, Lahore. ELI:00765 Evaluator: DD-III	Legal Manufacturer: ForaCare Suissae AG, Neugasse 55, 9000 St. Gallen, Switzerland Original FSC: Switzerland Valid till: 2022/06/25	FORA COMFORT BLOOD GLUCOSE TEST STRIPS ACS045, ACS047, ACS046, ACS040, ACS041, ACS042, ACS044, ACS043) (Blood Glucose Test Strips) Class-C Shelf life:27 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Updated and original FSC. • Original & valid FSC duly attested by embassy • Updated Full QA certificate • Credentials of manufacturer abroad duly
24.	M/s Biliness (SMC) Private Limited, Ground Floor Hameed Building, Bakkar	Legal Manufacturer: ForaCare Suissae AG, Neugasse 55, 9000 St. Gallen, Switzerland	FORA BLOOD GLUCOSE MONITORING SYSTEM (FORA G30a)	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Updated and original FSC • Original & valid FSC duly attested by embassy • Updated Full QA certificate

	Mandi, Band Road, Lahore. ELI:00765 Evaluator: DD-III	Original FSC: Switzerland Valid till: 2022/06/25	(BLOOD GLUCOSE MONITORING SYSTEM (FOR A G30a) Codes & Sizes: As per FSC Class-C Shelf Life: 27 months	<ul style="list-style-type: none"> Credentials of manufacturer abroad duly notarized from country of origin Declaration on stamp paper as per form-7A Grouping of medical device as per MDR 2017 MRP of the applied device
25.	M/s AA Enterprizes, 57, 15-16 First Floor Mobi Plaza Haider Road, Saddar, Rawalpindi ELI:00525 Evaluator: DD-III	Legal Manufacturer: SCHWIND eye-tech-solutions GmbH Mainparkstrasse 6-10 63801 Kleinostheim Germany FSC: Germany Date of Issue: 14/10/2020	SCHWING ATOS ® (SCHWING ATOS ®) Codes & Sizes: As per FSC Class-C Shelf Life: N/A	Deferred for the provision of following documents: <ul style="list-style-type: none"> Service life/shelf life of components of medical device Generic name List of components Justify the grouping of medical device as kit under MDR 2017, while in product description it is classified as system Provide proper & notarized credentials of manufacturer Provide original & valid FSC duly attested by embassy QMS certificate (ISO 13485) is expired but valid at the time of submission Notarized QMS certificate (ISO 13485) Notarized Full QA certificate Original DOC Original, valid & notarized agency agreement Declaration on stamp paper as per form-7A
26.	M/s Azad Scientific 3-B/2 Mouj Darya Road, Lahore ELI: 00349 Evaluator: DD-III	Legal Manufacturer: ORGENTEC Diagnostika GmbH ,Carl-Zeiss-Straße 49-51, DE-55129 Mainz, Germany FSC: Germany Date of Issue: 01.10.2020	Orgentec diagnostika GmbH {Anti-TG ELISA KIT Anti-TPO ELISA KIT } Code: ORG-502-ORG-503 Class- B Shelf Life: 18 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> Justify the grouping of medical device under MDR 2017, Proper & notarized credentials of manufacturer Original & valid FSC duly attested by embassy Notarized QMS certificate (ISO 13485) Notarized Full QA certificate ORIGINAL & VALID DOC Original, valid & notarized agency agreement
27.	M/s Al-Waali Care Concept, 86-Allama Iqbal Road Gari Shahu, Lahore ELI: 00386	Legal Manufacturer: Shanghai Kindly Medical Instruments Co., Ltd No. 925 Jinyuan yi Road	Pressure Transducer (Pressure Transducer) Codes & Sizes: As per FSC	Deferred for the provision of following documents: <ul style="list-style-type: none"> proper & notarized credentials of manufacturer Original & valid FSC duly attested by embassy

	Evaluator: DD-III	201803 Shanghai P.R China FSC: China Date of issue: 17.08.2021	Class-B Shelf Life: 3 years	<ul style="list-style-type: none"> • Original & valid reference country FSC duly attested by embassy • Notarized QMS certificate (ISO 13485) • Notarized Full QA certificate • Original, valid & notarized agency agreement • As per attached DOC the medical device fall in class II b(class C) while the importer applied the case as class B, justify.
28.	M/s Iqbal & Company, Alfalah Manzil Opp. National Police Foundaton, Street # 26, Sector, E-11/4, Islamabad, Pakistan. ELI: 00117 Evaluator: DD-III	Legal Manufacturer Unimax Medical Systems Inc. 8F-2, No 127, lane 235 Pao Chiao Rd., Hsin Tien Taipei, Taiwan Site 1: No. 37, Sec., 2, Ligong 1st Rd Wujie Township, Yilan Country 268 Taiwan Site 2. 5F, Zhihai Industry Park, First Industrial Zone, Baihua Community, Guangming New District, Shenzhen City, Guangdong Provice, China FSC: Taiwan Date of issue. 21.07.2020	Drain Master TM (Chest Drainage System) Class-B Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Updated and original Letter of authorization, duly notarized • Updated and original FSC of country of origin • Updated ISO 13485 certificate
29.	M/s Feroszons Laboratorries Limited, P.O Feroszons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Evaluator: DD-III	Legal Manufacturer: Boston Scientific Corporation 300 Boston Scientific Way Malborough, MA USA 01752 Manufacturing for: Availmed S.A. de C.V. Ave. Industrial 20905 Interior A Tijuana, Baja California C.P 22444, Mexico FSC: Irland Valid till: 19/08/2025	irrigation Tubing Set (Tubing Set) M0041160 Class-B Shelf Life: 12 months	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Notarized credentials of manufacturer • Original & valid FSC duly attested by embassy • Notarized QMS certificate (ISO 13485) • Notarized Full QA Certificate • Original, valid & notarized agency agreement

30.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1878-P	<u>Legal Manufacturer:</u> VIRCELL, S.L, Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) <u>Manufacturing site:</u> Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1, 18320 Santa Fe, Granada, Spain FSC: Spain Date of issue 04.01.2018	Brucella ELISA 1gG/ 1gM test kit Class-B Shelf life: 21 months Codes: G1003 (96 tests) M1006	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Credentials of manufacturer's abroad. • Updated LOA, FSC, ISO 13485.
31.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1697-P	<u>Legal Manufacturer</u> AMEDA Labordiagnostik GmbH Krenngasse 12 8010 Graz Austria. FSC: AUSTRIA Date of issue: 20.07.2018 valid till 20-07-2020	AMP Clinical Chemistry Substrate Reagents Class -B Shelf Life: 24 months Codes as per FSC	Deferred for the provision of: <ul style="list-style-type: none"> • Original, updated and attested FSC, • Notarized ISO 13485. • Labels of applied codes. • Apply separately for other kits. • MRP of the device.
32.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1695-P	<u>Legal Manufacturer</u> AMEDA Labordiagnostik GmbH Krenngasse 12 8010 Graz Austria. FSC: AUSTRIA Date of issue: 20.07.2018 valid till 20-07-2020	AMP Clinical Chemistry Electrolyte Reagents Class -B Shelf Life: 30 months Codes as per FSC	Deferred for the provision of original, updated and attested FSC and notarized ISO 13485.
33.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1696-P	<u>Legal Manufacturer</u> AMEDA Labordiagnostik GmbH Krenngasse 12 8010 Graz Austria. FSC: AUSTRIA Date of issue: 20.07.2018 valid till 20-07-2020	AMP Clinical Chemistry Lipid Reagents Class -B Shelf Life: 24 months Codes as per FSC	Deferred for the provision of original, updated and attested FSC and notarized ISO 13485.

