Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
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DECISIONS OF THE 34TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 25-06-2021

Item No.I. **APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES**

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge	Decision:
1.	M/s Al-Technique Corporation of Pakistan Ltd.	Plot No.11, Sufi Tabassum Road, H-8/1, Islamabad	Mr. Fateh Muhammad (Production Incharge) Biomedical Engineer	Mr. Shariq Sibtain (QC Incharge) Biomedical Engineer	**The Board discussed and approved the grant of Establishment License to M/s Al-Technique Corporation of Pakistan Ltd, Plot No.11, Sufi Tabassum Road, H-8/1, Islamabad for manufacturing of medical devices i.e. ventilators.**
2.	M/s National Engineering and Scientific Commission of Pakistan	Opposite EME College near Golra More, Peshawar Road, Rawalpindi.	Muhammad Amjad Bhatti (Production Incharge) BS Biomedical	Mr. Umair Hammad (QC Incharge) BS Biomedical	**The Board discussed and approved the grant of Establishment License to manufacture medicl devices to M/s National Engineering and Scientific Commission of Pakistan, Opposite EME College, near Golra More, Peshawar Road, Rawalpindi for manufacturing of medical devices i.e. ventilators.**
3.	M/s Malik Auto & Agriculture Industires (Pvt) Ltd.	Guard Filter Factory, near Mumtaz Bahktawar Hospital, Wahdat Road,	Not mentioned	Not mentioned	**The Board decided to re-inspect M/s Malik Auto & Agriculture Industires (Pvt) Ltd., Lahore and Director MDMC Division will constitute new panel of**

		Lahore.			**inspectors.**
4.	M/s Kamtex Industries	44-KM, G.T Road, Kamoke, Gujranwala	Mrs. Sana Tahir (Production Incharge) Pharm-D	Mr. Khubaib Tahir (QC Incharge) Pharm-D	**Based on the report of the panel, the Board decided to issue show cause notice and provide opportunity of personal hearing to the company / firm for cancellation of license.**

Item No.II. **REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE (Form 7) (VENTILATORS)**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s NESCOM, Opposite EME College, Golra More, Peshawar Road, Rawalpindi (ELM- Applied)	PAKVENT-1 (ICU Ventilator) Class C Claimed Shelf Life: 10 Years. Rs.20,000/-	PAKVENT-1 has been manufactured for ICU patients and can also be used for COVID-19 patients in isolation centers with O2 cylinder (if required)	**Approved.**
2.	M/s Al-Technique Corporation of Pakistan Ltd., Plot No.11, Sufi Tabassum Road, H-8/1, Islamabad (ELM-Applied)	i-Live (ICU Ventilator) Class C Shelf Life: N/A Rs.25,000/-	Indigenous Ventilator for ICU adult Subjects	**Approved.**

Item No. III. **APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.**

S.No	Name of Establishment	Director/Proprietor /partners	Cold Chain (Yes/No)	Decision
1.	M/s. Life Line Distributer, Street 1, Gondal plaza, Model Town, Mandi	Mr. Kashif Mahmood	No	**Approved** for storage of room temperature medical devices.

	Bahuddin.			
2.	M/s SA Corporations, 44-Commercial Building, Shahra-e-quaid-e-azam, The mall Lahore.	Syed Muhammad Haris	No	**Rejected,** as the firm has shifted their office and godown location at Office No.3, Al-Maraj Arcade, Chowk Choburji, Lahore after constitution of panel. The decision is in line with the MDB 32nd meeting, where it ws decided to reject the applications for grant of establishment licence to import medical devices if the constituted panel visits at the given address but the firm has changed their address and directed such firms to apply afresh for grant of establishment license to import medical devices with new addresses.
3.	M/s Usman Enterprise, Plot No. A/116, PH-I, S.I.T.E., Super Highway, Karachi	Taimur Usman	No	**Approved** for storage of non cold chain medical devices.
4.	M/s. Saakh Technologies Private Ltd, SB33 Chayell Apartments Ground Floor, Gulistan- e-Johar, Block 11, Near Kamran Chorangi, Karachi.	Syed Mustafa Hussain Kazmi Nida Moughal Mr.Shakeel Khaliq Mr.Masood Ahmed	No	**Approved** for storage of non cold chain medical devices.
5.	M/s Mabtech, Mezzanine 2, 10-C, 33rd Street Tauheed Commercial, Phase VI, DHA, Karachi.	Muhammad Ali Basar	No	**Approved** for storage of non cold chain medical devices.
6.	M/s. Maxitech Pharma (Pvt) Ltd, E-178, S.I.T.E, Super Highway Phase-II, Karachi	Mr. Nadir Hassan Khan Mr. Zeeshan Hassan Khan	No	**Approved** for storage of non cold chain medical devices.
7.	M/s. MKJ Associates, G-12, JK Plaza, Universcity Road, Peshawar. **Godwon**: G-11, Jk Universcity Road, Peshawar	Muhammad Kashif Jamal	No	**Approved** for storage of non cold chain medical devices.
8.	M/s. Altimi System (Pvt) Ltd, D-92/1, Sharah-e-Attar, Block	Khalil Memon Syed Tanveer	Yes	**Approved** for storage of room temperature and cold chain medical devices.

	4, Scheme No. 5, Clifton, Karachi	Hussain Musvi Abdul Rasheed Awan		
9.	M/s Raza Enterprises, 19-C, Karachi Market Khyber Bazar Peshawar. **Godown Address:** Office No.MF-6, M Floor, Pak Medical Centre, Khyber Bazar, Peshawar.	Mr. Raza Yousafzai Mr. Dost Muhammad	No	**Approved** for storage of non cold chain medical devices.
10.	M/s Combine Medical System, Showroom No. 29, Ground Floor, Karachi Market, Khyber Bazar, Peshawar.	Mr. Khurram Shahzad	No	**Approved** for storage of non cold chain medical devices.
11.	M/s. Medifa Enterprises, TF-185, Deans Trade Center Peshawar Cantt	Fareed Ullah	No	**Approved** for storage of non cold chain medical devices.
12.	M/s Fabnos Traders (Pvt) Ltd, Building # 26-,rd Floor, Touheed Commercial Area, 26th Street, Phase V DHA, Karachi. **Godown Address:** Plot No.8-C, ShopNo.02, Badar Commercial Area, DHA, Karachi.	MR. Burhanuddin Banday Mr. Muhammad Afzal Mr. Muhammad Awais Mr. Muhammad Zeeshan	No	**Approved** for storage of non cold chain medical devices.
13.	M/s Mercy Enterprises, Office No. 532, 5th Floor Pak Medical Center Khyber Bazar, Peshawar.	Ashfaq Ahmed	No	**Rejected** due to change of address of the warehouse.
14.	M/s Meer Medicine & Surgical, Office No. A-24, Al-Mansoor Medicine Market Namak Mandi, Peshawar.	Naveed Iqbal	No	**Approved** for storage of non cold chain medical devices.