34.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 3509-P	Legal Manufacturer: M/s Sophonix Co., Ltd, Room 301, Block 19A, 8# Liangshuihe 2nd Street, Economic-Technological Development Zone, 100176, Beijing, China FSC China validity 2023/01/05	Sophonix, Fertility Harmons Reagents, cluster Class -B Shelf Life: 12 months Codes as per FSC	Deferred for the provision of original, updated and attested FSC and notarized ISO 13485. Apply separately for Prolactin kit.
35.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1961-P	Legal Manufacturer: GeneProof, a.s. Videnska 101/119 Dolni Herspice 61900 Czech Republic FSC: Czech Republic (Original FSC) Date of issue: 18.08.2020	Gene Proof SARS-CoV-2 PCR Kit Class-B Shelf Life: 12 months Code: COV2/GP/100	Deferred for the provision of following documents: <ul style="list-style-type: none"> Differential fee of 25, 000/- as the device is registered in Class-C. Original and updated LOA and ISO 13485.
36.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 1963-P	Legal Manufacturer: GeneProof, a.s. Videnska 101/119 Dolni Herspice 61900 Czech Republic FSC: Czech Republic (Original FSC) Date of issue: 18.08.2020	GeneProof SARS-CoV-2 Screening PCR Kit Class-B Shelf Life: 12 months Code: CoV2S/GP/100	Deferred for the provision of following documents: <ul style="list-style-type: none"> Differential fee of 25, 000/- as the device is registered in Class-C. Original and updated LOA and ISO 13485.
37.	M/s Med Lab Services, Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. ELI-00056 AD-III 2172-P	Legal Manufacturer: M/s VIRCELL, S.L, Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) and Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1, 18320 Santa Fe, Granada, Spain FSC: Spain issuance 10-07-2020	Covid-19 ELISA 1gM+1gA (ELISA test kit) Class-B Shelf Life: 21 months Code: MA1032 (96 tests)	Deferred for the provision of following documents: <ul style="list-style-type: none"> Differential fee of 25, 000/- as the device is registered in Class-C. Original and updated LOA and ISO 13485.

38.	Medic Ally (Pvt) Ltd, 403-Nishtar Block, Allama Iqbal Town, Lahore ELI: 00719 3586-P AD-III 17-08-2022	<u>Legal Manufacturer:</u> M/s Humeca B.v. Oostermaat 5 7623 CS Borne The Netherlands Netherlands Valid till: 26/05/2024	Humeca Dermatome (Dermatomes) Class-C Shelf Life: N/A Codes & Sizes: As per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • Properly filled and stamped Form-7A • Original DoC
39.	M/s Mais Medical Products (Pvt) Ltd, Office No. 8 Second Floor Qartaba center 7/8 Jail Road Muzung Chungi, District, Lahore. ELI: -00693 3064-P 18/02/2022	<u>Legal Manufacturer:</u> M/s Saudi Mais Co. for Medical Products, Third Industrial Area, Al Kharj Road, Street No. 256, Riyadh Saudi Arabia FSC: Malta Date of issue: 09.11.2021 valid for 3 years.	Maicath I.V Cannula, without port, sterile (I.V. Cannula/ I.V Catheter) Class-B Shelf Life 5 year Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • All the legal documents submitted are copies. Provide original documents. • FSC of Country of origin. • Submitted FSC issued by Medicine agency, Malta since Malta is not the reference country, so provide FSC of any SRA country, duly attested. It is to mentioned here that the FSC issued by Malta Medicines agency is issued to EU authorized representative of M/s Saudi Mais Co. for Medical Products, Third Industrial Area not to the manufacturer itself. Clarification is required • The label specimen submitted is the draft, provide approved labels. clarify • Apply separately for other types of Cannula.
40.	M/s Mais Medical Products (Pvt) Ltd, Office No. 8 Second Floor Qartaba center 7/8 Jail Road Muzung Chungi, District, Lahore. ELI: -00693 3572-P 24-08-2022	<u>Legal Manufacturer:</u> M/s Saudi Mais Co. for Medical Products, Third Industrial Area, Al Kharj Road, Street No. 256, Riyadh Saudi Arabia FSC: Malta Date of issue: 09.11.2021 valid for 3 years.	Endotracheal tube (Endotracheal tube, uncuffed) Class-B Shelf Life 5 year Sizes as per FSC	Deferred for provision of following documents: <ul style="list-style-type: none"> • Brand name of the device. • All the legal documents submitted are copies. Provide original documents. • FSC of Country of origin. • Submitted FSC issued by Medicine agency, Malta since Malta is not the reference country, so provide FSC of any SRA country, duly attested. It is to mentioned here that the FSC issued by Malta Medicines agency is issued to EU authorized representative of M/s Saudi Mais Co. for Medical Products, Third Industrial Area not to the manufacturer itself. Clarification is required • The label specimen submitted is the draft, provide approved labels. Clarify • Apply separately for other types of Endotracheal tubes.
41.	M/s Mais Medical Products (Pvt) Ltd, Office	<u>Legal Manufacturer:</u> M/s Saudi Mais Co. for Medical Products,	Nelaton Catheter (Nelaton Catheter, female)	Deferred for provision of following documents: <ul style="list-style-type: none"> • Brand name of the device.