	Godown Address: Office No.08, Ground Floor, Chamkani Tower, Dalazak Road, Peshawar.			
15.	M/s Alkhair Traders, Phool Ghulab Road Ashraf Plaza Shop No. 14, Opp, Gate No. 2 Ayub Medical complex Abbotabad.	Yasir Ur Rehman	No	**Approved** for storage of non cold chain medical devices.
16.	M/s. Kapai Pharma (Pvt) Ltd, Suit No. 108, Plot G-7, 1st Floor The plaza, Khayban-e-Iqbal Block 9, Clifton Karachi	Khalil Memon Dr. Ghulam Murtaza Randhawa Syed Shan Haider Musavi	No	**Approved** for storage of non cold chain medical devices.

Item No.IV. APPLICATIONS FOR SITE VERIFICATION FOR ESTABLISHMENT OF A MANUFACTURING UNIT OF MEDICAL DEVICES.

Case. No.1:

Decision: The Board approved the site for establishment of manufacturing unit of medical devices of M/s Nizam Sons (Pvt) Limited, located at Toorabad Daska Road, Sialkot.

Item No.V. TRANSFER OF REGISTRATION OF IMPORTED MEDICAL DEVICES.

Sr. No	Company Name	Manufacturer Name	Medical Device Name	Registration No.	Date of Issuance
1	M/s Pharma Consultant Pakistan (Pvt) Ltd, Lahore.	M/s Sorin Group Italia S.r.l.,Via Crescentino sn, 13040 Saluggia (VC) Italy	Carbomedics Standard Mitral	MDIR-0000472	26-06-19
2	-do-	-do-	Carbomedics Standard Aortic	MDIR-0000473	26-06-19

3	-do-	-do-	Carbomedics Annuloflo	MDIR-0000475	26-06-19
4	-do-	-do-	Carbomedics Carbo-Seal	MDIR-0000476	26-06-19
5	-do-	-do-	Pericarbon More-modMitral	MDIR-0000477	26-06-19
6	-do-	-do-	Memo 3D	MDIR-0000478	26-06-19
7	-do-	-do-	Inspire (Adult and small Oxygenators)	MDIR-0000745	1/10/2019
8	-do-	-do-	DIDECO D902 LILLIPUT 2 (Infant-Newborn Oxygenators)	MDIR-0000746	1/10/2019
9	-do-	-do-	DIDECO D901 LILLIPUT 1 (Infant-Newborn Oxygenators)	MDIR-0000747	1/10/2019
10		M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA	LivaNova Venous Cardiopulmonary Bypass Cannulae	MDIR-0000762	1/10/2019
11	-do-	-do-	LivaNova Coronary Sinus Cannulae	MDIR-0000764	1/10/2019
12	-do-	-do-	LivaNova Arterial Cardiopulmonary Bypass Cannulae	MDIR-0000765	1/10/2019
13	-do-	-do-	LivaNova Cardioplegia Cannulae VC	MDIR-0000766	1/10/2019

14		M/s. Sorin Group Italia S.r.I Via Benigno Crespi 17, 20159 Milano (MI), Italy M/s Via statale 12 Nored 86, 41037 Mirandola(MO) Italy	DIDECO PERFUSION TUBING SYSTEMS (Perfusion Tubing System)	MDIR-0000796	8/10/2019
15		M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy	Carbomedics CarboSeal Valsalva (Aortovalvular Prostheses)	MDIR-0000921	11/20/2019
16	-do-	-do-	Memo 3D ReChord	MDIR-0000922	11/20/2019
17	-do-	-do-	Carbomedics Annuloflex (Annuloplasty Ring)	MDIR-0000923	11/20/2019
18	-do-	M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy M/s Sorin Group Italia S.r.I, Via statale 12 Nored 86, 41037 Mirandola(MO) Italy	SORIN Venous Femoral Cannulae	MDIR-0000929	11/20/2019
19	-do-	-do-	SORIN Paediatric Arterial Cannulae	MDIR-0000930	11/20/2019
20	-do-	-do-	SORIN Arterial Femoral	MDIR-0000932	11/20/2019

			Cannulae		
21	-do-	M/s. LivaNova USA, Inc 14401 West 65th Way Arvada, CO 80004 USA	LivaNova Ventricular Vent Catheters	MDIR-0001273	2/12/2020

Decision: The Board cancelled the products of M/s Pharma Consultant from serial 1 to 21 in para 1 above and asked M/s Vertex to make fresh applications of the products they want to market in Pakistan.

Item No.VI. POST LICENSE VARIATIONS.

Case No.1.

M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garen, Plot No.3, MCHS Soceity, Shaheed-e-Milat Road, Karachi has requested for approval of change of their qualified person/technical person in their ELI-00274 issued on 19-10-2018 as per detail given below:-

Existing Qualified Technical Person	Proposed Qualified Technical Person
Mr. Abdul Quddoos, House No.279, G Area Koangi 5-1/2, Karachi. CNIC No.42201-6673166-1	Dr. Mahrukh Ali, House No.101-A, Block-1, Mohallah Sharifabad, FB Area, Karachi Central. CNIC No.17201-9673701-8 Pharm-D

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-

Previous Qualified Technical Person	New Approved QualifiedTechnical Person
Mr. Abdul Quddoos, House No.279, G Area Koangi 5-1/2, Karachi. CNIC No.42201-6673166-1	**Dr. Mahrukh Ali, House No.101-A, Block-1, Mohallah Sharifabad, FB Area, Karachi Central. CNIC No.17201-9673701-8 Pharm-D**

Case No.2.

M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi has requested for approval of change of their qualified person/technical person in their ELI-00090 issued on 03-08-2018 as per detail given below:-

Existing Qualified Technical Person	Proposed Qualified Technical Person
Mr. Faisal Iqbal, Flat No.A-89, ZamanAbad, Landhi # 4, Malir, Karachi. CNIC No.45102-1423144-1	Ms. Rida Khalid Rao, Flat No.34-1, Block-16, Mohallah UK Square, F.BArea Karachi Central. CNIC No.42101-5831987-2 Pharm-D

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-

Previous QualifiedTechnical Person	New Approved QualifiedTechnical Person
Mr. Faisal Iqbal, Flat No.A-89, ZamanAbad, Landhi # 4, Malir, Karachi. CNIC No.45102-1423144-1	**Ms. Rida Khalid Rao, Flat No.34-1, Block-16, Mohallah UK Square, F.B Area Karachi Central. CNIC No.42101-5831987-2 Pharm-D**

Case No.3.

M/s Medichem Enterprises, 331/C, Block No.3, DMCH Society,Alamgir Road, Karachi has requested for approval of change of their qualified person/technical person in their ELI-00252 issued on 19-10-2018 as per detail given below:-

Existing Qualified Technical Person	Proposed Qualified Technical Person
Mr. Muhammad Ali Qasmi, house No.A-5, Block 9, Dastagir Colony, FB Area, Karachi. CNIC No. 42101-1898160-1	Mr. Mohammad Saleem, House No.32-IF, MohallahBhar Ghari, Khairpur, Sindh. CNIC No.45203-6190391-9 Pharm-D

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-

Previous QualifiedTechnical Person	New Approved QualifiedTechnical Person
Mr. Muhammad Ali Qasmi, house No.A-5, Block 9, Dastagir Colony, FB Area, Karachi. CNIC No. 42101-1898160-1	Mr. Mohammad Saleem, House No.32-IF, MohallahBhar Ghari, Khairpur, Sindh. CNIC No.45203-6190391-9 Pharm-D

Item No.VII. POST REGISTRATION VARIATIONS (AD-III).

Case No.1.

M/s Abbott Laboratories (Pakistan) Ltd Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi has requested for approval of change of brand name and manufacturer name for their already registered medical devices for import as per detail given below. They have further stated that product name will also be changed: -

S.No.	Regn.No.	Existing Brand Name	Proposed brand name	Existing Name and Address of Manufacturer	Proposed Name and Address of Manufacturer
1.	MDIR-0000347	SD BIOLINE HCV	BIOLINE ™ HCV	M/s Standard Diagnostic Inc, 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.	M/s Abbott Diagnostic Korea Inc, 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099 Republic of Korea.
2.	MDIR-0000348	SD BIOLINE HIV 1/2 3.0	BIOLINE ™ HIV 1/2 3.0	-do-	-do-
3.	MDIR-0000349	SD BIOLINE HIV/ Syphilis Duo	BIOLINE ™ HIV/ Syphilis Duo	-do-	-do-

Decision: The Board acceded to the request of the firm /company and approved the change of brand name and manufacturer name of their following registered medical devices as mentioned below :-

S.No.	Regn.No.	Previous Brand Name	New Approved brand name	Previous Name and Address of Manufacturer	New Approved Name and Address of Manufacturer
1.	**MDIR-0000347**	**SD BIOLINE HCV**	**BIOLINE ™ HCV**	**M/s Standard Diagnostic Inc, 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.**	**M/s Abbott Diagnostic Korea Inc, 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099 Republic of Korea.**
2.	**MDIR-0000348**	**SD BIOLINE HIV 1/2 3.0**	**BIOLINE ™ HIV 1/2 3.0**	**-do-**	**-do-**
3.	**MDIR-0000349**	**SD BIOLINE HIV/**	**BIOLINE ™ HIV/ Syphilis**	**-do-**	**-do-**

		Syphilis Duo	**Duo**		

Case No.2.

M/s Abbott Laboratories (Pakistan) Ltd Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi has requested for approval of change of manufacturer for their already registered medical devices for import as per detail given below. They have further stated that product name and catalogue will remain same: -

S.No.	Product Name	Regn. No.	Existing Name and Address of Manufacturer	Proposed Name and Address of Manufacturer
1.	m-PIMA HIV-1/2 VL Cartridge System (Ref:270150050)	MDIR-0002437	M/s Alere Technologies GmbH Loebstedter Starrse 103-105, 07749 Jena, Germany.	M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.

Decision: The Board acceded to the request of the firm /company and approved the change of manufacturer of their following registered medical devices as mentioned below:-

S.No.	Product Name	Regn. No.	Previous Name and Address of Manufacturer	New Approved Name and Address of Manufacturer
1.	**m-PIMA HIV-1/2 VL Cartridge System (Ref:270150050)**	**MDIR-0002437**	**M/s Alere Technologies GmbH Loebstedter Starrse 103-105, 07749 Jena, Germany.**	**M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.**

Case No.3.

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, Karachihas requested for correction in address of manufacturer and description of their following registered medical devices for import (typographical mistake) as per detail given below:-

S.No.	Red No.	Name and ddescription of Medical Device Mentioned on regitration lettter.	Correction required in name and description of medical device	Address of manufacturing site mentioned on registration letter	Correction required in manufacturing site address
1.	MDIR-0002227	Karmi Blood Bag Double 500ml,Triple	Karmi Blood Bag Double 250ml	M/s Kawasumi Laboratories (Thailand) Co.Ltd, 48 MU 8 Ratchasima-Chok Chai	M/s Kawasumi Laboratories (Thailand) Co. Ltd (**KORAT)**, 48 MU 8,

		500ml with safety accessories.	500ml Double 250ml with Safety Accessories. 500ml with Safety Accessories.	Road, TambonTha Ang,AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand	Ratchasima-Chok Chai Road, TambonTha Ang,AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand

Decision: The Board acceded to the request of the firm /company and approved the corrections in brand name, description and manufaturing site of already registered medical device as per detail mentioned below:-

S.No.	Regn. No.	Previous Name and ddescription of Medical Device	New corrected name and description of medical device	Previous Name and Address of manufacturing site	New Approved Name and Address of manufacturing site
1.	**MDIR-0002227**	**Karmi Blood Bag Double 500ml,Triple 500ml with safety accessories.**	**Karmi Blood Bag Double 250ml 500ml Double 250ml with Safety Accessories. 500ml with Safety Accessories.**	**M/s Kawasumi Laboratories (Thailand) Co.Ltd, 48 MU 8 Ratchasima-Chok Chai Road, TambonTha Ang,AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand**	**M/s Kawasumi Laboratories (Thailand) Co. Ltd (KORAT), 48 MU 8, Ratchasima-Chok Chai Road, TambonTha Ang,AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand**

Case No.4.