	<p>No. 8 Second Floor Qartaba center 7/8 Jail Road Muzung Chungi, District, Lahore.</p> <p>ELI: -00693 3571-P 24-08-2022</p>	<p>Third Industrial Area, Al Kharj Road, Street No. 256, Riyadh Saudi Arabia</p> <p>FSC: Malta Date of issue: 09.11.2021 valid for 3 years.</p>	<p>Class-B Shelf Life 5 year Sizes as per FSC</p>	<ul style="list-style-type: none"> All the legal documents submitted are copies. Provide original documents. FSC of Country of origin. Submitted FSC issued by Medicine agency, Malta since Malta is not the reference country, so provide FSC of any SRA country, duly attested. It is to mentioned here that the FSC issued by Malta Medicines agency is issued to EU authorized representative of M/s Saudi Mais Co. for Medical Products, Third Industrial Area not to the manufacturer itself. Clarification is required The label specimen submitted is the draft, provide approved labels. Clarify Codes of Female catheters are mentioned only in FSC provided (attached list of configurations/ variants) Apply separately for other types of Catheter.
42.	<p>M/s HealthBee Projects (PVT)Ltd, Ground Floor, Momi Plaza, Plot No. 43, Business Square Phase 7, Bahria Town, Rawalpindi Eli-00814 966-C AD-III 28-12-2022</p>	<p>Legal Manufacturer: Maxigen Biotech. Inc 88 (2F' 3F) and 4th floor (4F'5F), Keji, First road, Gulshan District Taoyuan City, Taiwan, ROC</p>	<p>HealiAid ® Collagen Wound Dressing Class-D Shelf life: 3 years Codes: Provided only in Agency agreement</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> Credentials of manufacturer abroad as per format approved in MDB 3rd meeting. Original and attested FSC in the country of origin and any SRA country. MRP.
43.	<p>M/s. Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi.</p> <p>Evaluator AD-IV [885-P]</p>	<p>Legal Manufacturer: M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy</p> <p>FSC Italy issued on 17-6-2019</p>	<p>Delta Ven I (IV single entry catheter without injection valve)</p> <p>Codes as per FSC Italy dated 17-06-2019</p> <p>Class B</p> <p>Shelf life: 5 years</p>	<p>The board deferred the case for the provision of clarification from M/s Intra Health, Karachi that whether they are still the authorized distributor of the said manufacturer M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy or the manufacture has terminated the agreement. The firm may appear before Board for personal hearing in the forthcoming meeting.</p>
44.	<p>M/s IBL Healthcare Limited, Section A, 2nd Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan</p>	<p>Suzhou Zoey Medical Device Co., Ltd. 2nd Floor, Building 18, Guanpu Road No. 333, Guoxiang Street, Wuzhong Economic Development Zone, 215100 Suzhou,</p>	<p>Hollow Fiber Hemodialyzer Class C Shelf Life: 3 years(claimed)</p>	<p>Deferred for the provision of the followings:</p> <ul style="list-style-type: none"> Brand name of the product is not mentioned in the application form, nor it is mentioned in LOA, Certificate of china, FSC of Spain other documents. FSC of China not provided however Export only certificate is provided.

	Road, Off Shahrah-e-Faisal, Karachi. (ELI-00119) 3823 Evaluator: DD-I	Peoples Republic of China FSC Spain(Copy) Date of issuance: 02.01.2021		<ul style="list-style-type: none"> Original, Valid and Embassy attested FSC of Spain not provided, However , only copy of FSC of Spain is attached. ISO 13485 is expired(valid upon submission). Stability study data and report supporting claimed shelf life of 3 years ,not provided.
45.	M/s IBL Healthcare Limited, Section A, 2nd Floor, One IBL Centre, Plot No.1, Block 7 & 8, DMCHS, Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi. (ELI-00119) 3837 Evaluator: DD-I	Ares Medikal San. Tic. Ltd. Sti Asik Veysel Mah. 5821/1 Sk. No:6 Karabaglar 35110, Izmir Turkey FSC: Spain Issueance date: 6-10-2022	HEMODIALYSIS CATHETER KIT Class B Shelf Life: 3 years (claimed)	<p>Deferred for the provision of the followings:</p> <ul style="list-style-type: none"> Brand name of the product is not mentioned in the application form. ISO 13485 expired (valid upon submission). Claimed shelf life is 3 years however, stability study data of the applied product is not provided.
46.	M/s A.J. Mirza Pharma (Pvt) Ltd, 1st Floor, Shafi Court, Merawether Road, Civil lines, Karachi. Eli-000321 Evaluator: DD-I	Biohit Healthcare (Hefei) Co., Ltd., Biouhan Biotech Industrial Estate, Northeast corner, Intersection of Kongque road and changan road, high-tech zone, 230000 hefei, anhui China	Biouhan SARS-CoV-2 Antigen Rapid Test (Colloidal gold Method) (Anterior Nasal Test) Class D Shelf Life: 18 months	<p>Deferred for the provision of the followings:</p> <ul style="list-style-type: none"> Valid and Embassy attested FSC of any reference country as mentioned in Rule 67 of MDR, 2017. Valid and notarized FQA system certificate.
47.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	<p>Manufacturer: PharmamedMedikalÜr ünler San. ve Tic. Ltd. Şti. Liman Sb.Mah. B-1 Cad. Pharmamed Blok No:9 Konyaaltı/Antalya / TÜRKİYE</p> <p>Medtronic Cardiac Surgery Division Europe, Valkenhuizerlaan 16, 6466 ND Kerkrade, The Netherlands</p>	<p>Tubing set Codes: M110318A, M110317A M110603A, PTS0005 PTS0117, PTS0061</p> <p>Class: B Shelf life: 2 years</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> The firm shall submit fee of Re.25000/-. Since the fee attached with the dossier is for Smartsync case. The firm has submitted copy of FSC which don't have products name. Therefore submit original valid and embassy attested FSC of turkey and Original Embassy attested FSC of any reference regulatory Authority. The firm has not submitted letter of Authorization therefore provide Notarised LOA. Provide Notarised ISO 13485& FQA , since not provided. Stability studies not provided therefore, submit stability studies . Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.

48.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000	MiniMed 640G Insulin Pump MMT-1860 Shelf life: 3 years Class: C	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm shall submit fee of Re.50000/- Since the fee attached with the dossier is for pump kit or clarify. • The firm has submitted original embassy attested expired FSC of USFDA • The firm has submitted Copy of LOA provide notarized LOA. • The firm has submitted expired and notarized ISO 13485 certificate therefore provide valid ISO 13485 • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
49.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000	MiniMed 780G Insulin Pump MMT-1885 MMT-1886 MMT-1895 MMT-1896 Class: C Shelf life: 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitte copy of FSC. Therefore submit original valid and embassy aattsted FSC. • The firm has submitted Copy of LOA provide notarized LOA or clarify. • The firm has submitted expired and notarized ISO 13485 certificate therefore provide valid ISO 13485 • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
50.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000	MiniMed 720G Insulin Pump MMT-1860 MMT-1810 Class: C Shelf life: 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has not submitted FSC. Therefore submit original valid and embassy aattsted FSC. • The firm has submitted Copy of LOA provide notarized LOA or clarify. • The firm has submitted expired and notarized ISO 13485 certificate therefore provide valid ISO 13485 • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.

51.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator: AD-VIII</p>	<p>Manufacturer: M/s Unomedical a/s Aaholmvej 1-3 Osted 4320 Lejre Denmark</p>	<p>MiniMed Mio® MMT-921, MMT-941 MMT-961, MMT-923 MMT-943, MMT-943T MMT-963, MMT-925 MMT-945, MMT-965 MMT-975, MMT-975T, MMT-921A, MMT-921A600, MMT-961A, MMT-923A, MMT-923A600, MMT-943AT, MMT-963A, MMT-925A, MMT-925A600, MMT-965A, MMT-975A, MMT-975A600, MMT-975AT, MMT-905, MMT-905T, MMT-906, MMT-905A MMT-905A600, MMT-905AT, MMT-906A, MMT-906A600</p> <p>Shelf life: 3 years Class: C</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm shall submit fee of Re.50000/- Since the fee attached with the dossier is for instt mmt-921 or clarify. • Clarify codes as per FSC • The firm has submitted copy of FSC therefore submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 nor FQA therefore provide notarized ISO 13485 & FQA • LOA not provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
52.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator : AD-VIII</p>	<p>Legal manufacturer: M/s Medtronic Inc.710 Medtronic Parkway Minneapolis MN 55432, USA Manufacturing sites: Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. FSC original Netherland date of issue September 2022, valid till December 2026</p>	<p>Onyx TruStarZotarolimu s Eluting Coronary Stent System Codes As per FSc</p> <p>Shelf life: 3 years Class D</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm has submitted original and valid FSC of netherlands however attested by the embassy of egypt. Submit original embassy attested FSC duley attested by the embassy of Pakistan • The firm has neither provided copy of ISO 13485 nor FQA therefore provide notarized ISO 13485 & FQA • Copy of LOA provided. Submit notarized & original LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • The firm has not submitted notarized Design Examination certificaite. Therefore submit notasrided and valid DE certificaite.


				<ul style="list-style-type: none"> • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
53.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturing site: Micro Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 USA Sterilization facility: Sterigenics U.S., LLC 4900 Gifford Avenue Los Angeles, CA 90058, USA	Cragg McNamara 4F Valved Infusion Catheter 41032-01 ,41036-01 41040-01,41033-01 41037-01 ,41041-01 41034-01, 41038-01 41042-01, 41035-01 41039-01 Class : C Shelf life : 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted expired copy FSC. Therefore, submit original valid and embassy aattsted FSC. • The firm has submitted Copy of LOA provide notarized LOA or clarify. • The firm has submitted expired ISO 13485 &FQA certificate therefore provide valid and notarized ISO 13485 & FQA • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
54.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturing facility: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine CA 92618 USA	Pro stream Multiple sidehole infusion wire 41272-01, 41274-01, 41277-01, 41273-01, 41276-01, 41278-01 Shelf life: 3 years Class: D	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm shall submit fee of Re.50000/- . Since the fee attached with the dossier is not for this product clarify? • The firm has submitted copy of FSC therefore submit embassy attested original and valid FSC • The firm has provided copy of ISO 13485 & FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • DOC not submitted submit DOC • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
55.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Legal manufacturer: MEDTRONIC INC ,710 Medtronic Pkwy Minneapolis MN USA 55432 Manufacturing site: Medtronic INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO	Selectsite Deflectable Catheter C304-HIS Shelf life: 3 years Class: D	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC but name of the product not clear. Therefore, calriy and submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP

		<p>OPERATIONS CO VILLALBA RD, 149 KM 56.3 Call Box 6001, Villalba PR USA 00766</p> <p>PlexusManufacturingS dnBhd, BayanLepas Free Industrial Zonephase II, BayanLepasPulau Pinang MALAYSIA 11900</p>		<ul style="list-style-type: none"> Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
56.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator : AD-VIII</p>	<p>Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA</p>	<p>Guardian Connect App CSS7200</p> <p>Shelf life: 3 years</p> <p>Class : B</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> The firm has not submitted FSC. Therefore submit embassy attested original and valid FSC The firm has provided expired copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
57.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator : AD-VIII</p>	<p>Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-</p>	<p>Guardian Connect SenSor 3 MMT-7020C, MMT-7020D Class: C Shelf life: 2 year</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> The firm has submitted copy of FSC. Therefore submit embassy attested original and valid FSC The fee is submitted for guardian link 3 transmitter kit however, the applied brand name on the Form-7A is guardian connect sensor 3. Therefore clarify or submit fee 50000/- The firm has not provided ISO 13485 & FQA therefore provide notarized ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.

58.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA	Guardian Connect transmitter Kit MMT-7820LWE Class: B Shelf life: 6 months	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC. Therefore submit embassy attested original and valid FSC • The firm has not provided ISO 13485 & FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
59.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Legal manufacturer: M/s Medtronic Inc 710 Medtronic Parkway N.E Minneapolis MN 55432 USA Manufacturing site: MEDTRONIC SINGAPORE OPERATIONS PTE LTD 49 CHANGAI SOUTH AVENUE 2, NASACO TECH CENTRE SINGAPORE 486056	Medtronic Sphera L DR MRI SureScan SPDRL1 Dual Chamber Rate Responsive Pacemaker SPDRL1 Shelf life: 2 years Class: D	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC of HSA. Therefore submit embassy attested original and valid FSC of RRA • The fee is submitted for sphere srmrisurescan however, the applied brand name on the Form-7A is Medtronic Sphera L DR MRI SureScan. Therefore, clarify or submit fee 50000/- • The firm has not provided ISO 13485 and has submitted expired copy of FQA therefore provide notarized and valid ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Submit DOC • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
60.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000	Starter Kit MMT-7810W3 Class: C Shelf life: 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has not submitted FSC. Therefore submit embassy attested original and valid FSC of • The firm has provided expired copy ISO 13485 and has not submitted copy of FQA therefore provide notarized and valid ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP

				<ul style="list-style-type: none"> Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
61.	M/s Medtronic Pakistan Private Limited Evaluator AD-VIII	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000 Manufacturing site: MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus Manufacturing SdinBhd Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900	Medtronic Slitter Adjustable Slitter 6232ADJ Universal Slitter II 6230UNI Shelf life: 3 years Class: D	Deferred for submission of the following: <ul style="list-style-type: none"> The firm has submitted expired copy FSC. Therefore submit embassy attested original and valid FSC of The firm has provided expired copy FQA and has not submitted copy of ISO 13485 therefore provide notarized and valid ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Design examination not provided therefore provide notarized Design examination certificate Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
62.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Manufacturer: M/s Medtronic Inc. (Mounds View) 8200 Coral Sea Street NE MN 55112 Mounds View, USA Manufacturing Sites: Medtronic B.V. Earl Bakkenstraat 10 6422 PJ IJdoerlen THE NETHERLANDS	EVOLUT PRO+ CFN/Codes: EVPROPLUS-23, EVPROPLUS-26 EVPROPLUS-29 EVPROPLUS-34 Class: D Shelf life: 3 year	Deferred for submission of the following: <ul style="list-style-type: none"> The firm has submitted copy FSC of Netherlands. Therefore submit embassy attested original and valid FSC Brand name of the product in form-7A not aligned with the FSC clarify The firm has provided expired copy FQA and ISO 13485 & Design examination certificate therefore provide notarized and valid ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify

		<p>Medtronic CoreValve LLC 1851 E. Deere Ave, Santa Ana, CA 92705 USA</p> <p>Medtronic Mexico S.de R.L. de CV ,Avenida Paseo Cucupah 10510 El Lago C.P 22210 Tijuana, Baja California, MEXICO.</p> <p>Medtronic Ireland,Parkmore Business Park West Galway, Ireland</p>		<ul style="list-style-type: none"> • The firm has not submitted EPSP, therefore provide EPSP • Designe examination not provide therefore provide notarsied Designn examination certificate • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
63.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator AD- VIII</p>	<p>Legal manufacturer: Medtronic Inc. 710, Medtronic Parkway, Minnieapolis, MN 55432 USA</p> <p>Manufacturing sites: Medtronic Mexico S. de R L de CV, Av Paseo Cucupah 10510 El Lago, Tijuana, Bja California, MEXICO C.P. 22210</p> <p>Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II . Bayan LepasPulau Pinang MALAYSIA 11900</p>	<p>ATLGIQ_ Autolog IQ™ ATLGIQ1, ATLGIQE, ATLGIQR, ATLGIQ1R Shelf Life : 3 years</p> <p>Class: D</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm has submitted copy FSC of USFDA wherein refurbished written against some products clarify? And Therefore also submit embassy attested original and valid FSC • The firm has not provided FQA and ISO 13485 & Designn examination certificate therefore provide notarized and valid ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Designe examination not provide therefore provide notarsied Designn examination certificate • Stability studies not provided therefore, submit stability studies. • Submit DOC • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
64.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator: AD-VIII</p>	<p>Legal manufacturer: M/s Medtronic Inc.710 Medtronic Parkway Minneapolis MN 55432, USA</p> <p>Manufacturing sites: Medtronic Ireland, Parkmore Business Park West, Galway, Ireland.</p>	<p>Onyx TruCor Zotarolimus Eluting Coronary Stent Codes A sper FSC Shelf life: 3 years Class:D</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm has submitted copy of FSC of netherlands. Therefore Submit original embassy attested FSC duley attested by the embassay of Pakistan • The firm has neither provided copy of ISO 13485 nor FQA therefore provide notarized and valid ISO 13485 & FQA • Copy of LOA provided. Submit notarized & original LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP


		Copy of FSC Netherland		<ul style="list-style-type: none"> Stability studies not provided therefore, submit stability studies. The firm has not submitted notarized Design Examination certificate. Therefore submit notarized and valid DE certificate. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
65.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturing site: Micro Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 USA Sterilization facility: Sterigenics U.S., LLC 4900 Gifford Avenue Los Angeles, CA 90058, USA	Cragg McNamara 5F Valved Infusion Catheter 41043-01, 41049- 01, 41055-01, 41044-01 41050-01 41056-01 41045-01 41051-01 41057-01 41046-01 41052-01 41058-01 41047-01 41053-01 41059-01 41048-01 41054-01 41060-01 Class : C Shelf life : 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> The firm has submitted expired copy FSC of USFDA. Therefore, submit original valid and embassy attested FSC. The firm has submitted Copy of LOA provide notarized LOA or clarify. The firm has submitted expired ISO 13485 & FQA certificate therefore provide valid and notarized ISO 13485 & FQA The firm has not submitted EPSP, therefore provide EPSP Stability studies not provided therefore, submit stability studies. Submit DOC Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
66.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA Manufacturing site: MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus Manufacturing SdinBhd	Patient and Surgical Cables 5832S, 2292, 5833S 5833SL, 5487 5487L, 5433A 5433AL, 5433V, 54 33VL 5846A, 5846AL 5846V, 5846VL ,5492AL ,5492VL Shelf Life: 3 years Class: D	Deferred for submission of the following: <ul style="list-style-type: none"> The firm has submitted valid and original and embassy attested FSC at the time of submission now expired. Therefore, submit original FSC. The firm has submitted fee for the epg patient and surgical cable While the brand name on the form 7A is Patient and Surgical Cables, clarify The firm has submitted Copy of LOA provide notarized LOA or clarify. The firm has submitted expired ISO 13485 & FQA certificate therefore provide valid and notarized ISO 13485 & FQA The firm has not submitted EPSP, therefore provide EPSP Stability studies not provided therefore, submit stability studies. Submit DOC Submit notarized Design examination certificate Submit undertaking on the stamp paper for correctness and genuineness of the documents etc. 


		<p>Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900</p> <p>Original FSC of USFDA valid till December 22,2022</p>		
67.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator : AD-VIII</p>	<p>Manufacturer: Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428</p> <p>Manufacturing sites: Medtronic Mexico S.de R.L de CV. Av. Paseo Cucupah 10510 El Lago tijuana Baja California MEXICO C.P 22210.</p> <p>MEDTRONIC PERFUSION SYSTEMS 18501 E Plaza Dr PARKER CO USA 80134</p> <p>KLUGE DESIGN INC 14150 Northdale Blvd Rogers, MN USA 55374</p> <p>KYOCERA Corporate ShingaYasu Plant 800 Ichimiyake Yasu-shi, Shiga JAPAN 520-2382</p> <p>Measurement SpecialitiesInc 1711 139th Ln NW Andover, MN USA 55304</p> <p>Vant Medical Inc 620 Watson SW GR, MI USA 49504</p> <p>Plexus Manufacturing SdnBhd</p>	<p>ACT Barcode Scanner ACTSC66, ACTSCC4 Shelf life: 3 years Class : B</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm has submitted copy of FSC of USFDA . Therefore, submit original valid and embassy attested FSC in the country . • The firm has submitted Copy of LOA provide notarized LOA or clarify. • The firm has not submitted ISO 13485 &FQA certificate therefore provide valid and notarized ISO 13485 & FQA • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit DOC • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.