M/s Johnson & Johnson Pakistan (Pvt) Limited, Office No.806, 8th Floor Horizon Towers, Block 3, Scheme No.5, Clifton, Karachi has requested for grant of approval of additional sizes of their following registered imported medical device as per detail mentioned below: -

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0001433	Vicryl (Polyglactin 910)Suture	J434H, J442H, J544G, W9105, W9221, W9391, W9442, W9443, W9444, W9506T, W9510T, W9511T, W9521T, W9522T, W9552, W9560, W9561, W9565, W9567, W9580T, W9581T, W9582T, W9718, W9719,	W9500T, W9514T, W9531T, W9566, W9575, W9577, W9831T, W9832T, J979H, JB977H, W9982, W9981 J212H, J213H, J214H, J341H, J381H, J663H, J664H, J978H, J979H, JB977H

			W9828	
	MDIR-0001436	PROLENE Polypropylene Suture(Polypropylene,Monofilament, Sterile,Synthetic, NonAbsorbable Surgical Suture)	8434H, 8435H, 8521H, 8522H, 8556H, 8623H, 8632G, 8634G, 8635G, 8702H, 8706H, 8833H, EP8704H, W1713, W2777, W525, W527, W621, W8003T, W8005T, W8006T, W8007T, W8010T, W8014T, W8020T, W8021T, W8025T, W8026T, W8101, W8305, W8307, W8310, W8316, W8329, W8330, W8340, W8430, W8522, W8525, W8549, W8556, W8557, W8558, W8571, W8597, W8623, W8683, W8689, W8697, W8702, W8703, W8704, W8706, W8707, W8710, W8721, W8731, W8761, W8802, W8803, W8807, W8831, W8840, W8937, W8977, 8357H, 8634H, W8430G, W8307G, W8731G, W8761G, 8686H	1771G, 2790G, 2793G, 2794G, 8305H, 8307H, 8325H, 8356H, 8411H, 8412H, 8422H, 8423H, 8424H, 8433H, 8454H, 8455H, 8523H, 8526H, 8528H, 8534H, 8556G, 8557H, 8558H, 8559H, 8580H, 8610H, 8622H, 8630G, 8631G, 8632H, 8635H, 8636G, 8636H, 8649H, 8661G, 8663G, 8680G, 8681G, 8681H, 8682G, 8682H, 8683G, 8687H, 8689H, 8695H, 8696G, 8698H, 8699G, 8699H, 8711H, 8717H, 8726H, 8735H, 8741H,8766H, ,8805H, 8806H, 8825G, 8831H, 8832H, 8870H, 8871H, 8881H, 8890H, 8934H, 8935H, 8975H, 8977H, 8978H, EH7167H, EH7257H, EH7691H, EH7756H, EH7758H, EH7764H, EP8702H, EP8703H, EP8704SLH, EP8706H, EP8708H, EP8709H, EP8711H, EP8726H, EP8729H, EP8730H, EP8732H, ,EP8734H, P8735H, EP8740H, EP8741H, EP8747H, EP8755H, EP8766H, EP8805H, EP8807H, EP8812H, EPH7477H, EPH8710H, EPH8716H, EPH8720H, EPH8725H, EPH8890H, EPH9702H, EPM8737, F1801H, F1821, F1830, F1840H, F1861H, F2831H, F2832H, F2845, F2847H, F2854H, F2858H, F2859H, F2860H, M8203, M8752, M8754, M8805, P8935H, W1710, W295, W295H, W486, W486G, W523, W534G, W538G, W742, W742G, W753G, W8025H, W8304, W8304G, W8321, W8440G, W8450, W8450G, W8475G, W8521, W8526, W8664, W8684G, W8702S, W8711, W8712, W8718G, W8725G, W8770G, W8801, W8814, W8830, W8843,

				W8844, W8845, W8850, W8852, W8868T, W8870T, W8871T, W8872T, W8881T, W8884T, W8890, W8976, W8998G, W982, W982G

Decision: The Board approved the additional sizes of above mentioned medical devices as mentioned above against each.

Item No.VIII. APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.

Decision: The MDB approved and ratified the issuance of Import Permit (Form-10) to M/s DRK Pharma Solution (Pvt) Limited, 1st Floor, Building No.2, The Enterprise 15 KM Multan Road, Lahore to import 10,000 SARS-CoV-2 IgM/IgG Antibody detection kits for the purpose of clinical investigation, examination, test or analysis at clinical trial sites and clinical labs, under rule 22(1) of Medical Devices Rules, 2017.

Item No.IX. CLARIFICATION REGARDING SOLE AGENCY AGREEMENT.

It is submitted that following products applied by M/s DKT Pakistan (Pvt)Limited, 37-C, RJ Building, 2nd Stadium Lane, Phase-V, Defense Housinng Authority, Karachi were placed before the MDB in its 24th meeting held on 19-11-2020 and were deferred as mentioned against each:-

1.	M/s DKT Pakistan Pvt. Ltd, 37-C RJ Building, 2nd Stadium Lane, Phase V, Defence Housing Authority, 75500 Karachi Pakistan. (ELI-	Legal Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited. 49, 49/ 1 LaemChabang Industrial Estate, Moo 5 , Sukhumvit Road, ThungSukhlaSubdistrict, Si Racha District, Chon Buri Province 20230.	Condom Prudence Condom Condom Prudence Condom Class C Shelf Life: 5 Years	Buttercup condoms are an effective from of contraception. If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many others sexullay transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	Deferred for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore.

2.	-do-	**Legal Manufacturer: M/s** Thai Nippon Rubber Industry Public Company Limited. LaemChabang Industrial Estate 49-49/ 1 Moo 5 , Sukhumvit Road, ThungSukhlaSubdistric t, Si Racha District, Chon Buri Province 20230.	Condom Buttercup Condom Buttercup Class C Shelf Life: 5 Years	Buttercup condoms are an effective from of contraception. If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many others sexullay transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	**Deferred** for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore.
3.	-do-	**Legal Manufacturer:** M/s Thai Nippon Rubber Industry Public Company Limited. LaemChabang Industrial Estate 49-49/ 1 Moo 5 , Sukhumvit Road, ThungSukhlaSubdistric t, Si Racha District, Chon Buri Province 20230.	Condom UniquePull Condom UniquePull Class C Shelf Life: 5 Years	Buttercup condoms are an effective from of contraception. If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many others sexullay transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	**Deferred** for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore

Decision: The Board discussed and decided to call the representatives of both the firms for personal hearing in the next MDB meeting.

Item No.XII. <u>APPLICATION FOR REGISTRATION OF MEDICAL DEVICE FOR LOCAL MANUFACTURE.</u>

M/s National Radio and Telecommunication Corporation,T& T Complex,Haripur has applied for registration of medial device namely **SAFE-VENT VS-100** for local manufacture.

Decision: The Board deferred the registration of ventilator since the technical evaluation report by Pakistan Engineering Council is still to be provided.