		Bayan Lepas Free Industrial Zone, Phase II Bayan Lepas, Pulau, Pinang MALAYSIA 11900		
68.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Legal manufacturer: MEDTRONIC INC 710 Medtronic Pkwy Minneapolis, MN USA 55432 Manufacturing site: Medtronic, Inc (Minneapolis MN 55447) 3800 ANNAPOLIS LANE Minneapolis MN USA 5544	Cryoflex Clamp & Probe 60CM1 Class : D Shelf life: 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC of US FDA but name of the product not clear. Therefore, clarify and submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit DOC and notarized Design examination certificate • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
69.	M/s Medtronic Pakistan Private Limited Evaluator : AD-VIII	Legal Manufacturer: MEDTRONIC INC 710 Medtronic Pkwy Minneapolis MN USA 55432 Manufacturing facilities: MEDTRONIC PERFUSIONS SYSTEMS 7611 Northland Dr Minneapolis MN USA 55426 Medtronic Mexico S.de R.L de CV Av. Paseo Cucupah 10510 El Lago Tijuana Baja California Mexico C.P 22210 Medtronic PERFUSION SYSTEMS 108501 E Plaza Dr PARKER CO USA 80134	HMS Plus Instrument 30514, 30515, 30517, 30518, 30522, 30524, 30526, 30527, 30528 Shelf life: 3 years Class: B	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC of US FDA but name of the product not clear. Therefore, clarify and submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc. 


70.	<p>M/s Medtronic Pakistan Private Limited</p> <p>Evaluator : AD-VIII</p>	<p>Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA</p> <p>Manufacturing site: MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766</p> <p>Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432</p> <p>Plexus Manufacturing SdnBhd Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900</p>	<p>Transvene SVC Lead 6937-35 6937-52 6937-58 6937-110 Shelf life: 3 years Class: D</p>	<p>Deferred for submission of the following:</p> <ul style="list-style-type: none"> • The firm has not submitted FSC Therefore, submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit DOC and notarized Design examination certificate • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
71.	<p>M/s A One Traders, Makkah Tower, 3rd Floor, Room NO, 303, Namak Mandi Peshawar, Pakistan</p> <p>ELI: 00480 Evaluator: DD-III</p>	<p>Legal Manufacturer: Zhenjiang Bangli Medical Products Co. Limited, No. 118, Yuegui, South Road City West new District, Yongkang City, Zhejiang China</p> <p>FSC: China</p> <p>Valid till: 2021.12.18</p>	<p>Zinc oxide plaster cotton material Tape</p> <p>Codes & Sizes: 2.5cmx1.75m 2.5cmx2.75m 2.5cmx3.75m 2.5cmx4.75m 2.5cmx5.75m 2.5cmx6.75m</p> <p>Class: A</p> <p>Shelf Life: 3 year</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • Brand name not provided • original, valid & notarized agency agreement • declaration as per form-6 A must be on stamp paper duly notarized & signed & stamped by importer. • original & notarized Doc • essential principle checklist • approved labels of product • details of manufacturing process • stability studies data • notarized copy of production QMS(ISO 13485) certificate • notarized copy of full QA certificate • Specify the grouping of MDs on form 6-A • FSC duly attested by embassy • proper reference of the product in FSC with codes as it's not mentioned in FSC. • original FSC of reference country duly attested by embassy

				<ul style="list-style-type: none"> proper MRP(with unit currency) of the applied device
72.	M/s A One Traders, Makkah Tower, 3rd Floor, Room NO, 303, Namak Mandi Peshawar, Pakistan ELI: 00480 Evaluator: DD-III	Legal Manufacturer: Zhenjiang Bangli Medical Products Co. Limited, No. 118, Yuegui, South Road City West new District, Yongkang City, Zhejiang China FSC: China Valid till: 2021.12.18	Medioplast (Saniplast) Codes & Sizes: 2x3 or 4 size Class: A Shelf Life: 3 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> Brand name not provided original, valid & notarized agency agreement declaration as per form-6 A must be on stamp paper duly notarized& signed & stamped by importer. original & notarized Doc essential principle checklist approved labels of product details of manufacturing process stability studies data notarized copy of production QMS(ISO 13485) certificate notarized copy of full QA certificate Specify the grouping of MDs on form 6-A FSC duly attested by embassy proper reference of the product in FSC with codes as it's not mentioned in FSC. original FSC of reference country duly attested by embassy proper MRP(with unit currency) of the applied device
73.	M/s A One Traders, Makkah Tower, 3rd Floor, Room NO, 303, Namak Mandi Peshawar, Pakistan ELI: 00480 Evaluator: DD-III	Legal Manufacturer: Zhenjiang Bangli Medical Products Co. Limited, No. 118, Yuegui, South Road City West new District, Yongkang City, Zhejiang China FSC: China Valid till: 2021.12.18	Surgical Paper tape Codes & Sizes: 2cmx1, 2cmx3, 2cmx4, 2cmx5, 2cmx6 Class: A Shelf Life: 3 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> Brand name not provided original, valid & notarized agency agreement declaration as per form-6 A must be on stamp paper duly notarized& signed & stamped by importer. original & notarized Doc essential principle checklist approved labels of product details of manufacturing process stability studies data notarized copy of production QMS(ISO 13485) certificate notarized copy of full QA certificate Specify the grouping of MDs on form 6-A FSC duly attested by embassy proper reference of the product in FSC with codes as it's not mentioned in FSC. original FSC of reference country duly attested by embassy proper MRP(with unit currency) of the applied device


74.	M/s A One Traders, Makkah Tower, 3rd Floor, Room NO, 303, Namak Mandi Peshawar, Pakistan ELI: 00480 Evaluator: DD-III	Legal Manufacturer: Zhenjiang Bangli Medical Products Co. Limited, No. 118, Yuegui, South road City West new District, Yongkang City, Zhejiang China FSC: China Valid till: 2021.12.18	Non-woven wound dressing Codes & Sizes: As per FSC Class-A Shelf Life: 3 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Brand name not provided • original, valid & notarized agency agreement • declaration as per form-6 A must be on stamp paper duly notarized& signed & stamped by importer. • original & notarized Doc • essential principle checklist • approved labels of product • details of manufacturing process • stability studies data • notarized copy of production QMS(ISO 13485) certificate • notarized copy of full QA certificate • Specify the grouping of MDs on form 6-A • FSC duly attested by embassy • proper reference of the product in FSC with codes as it's not mentioned in FSC. • original FSC of reference country duly attested by embassy • proper MRP(with unit currency) of the applied device
75.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 371-P Evaluator: AD-III	Legal Manufacturer: AB Medical Inc, Korea, 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollannam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V-TUBE™ Plastic Tube Serum Separator Gel Tube (Evacuated Blood Collection Tube) Class-A Shelf life: 9 months Codes: 301502 311352	Deferred for the provision of following documents: <ul style="list-style-type: none"> • <u>Original and updated LOA, ISO 13485.</u> • <u>Original and attested FSC of any SRA country</u>
76.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 372-P Evaluator: AD-III	Legal Manufacturer: AB Medical Inc, Korea , 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollannam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V-TUBE™ Plastic Tube: HEPARIN TUBE (Evacuated Blood Collection Tube) Class-A Shelf life: 9 months Codes: 720605 710405 800905 820605 810405 701806 721506 711356	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original and updated LOA, ISO 13485. • Original and attested FSC of any SRA country 

77.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 373-P Evaluator: AD-III	<u>Legal Manufacturer:</u> AB Medical Inc, Korea , 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollannam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V-TUBE™ Plastic Tube: Serum Tube (Evacuated Blood Collection Tube) Class-A Shelf life: 9 months Codes: 300901 320601 310401	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original and updated LOA, ISO 13485. • Original and attested FSC of any SRA country
78.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 374-P Evaluator: AD-III	<u>Legal Manufacturer</u> Remel Inc, a subsidiary of Thermo Fisher Scientific USA, 12076 Santa Fe Trail Drive, Lenexa, Kansas, USA <u>Manufacturing Site:</u> Thermo Fisher Scientific LLC located at 275 Aiken Road Asheville, NC 288804 USA FDA U.S FOOD & DRUG Valid Till: 07.05.2021	Versa Trek Redox (Blood Culture Media) Class-A Shelf life: Provided Codes: 7102-44 7103-44 7106-44 7107-44 7110-44 7150-44 (Versatrek connector)	Deferred for the provision of following Documents: <ul style="list-style-type: none"> • Updated form 7A • Valid FSC • Valid ISO 13485 • Differential fee of Rs.20,000/- as the device is approved in Class-B.
79.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 375-P Evaluator: AD-III	<u>Legal Manufacturer:</u> AB Medical Inc, Korea , 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollannam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V-TUBE™ Plastic Tube: EDTA TUBE (Evacuated Blood Collection Tube) Class-A Shelf life: 9 months Codes: 500903, 520603, 510403, 510303, 400903, 420603, 410403, 410303, 421504, 411354	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original and updated LOA, ISO 13485. • Original and attested FSC of any SRA country
80.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 376-P Evaluator: AD-III	<u>Legal Manufacturer:</u> AB Medical Inc, Korea , 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollannam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V- TUBE™ Plastic Tube: Glucose Tube (Evacuated Blood Collection Tube) Class-A Shelf life: 9 months Code: 910408	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original and updated LOA, ISO 13485. • Original and attested FSC of any SRA country 

81.	M/s Vantage Technologies, House NO. 251, Street No, 11-B, Phase-1 Ghouri, Town, Islamabad. ELI: 00219 377-P Evaluator: AD-III	Legal Manufacturer: AB Medical Inc, Korea , 6-24 Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollanam-do, (57248) Korea FSC: Korea Date of issue: 2019.10.28 ARTG Entry: 323191	V-Tube TM Plastic Tube, Citrate Tube (Evacuated Blood Collection tube) Class-A Shelf Life: Codes: 630277 630187	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Original and updated LOA, ISO 13485. • Original and attested FSC of any SRA country
82.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Legal Owner: Medtronic B.V. Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS Manufacturing facility: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine CA 92618 USA	Onyx TM Syringe-Catheter Interface Adapter (SCIFA) 103-1207 Class: A Shelf life : 3 years	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has submitted copy of FSC Therefore, submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
83.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	Carelink TM Personal Softwear MMT-7350 Class: A Shelf life : NA	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has not submitted FSC Therefore, submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Submit DOC • Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
84.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	Carelink TM System MMT- 7333 Class:A Shelf life: NA	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has not submitted FSC Therefore, submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP

				<ul style="list-style-type: none"> • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc. • Name of the product on form-6a is different then the applied product on letter.
85.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	Charger MMT-7715 Class: A Shelf life: NA	Deferred for submission of the following: <ul style="list-style-type: none"> • The firm has not submitted FSC Therefore, submit embassy attested original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Submit DOC • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc.
86.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus Manufacturing SdinBhd Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900	Patient Connector 24967 Shelf life: 5 years Class: A COPY of USFDA FSC valid till June 2022	Deferred for submission of the following: <ul style="list-style-type: none"> • Fee not submitted for this product therefore submit RS 5000/- or clarify. • The firm has submitted valid and embassy attested FSC However the FSC is now expired Therefore, submit original and valid FSC • The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA • LOA copy provided. Submit notarized LOA or clarify • The firm has not submitted EPSP, therefore provide EPSP • Submit DOC • Stability studies not provided therefore, submit stability studies. • Submit undertaking on the stamp paper for correct ness and genuiness of the documents etc. 
87.	M/s Medtronic Pakistan Private Limited	Manufacturer: Medtronic MiniMed 18000 Devonshire	Tester MMT-7736WW, MMT-7736L	Deferred for submission of the following:

	Evaluator: AD-VIII	Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000	Shelf life: NA Class: A	<ul style="list-style-type: none"> The firm has submitted expired copy of FSC Therefore, submit original and valid embassy attested FSC The firm has not provided ISO 13485 & has provided copy of FQA therefore provide notarized ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Submit DOC Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
88.	M/s Medtronic Pakistan Private Limited Evaluator: AD- VIII	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA MEDTRONIC INC 8200 Coral Sea Street NE Mounds View MN USA 55112 MEDTRONIC PUERTO RICO OPERATIONS CO. VILLALBA RD.149 KM 56.3 Call Box 6001 Villalba PR USA 00766 Medtronic Inc 7000 Central Ave N.E Minneapolis MN USA 55432 Plexus Manufacturing SdnBhd, Bayan Lepas Free Industrial Zone, Phase II. Bayan LepasPulau Pinang MALAYSIA 11900	Patient Connector 24967 Shelf life: 2 years Class: A	Deferred for submission of the following: <ul style="list-style-type: none"> Fee not submitted for this product therefore submit RS 5000/- or clarify. The firm has submitted valid and embassy attested FSC However the FSC is now expired Therefore, submit original and valid FSC The firm has neither provided copy of ISO 13485 & nor FQA therefore provide notarized ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Submit DOC Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
89.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Manufacturer: M/s Medtronic Inc. (Mounds View) 8200 Coral Sea Street NE MN 55112 Mounds View, USA Manufacturing site:	Patient Cables 5492A, 5492AL, 5492VL, 5492VL Shelf life: 3 years Class: A USFDA FSC valid till December 2022	Deferred for submission of the following: <ul style="list-style-type: none"> Fee submitted for patient reader for smartsync and the brand name on the Form6A is Patient Cables, therefore submit RS 5000/- or clarify The firm has submitted valid and embassy attested FSC However the FSC is now expired Therefore, submit original and valid FSC