Item No.XIII. <u>ACTION PLAN FOR INJECTION SAFETY TO BE IMPLEMENTED BY DRAP.</u>

Decision: Board after thorough deliberations, in the larger public interest under clause (c) of sub-rule 15 of rule 19 of Medical Devices Rules, 2017, hereby decided to issue Show Cause Notice to all manufacturers of conventional disposable syringes(2. 2.5, 3 & 5ml) (List at Annex-I) under rule 20 of the said rules, that why not your enclosed product(s) be suspended/ cancelled/deregistered.

MDB also decided to issue show cause notice to M/s Lahore Medical Instruments (Pvt) Ltd, 48-KM, Lahore kasur Road, District Kasur for their registered disposable syringes namely INJEKT Disposable Syringe 3ml (Regn.No. 069231) and INJEKT Disposable Syringe 5ml (Regn.No.069232).

Item No.XIV. <u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).</u>

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s. Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera KPK ELI-00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing site: Venusa de Mexico S. de R.L de C.V. CALLE HERTZ 1525, Parque Industrial J. Bermudez CIUDAD JUAREZ, Chihuahua, MEXICO 32470 FSC US FDA valid till 28th May, 2021	Stone Cone™ Nitinol Urological Retrieval Coil (Urinary Stone Retrieval basket) Sizes and Codes: M0063903100 08714729430209 3F/7mm M0063903200 08714729430223 3F/10mm Class B Shelf Life: 36 Months	Intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract. Sterile, single use	**Approved.** Firm shall submit valid ISO:13485.

2.	-do-	**<u>Legal Manufacturer:</u>** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **<u>Manufacturing sites:</u>** Boston Scientific Corporation 2546 First Street, Propark, El Coyol, Alajuela, COSTA RICA 20904. FSC US FDA valid till: 21st January,2021	UroMax Ultra™ Balloon Dilatation Catheter **(**Ureteral Dilatation Catheter) M0062251000 08714729341109 12Fr (4mm) x 4cm M0062251010 08714729341116 15Fr (5mm) x 4cm M0062251020 08714729341123 18Fr (6mm) x 4cm M0062251030 08714729341130 21Fr (7mm) x 4cm M0062251040 08714729341147 24Fr (8mm) x 4cm M0062251050 08714729341154 30Fr (10mm) x 4cm M0062251060 08714729341161 12Fr (4mm) x 6cm M0062251070 08714729341178 15Fr (5mm) x 6cm M0062251080 08714729341185 18Fr (6mm) x 6cm M0062251090 08714729341192 21Fr (7mm) x 6cm M0062251100 08714729341208 24Fr (8mm) x 8cm M0062251110 08714729341222 30Fr (10mm) x 8cm M0062251150 08714729341239 12Fr (4mm) x 10cm M0062251160 08714729341246 15Fr (5mm) x	Uromax UltraTM Balloon Dilatation Catheters are recommended for dilatation of the urinary tract.	**Approved.** Firm shall submit valid FSC and ISO:13485.

			10cm M0062251170 08714729341253 18Fr (6mm) x 10cm M0062251180 08714729341260 21Fr (7mm) x 10cm Class: B Shelf Life: 36th Months		
3.	M/s Nipro Medical Private Limited, Building No. 24 Central Commercial Area, DHA Phase 8, Ex-Park View, Lahore. ELI-00530	Legal manufacturer Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan Manufacturing site: Nipro Corporation Odate Factory 8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 Japan FSC Japan issued on 11.05.2017	Nipro Sureflux Hemodialyzer Code: Sureflux E Sureflux G Sureflux L Sureflux N Class: C Shelf Life: 3 years	Indicated for patients having acute or chronic renal failure when dialysis is prescribed by the physician. Sterile, single use	**Approved.**
4.	M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi (ELI-00007)	Legal manufacturer: Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan Manufacturing site: Nipro (Thailand) Corporation Limited 10/2 Moo 8, Bangnomko, Sena, Phra Nakhon Si Ayuthaya 13110 Thailand FSC Thailand valid till 22-8-	Nipro Scalp Vein Set (PSV set) Sizes: 19G 20G 21G 22G 23G 24G 25G 27G Class: B Shelf Life: 5 years	Device for intravascular administration and is indicated for the administration of fluids and drug transport. Sterile, single use	**Approved.**

		2021 FSC Australia issued on 22-4-2020			
5.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	**Manufacturer**: M/s Johnson & Johnson International C/o European Logistics Centre Leonardo Da Vincilaan 15, BE-1831 Diegem, Belgium. **Physical Manufacturer:** M/s Johnson & Johnson Medical Ltd., Simpson Parkway, Kirkton Campus, Livingston EH54 7AT, UK M/s Johnson & Johnson Medical GmbH, Robert-Koch-Strasse 1, 22851 Norderstedt, Germany (FSC Belgium issuance date 02-09-2019)	PDS ™ II (Polydioxanone) Monofilament Suture, Dyed and Undyed Class D Shelf Life: 05 Years Codes & Sizes as per FSC	They are intended fo ruse in general soft tissue approx. including use in pediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery.	**MDB has acceded to the request of the firm for withdrawal of this registration application.**
6.	-do-	**Manufacturer**: M/s Johnson & Johnson International C/o European Logistics Centre Leonardo Da Vincilaan 15, BE-1831 Diegem, Belgium. **Physical Manufacturer:** M/s Johnson & Johnson Medical	Monocryl ™ Poliglecaprone 25 (Monofilament) Sterile Synthetic Absorbable Surgical Suture Class D Shelf Life: 05 Years Codes & Sizes as per FSC	They are intended for use in general soft tissue approx.. and/or ligation where an absorbable material is indicated.	**MDB has acceded to the request of the firm for withdrawal of this registration application.**

		Ltd., Simpson Parkway, Kirkton Campus, Livingston EH54 7AT, UK (FSC Belgium issuance date 02-09-2019)			
7.	-do-	Manufacturer: Johnson & Johnson International, c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE-1831, Belgium (FSC Belgium issued on 02-09-2019)	ULTRAPRO Hernia System Codes: UHSM ----- Medium UHSM6 ----- Medium UHSL ----- Large UHSL6 ----- Large UHSOV ----- Oval Class D Shelf Life: 5 years	Monocryl-prolene composite. Synthetic partially absorbable surgical mesh device indicated for open repair of abdominal wall hernia defects. Sterile, single use	**Approved.** Firm shall submit valid ISO:13485.
8.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	Contour Curved Cutter Stapler Reload Codes: CR40B CR40G Class D Shelf Life: 5 years	Sterile, single patient use reload of contour curved stapler intended for use in gastrointestinal surgical procedures for transection and resection of tissues	**Approved.** Firm shall submit valid FSC and ISO:13485.
9.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969	Ethicon Endo-Surgery Curved Intraluminal Staplers (with Adjustable Height Staples)	Sterile, single patient use anastomosis staplers which have applications throughout the	**Approved.** Firm shall submit valid FSC and

		USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	Codes: CDH21A CDH25A CDH29A CDH33A Class C Shelf Life: 5 years	alimentary tract for end-to-end, end-to-side and side-to-side anastomosis	ISO:13485
10.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (with Adjustable Height Staples) Codes: ECS21A ECS25A ECS29A ECS33A Class C Shelf Life: 5 years	Sterile, single patient use anastomosis staplers which have applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomosis	**Approved.** Firm shall submit valid ISO:13485 and FSC.
11.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Planta II; Calle Durango 2751, Colonia Lote Bravo 32575, Cuidad Juarez, Chihuahua, Mexico	Ethicon HARMONIC ACE+7 Shears with Advanced Haemostasis (Harmonic ultrasonic surgical device) Codes: HARH23 HARH36 HARH45 Class C Shelf Life: 5 years	Indicated for soft tissue incisions when bleeding control and minimal thermal energy are desired. Sterile, single patient use	**Approved.** Firm shall submit valid ISO:13485 and FSC.

		(FSC USFDA valid till 30-10-2020)			
12.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	ENDOPATH ETS45 Reload Codes: 6R45B Class D Shelf Life: 5 years	Sterile, single patient use reload of ENDOPATH ETS45 endoscopic linear cutter intended for transection, resection, and/or creation of anastomosis of tissues	**Approved.** Firm shall submit valid FSC and ISO:13485.
13.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	ENDOPATH ETS-FLEX 45 No-Knife Articulating Endoscopic Linear Stapler Codes: ATS45NK Class B Shelf Life: 5 years	Sterile, single patient use instrument with no knife intended for transection, resection, and/or creation of anastomosis.	**Approved.** Firm shall submit valid FSC and ISO:13485
14.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969	ENDOPATH ETS-FLEX 45 Articulating Endoscopic Linear Cutter	Sterile, single patient use instrument intended for transection, resection, and/or	**Approved.** Firm shall submit valid FSC and

		USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	Codes: ATS45 Class B Shelf Life: 5 years	creation of anastomosis.	ISO:13485
15.	-do-	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Avenida De Las Torres No.7125, Colonia Salvarcar 118 Cuidad Juarez, Chihuahua 32580, Mexico (FSC USFDA valid till 12-2-2020)	ECHELON 45 ENDOPATH Linear Cutter Reload Codes: ECR45B ECR45D ECR45G ECR45W ECR45M Class D Shelf Life: 5 years	Sterile, single patient use reload of ECHELON 45mm endoscopic staplers intended for transection, resection, and/or creation of anastomosis of tissues	**Approved.** Firm shall submit valid FSC and ISO:13485
16.	-do-	Manufacturer: Johnson & Johnson International, c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE-1831, Belgium (FSC Belgium issued on 02-09-2019)	ULTRAPRO comfort Plug™ (Partially absorbable hernia repair device) Codes: UPLUG401 UPLUG403 UPLUG406 UPLUG551 UPLUG553 UPLUG556 Class D Shelf Life: 5 years	Indicated for reinforcement of soft tissue, where weakness exists, in procedure involving soft tissue repair such as groin hernia defects. Sterile, single use	**Approved.** Firm shall submit valid ISO:13485
17.	-do-	**Legal Manufacturer:**	ENSEAL®	Indicated for	**Approved.**

		M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, 00969 USA **Manufacturing Site:** M/s Ethicon Endo-Surgery S.A. DE C.V. Planta II; Calle Durango 2751, Colonia Lote Bravo 32575, Cuidad Juarez, Chihuahua, Mexico (FSC USFDA valid till 30-10-2020)	Disposable Tissue Sealing Device (Temperature controlled tissue sealing technology) Codes: NSEAL514RH NSEAL525RH NSEAL535RH NSEAL545RH Class C Shelf Life: 2 years	bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. Sterile, single use	Firm shall submit valid FSC and ISO:13485
18.	-do-	**Legal Manufacturer:** Johnson and Johnson International c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE-1831 Diegem, Belgium (FSC Belgium issued on 02-07-2019)	Vicryl Rapide ™ (polyglactin 910) Synthetic Absorbable Suture Class D Codes: W9962 W9977 W9974 W9979 MPVR4970H MPVR4960H FSC of Belgium does not have codes. Manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 5 years	A synthetic absorbable sterile surgical suture composed of a copolymer made from 90 % glycolide and 10 % L-lactide. Intended for use in general soft tissue approximation where only short term wound support is required and where the rapid absorption of the suture would be beneficial	**Approved.**
19.	-do-	**Legal Manufacturer:** M/s Ethicon, LLC. 475 C Street, Los Frailes, Industrial Park, Suite 401, Guaynabo, PR	ETHILON™ Nylon Suture (Polyamide 6 or 6, 6 sterile synthetic non-absorbable suture)	Synthetic, sterile, monofilament, non-absorbable surgical suture indicated for use in general soft tissue approximation and / or ligation	**Approved.**

		00969, USA **Manufacturing Site:** Ethicon Inc., Calle Durango No. 2751 Lote Bravo Ciudad Juarez, Chihuahua Mexico CP 32575. (FSC US FDA valid till 11-02-2023)	Class D Codes: 1. 2881G 2. 1696G 3. W740G 4. W738G 5. W736G 6. W748 FSC of USFDA does not have codes. Manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 60 Months	including cardiovascular, ophthalmic, and neurological procedures. Single-use	
20.	-do-	**Legal Manufacturer:** M/s Ethicon, LLC. 475 C Street, Los Frailes, Industrial Park, Suite 401, Guaynabo, PR 00969, USA **Manufacturing Site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 08-06-2022)	STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device Class D Codes: SXPP1B103 SXPP1B104 SXPP1B105 SXPP1B110 SXPP1B113 SXPP1B114 SXPP1B201 SXPP1B202 SXPP1B203 SXPP1B204 SXPP1B205 SXPP1B401 SXPP1B402 SXPP1B403 SXPP1B405 SXPP1B406 SXPP1B407 SXPP1B408 SXPP1B409 SXPP1B410 SXPP1B411 SXPP1B412	An anti-bacterial mono-filament synthetic absorbable device consisting of polyester, poly(p-dioxanone). Indicated for use in general soft tissue approximation where use of an absorbable suture is appropriate. Sterile, single use	**Approved.**