		NEW DEANTRONICS TAIWAN LTD. 12F No.51 Sec.4 Zhongyang Rd. Tucheng Dist. New Taipei City, New Taipei TAIWAN 236		<ul style="list-style-type: none"> The firm has provided expired copy of ISO 13485 & copy of FQA therefore provide notarized ISO 13485 & FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Submit DOC Stability studies not provided therefore, submit stability studies. Submit undertaking on the stamp paper for correctness and genuineness of the documents etc.
90.	M/s Medtronic Pakistan Private Limited Evaluator: AD-VIII	Legal Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge CA, 91325 USA Ph. 00 1 763-514-4000 Contract manufacturer SMC costa rica Div SRL, Costa Rica Original US FDA FSC valid till April 2021	Minimed Quick-Serter® 305QS 305PS Shelf Life: 1 years Class: A	Deferred for submission of the following: <ul style="list-style-type: none"> The firm has submitted expired, original and embassy attested FSC Therefore, submit original and valid and embassy attested FSC of USFDA The firm has submitted notarized and valid ISO 13485 provided, now expired The firm has not provided FQA therefore provide notarized FQA LOA copy provided. Submit notarized LOA or clarify The firm has not submitted EPSP, therefore provide EPSP Stability studies not provided therefore, submit stability studies.
91.	M/s DKT Pakistan (Pvt) Ltd. RJ Building, 4 th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area, Phase V, DHA Karachi. (ELI-00515) 1220 Evaluator: AD-III	Legal Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited. 789/ 139 Moo 1 Pinthong Industrial estate Nonkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand validity 05-06-2024	Josh Condom (Male Latex Condom) Class-C Shelf life: 5 years Codes: JOSH Menthol 3's JOSH Menthol 4's JOSH Strawberry 3's JOSH Strawberry 4's	The board deferred the case for further deliberation 
92.	M/s. Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New	Legal Manufacturer: M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy FSC Italy issued on 17-6-2019	Delta Ven 2 (IV dual entry catheter with injection valve) Codes as per FSC Italy dated 17-06-2019	The board deferred the case for the provision of clarification from M/s Intra Health, Karachi that whether they are still the authorized distributor of the said manufacturer M/s. DELTA MED S.p.A Via Guido Rossa, 20, 46019 Viadana (MN), Italy or the manufacture has terminated the agreement for the above mentioned product at serial No. 43.

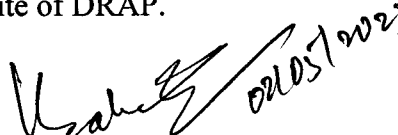
	Abadi Morgah, Rawalpindi. Evaluator AD-IV [886-P]		Class B Shelf life: 5 years	The firm may appear before Board for personal hearing in the forthcoming meeting.
93.	M/s Medicamp International Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah Rawalpindi, Pakistan ELI: 00200. Evaluator: AD-VI -1934-	Legal Manufacturer: •Kollsut International Inc. 1763 NE 162nd Street, North Miami Beach, FLS 33162, USA •FOOSIN MEDICAL SUPPLIES Imc Ltd No. 20 Xingshan rd, Weihai Torch Hi- Tech Science Park, Shandong P.R China, 264210 FSC: FDA. U.S FOOD & DRUG Valid till: 09.03.2022.	RADIK TM (Sterilized Absorbable Polyglactin Acid 910 Suture) Class-D Shelf Life: 5 years Codes are not provided.	The board deferred the case for the site verification of China as the site is not mentioned on FSC of US FDA
94.	M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi ELI-00091 Evaluator AD-VIII	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Breathing Circuits (Breathing Circuits) Class-B Shelf life: 5 years Codes as per FSC	Deferred for the provision of the following: <ul style="list-style-type: none">• Justify the system under the MDR 2017 and provide product brochure• Clarify the stability studies as finished product stability not clear• The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself. Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtroic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Calrify covedian & Mallinckrod DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.
95.	M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi ELI-00091	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037	DAR Breathing Filters (filters/ HMEs) Class-B Shelf life: 5 years Codes as per FSC	Deferred for the provision of the following: <ul style="list-style-type: none">• Justify the system under the MDR 2017 and provide product brochure• Clarify the stability studies as finished product stability not clear• The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself.

	Evaluator: AD-VIII	MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022		Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtronic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Clarify covidian & Mallinckrodt DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.
96.	M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi ELI-00091 Evaluator : AD-VIII	M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrodt DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Airway System (Guedel airways) Class-B Shelf life: 5 years Codes as per FSC .	Deferred for the provision of the following: <ul style="list-style-type: none"> • Justify the system under the MDR 2017 and provide product brochure • Clarify the stability studies as finished product stability not clear • The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself. Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtronic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Clarify covidian & Mallinckrodt DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.
97.	M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi ELI-00091 Evaluator: AD-VIII	M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrodt DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Breathing System kit () Class-B Shelf life: 5 years Codes as per FSC	Deferred for the provision of the following: <ul style="list-style-type: none"> • Justify the system under the MDR 2017 and provide product brochure • Clarify the stability studies as finished product stability not clear • The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself. Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtronic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Clarify covidian & Mallinckrodt DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.
98.	M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8,	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site:	DAR Airway Management kits Class-B Shelf life: 5 years Codes as per FSC	Deferred for the provision of the following: <ul style="list-style-type: none"> • Justify the system under the MDR 2017 and provide product brochure • Clarify the stability studies as finished product stability not clear

	<p>KMCHS, Karachi ELI-00091</p> <p>Evaluator : AD-VIII</p>	<p>Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022</p>		<ul style="list-style-type: none"> • The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself. Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtroic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Calrify covedian & Mallinckrod DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.
99.	<p>M/s Popular International (Pvt) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi ELI-00091</p> <p>Evaluator: AD-VIII</p>	<p>Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022</p>	<p>DAR Breathing system ROH Class-B Shelf life: 5 years Codes as per FSC</p>	<p>Deferred for the provision of the following:</p> <ul style="list-style-type: none"> • Justify the system under the MDR 2017 and provide product brochure • Clarify the stability studies as finished product stability not clear • The firm has provided original LOA where in popular international is authorized by the Medtronic Meta FZ LLC Dubai and not by the MEDTROINC USA directly. Medtronic is also operating in Pakistan by itself. Therefore Provide notarized authorization letter of MEDTRONIC USA to Medtroic Meta FZ LLC Dubai that they can authorize Popular international, pakistan for their products. Calrify covedian & Mallinckrod DAR link with Medtronic USA as well. Clarification is required about the codes need to be registered.

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

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


(BABAR KHAN)
 Additional Director (MDMC)/
 Secretary MDB