			SXPP1B413 SXPP1B415 SXPP1B416 SXPP1B417 SXPP1B419 SXPP1B420 SXPP1B421 SXPP1B422 SXPP1B423 SXPP1B424 SXPP1B427 SXPP1B428 SXPP1B429 SXPP1B430 SXPP1B431 SXPP1B450 SXPP1B451 SXPP1B452 SXPP1B101 SXPP1B414 SXPP1B453 SXPP1B454 SXPP1B455 SXPP1B456 Shelf Life: 24 Months		
21.	-do-	**Legal Manufacturer:** M/s Ethicon, LLC. 475 C Street, Los Frailes, Industrial Park, Suite 401, Guaynabo, PR 00969, USA **Manufacturing Site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 08-06-2022)	STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device Class D Codes: SXMP1B101 SXMP1B102 SXMP1B103 SXMP1B104 SXMP1B105 SXMP1B106 SXMP1B107 SXMP1B108 SXMP1B109 SXMP1B111 SXMP1B113 SXMP1B114 SXMP1B117	An anti-bacterial mono-filament synthetic absorbable device prepared from copolymer of glycolide and e-caprolactone. Indicated for use in soft tissue approximation where use of an absorbable suture is appropriate. Sterile, single use	**Approved.**

			SXMP1B118 SXMP1B119 SXMP1B120 SXMP1B408 SXMP1B409 SXMP1B410 SXMP1B413 SXMP1B414 SXMP1B415 SXMP1B416 SXMP1B417 SXMP1B419 SXMP1B420 SXMP1B421 SXMP1B424 SXMP1B425 SXMP1B427 SXMP1B428 SXMP1B429 SXMP1B433 SXMP1B434 SXMP1B435 Shelf Life: 24 Months		
22.	-do-	**Legal Manufacturer:** M/s Ethicon, LLC. 475 C Street, Los Frailes, Industrial Park, Suite 401, Guaynabo, PR 00969, USA **Manufacturing Site:** Ethicon Inc., Calle Durango No. 2751 Lote Bravo Ciudad Juarez, Chihuahua Mexico CP 32575 (FSC US FDA valid till 11-02-2023)	MERSILK™ Braided Silk Non-Absorbable Suture Class D Codes: W202, W203, W204, W205, W211, W212, W215, W223, W225, W562H, W199 FSC of USFDA does not have codes. Manufacturer has given list of codes (notarized) that are manufactured by them. Shelf Life: 60 Months	Intended for use in general soft tissue approximation and / or ligation including use in cardio vascular, ophthalmic and neurological procedures. Sterile, single-use	**Approved.**

23.	M/s Briogene (Pvt) Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015)	**Manufacturer:** QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden Germany (FSC Germany issued on 14-03-2019)	Ipsogen JAK2 RGQ PCR Kit Class C Codes: 673623 Shelf Life: 24 Months	Uses magnetic particle-technology for automated isolation and purification of DNA from biological specimens for in vitro diagnostic purposes	**Approved.**
24.	M/s Medtronics Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	**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)	Consulta™ CRT-P (Dual chamber implantable pacemaker with cardiac resynchronization therapy) Model: C3TR01 Class D Shelf Life: 18 Months	Multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing, sequential biventricular pacing and atrial tachyarrhythmia therapies. Sterile, single-use.	**Approved.** Firm shall submit valid FSC and ISO:13485.
25.	M/s Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI-00109)	Legal Manufacturer: BioMérieux S.A. 376 Chemin de l'Orme 69280 Marcy l'Etoile - France Manufacturing Site: BioMérieux S.A. 376 Chemin de l'Orme 69280 Marcy l'Etoile - France FSC France issued on 13-12-2017	VIDAS® CEA (S) Kit Code: 30453 Size: 60 tests Class: C Shelf Life: 12 months	An automated quantitative test for use on the VIDAS family instruments, for the quantitative measurement of Carcinoembryonic antigen (CEA) in human serum or plasma (lithium heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay).	**Approved.**
26.	-do-	**Legal Manufactur**	Cordis RAIN Sheath ™ Trans	RAIN sheath ™ device consists of a	**Approved.**

		CORDIS Corporation, 14201 N.W 6oth AVE, Miami Lakes, FL USA **<u>Manufacturing Site:</u>** Cardinal Health Mexico 244 S de Rl de CV Santiago Troncoso # 808 Parque Industrial Salvarcar Ciudad Juarez Chihuahua Mexico CP FSC FDA U.S FDA Valid till: 14 July, 2021	radial (Catheter Sheath Introducer) Class-B Shelf Life: 3 years Codes as per FSC	sheath introducer, a vessel dilator (0.021" guidewire compatible), an IV cannula needle or a bare access needle and a 45 cm 0.021" mini guidewire (either bare or hydrophilic). The device configurations with the hydrophilic guidewire contain only an IV cannula needle, whereas device configurations with the bare wire contain only a bare needle.	
27.	-do-	**<u>Legal Manufacturer:</u>** KANEKA Corporation 3-18, 2-Chome, Nakanoshima Kita-Ku Osaka-city, OSAKA, 530-8288, Japan **<u>Manufacturing site:</u>** KANEKA Corporation Osaka Plant 5-1-1, Torikai-Nishi, Settsu-city, OSAKA< 566-0072, Japan (Assembly, Packaging, Sterilization) FSC Japan issuance 20-10-2020	NEON PTCA Balloon Dilation Catheter (PTCA balloon Dilation Catheter) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	PTCA balloon Dilation Catheter	**Approved.** Firm shall subit valid ISO:13485.
28.	-do-	**<u>Legal Manufacturer:</u>** KANEKA Corporation 3-18, 2-Chome, Nakanoshima	NEON NC PTCA Balloon Dilation Catheter (PTCA balloon Dilation Catheter)	PTCA balloon Dilation Catheter	**Approved.** Firm shall subit valid ISO:13485.

		Kita-Ku Osaka-city, OSAKA, 530-8288, Japan **<u>Manufacturing site:</u>** KANEKA Corporation Osaka Plant 5-1-1, Torikai-Nishi, Settsu-city, OSAKA 566-0072, Japan (Assembly, Packaging,Sterilization) FSC Japan issuance 20-10-2020	Class-D Shelf Life: 3 years Codes & Sizes: As per FSC		
29.	-do-	**Legal Manufacturer:** M/s BioFire ® Diagnostics, LLC, 515 Colorow Drive, Salt Lake City, UT, 84108, Export only Certificate: USA valid till: 20.12.2022 FSC Belgium issuance 14-04-2021	BioFire ® Respiratory Penel 2.1 Plus (RP 2.1 Plus) (Viral nucleic acid detection assay) Class- C Shelf Life: 12 months Code: 423740	The BioFire Respiratory Panel 2.1 plus (RP2.1plus) is a multiplexed nucleic acid test intended for use with the BioFire FirmArray 2.0 or BioFire FilmArray Torch systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected to respiratory tract infection, including COVID-19.	**Approved.**
30.	M/s Verizon. 60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore. (ELI-00087)	Manufacturer: COOK, INC. 750 DANIELS WAY Bloomington, IN USA 47404 FSC US FDA valid till 07-07-2022	Tornado Embolization Coil Codes: Codes of only Tornado Embolization Coil as per FSC No. 11162-7-2020	Intended for embolization of selective vessel supply to arteriovenous malformations and other vascular lesions. Sterile, single use.	**Approved.** Submit separate application for Tornado Embolization MICRO Coil

			dated 8-07-2022 Class D Shelf Life: 05 years		
31.	M/s Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi. (ELI-00347)	**Manufacturer:** M/s Terumo Corporation, 44-1, 2-Chome, Hatagaya, Shibuya-ku, Tokyo, 151-0072, Japan. **Manufacturing Site:** Terumo Corporation, Fujinomiya Factory 818 Misonodaira, Fujinomiya City, Shizuoka Prefecture, Japan **FSC Japan issued on 15-02-2016**	Terumo Teruflex® Transfer Bag Class D Codes: Codes as per Free Sale Certificate of Japan Shelf Life: 36 Months	Intended for collection, preservation and transfusion of blood components. Sterile, single use	**Approved.** Firm shall submit valid FSC and ISO:13485
32.	M/s Usmanco International, 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121)	**Manufacturer:** Jiangxi Sanxin Medtec Co., Ltd. No.999 Fushan Road, Xiaolan Economic Development Zone Nanchang, Jiangxi, China (FSC China valid till 07-10-2021)	UCI Disposable Syringe Class B Shelf Life: 3 Years Sizes: 1 ml, 2 ml, 2.5 ml, 3 ml, 5 ml,10 ml, 20 ml, 30 ml, 50 ml, 60 ml	Sterile, disposable syringe for single-use.	**Approved** only 1 ml, 10 ml, 20 ml, 30 ml, 50 ml and 60 ml.
33.	-do-	Manufacturer: Shanghai Mekon Medical Devices Co., Ltd. 526, No. 697-3 Lingshi Road 200072 Shanghai, China FSC issued by China chamber of commerce for import & export of medicine and health products valid till 22-11-2022	U FLO Sterile I.V Catheter Sizes: G-18, G-20, G-22, G-24 Class B Shelf Life: 5 years	Sterile, single use IV catheter	**Approved.**

		FSC Germany issued on 27-02-2021			
34.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** M/s Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, USA. **Manufacturing Sites:** Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA USA 19355. Fujirebio Diagnostics, Inc. 940 Crossroads Blvd Segium, TX USA 78155. FSC US FDA valid till 18-05-2022.	Alinity i Sirolimus Reagent kit Alinity i Sirolimus Calibrators Alinity i Sirolimus Whole Blood Precipitation Reagent Class-C Shelf Life: Reagent kit: 14 Months Calibrators: 18 Months WBP Reagent: 18 Months Codes: Alinity i Sirolimus Reagent kit (09P41-20) Alinity i Sirolimus Calibrators (09P41-01) Alinity i Sirolimus Whole Blood Precipitation Reagent (09P41-40)	The Alinity i Sirolimus assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of Sirolimus in human whole blood on the Alinity i analyzer.	**Approved.** Firm shall submit valid ISO:13485.
35.	-do-	**Legal Manufacturer:** Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 19-07-2018)	Alinity c Urine/CSF Protein Class B Shelf Life: 24 Months Sizes & Codes as Per FSC 08P71-01 (Calibrator kit) 07P59-20 (Reagent kit) 07P59-30 (Reagent kit)	Alinity c Urine/CSF Protein assay is used for quantification of protein in human Urine/ Cerebrospinal fluid on Alinity c Analyzer.	**Approved.**

36.	M/s Zenith International, Room # 104, Tahir Plaza, A/20, Block 7&8. K.C.H.S.U Karachi. ELI-00090	**Legal Manufacturer:** M/s Zhejiang Yuantong Medical Appliances Co., Ltd., East Side of Xinqiao, Shuangxin Highway, Xinshi Town, Deqing County, Huzhou 313201, Zhejiang, China **Manufacturing Site:** M/s Ningbo Greetmed Medical Instruments Co. Ltd. 16F-1, Building 1 No.98, Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang, China FSC China Valid Till (31-01-2021) FSC Germany issuance 10-11-2019	Perfect Fine Disposable Nasal Oxygen Cannula, Sterile (Double prongs Nasal Oxygen Cannula) Class B Shelf Life: 5 Years Sizes: M: Adult S: Child XS: Infant XXS: Neonate	Nasal oxygen cannula is made up of medical grade PVC which is non-irritant to mucous membrane of nostril. It consists of tubing connectable to oxygen inlet for delivery of oxygen though nostrils of patient. It is a single use device.	**Approved.** Firm shall submit valid FSC of country of origin and ISO:13485.
37.	M/s Melamine Emporium, Office No.814, Star City Mall, Saddar, Karachi (ELI-00414)	**Legal Manufacturer:** M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen 518119, China FSC UK Issuance (26-03-2018)	Tianck balloon Inflation device Disposable Inflation device Class-B Shelf life: 3 years Codes as per FSC	In PTCA surgery, the disposable inflation device is used to inflate the balloon dilator, to expand the balloon, thereby expand the blood vessel or to hold the stent inside the vessel.	**Approved.** Firm shall submit valid QMS Certificate.
38.	-do-	**Legal Manufacturer:** M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen	Tianck Closure Pad Topical Hemostasis wound dressing pads Class-B Shelf life: 3 years	Clinically, the closure pad is used for hemostasis by compression after clinical puncture of radial artery. If necessary, it can be used with gauze and other	**Approved.** Firm shall submit valid QMS Certificate

		518119, China FSC UK Issuance (26-03-2018)	Codes as per FSC	hemostasis products. The closure pad uses physical methods to stop bleeding by compression and makes the body repair system coagulate automatically.	
39.	-do-	**Legal Manufacturer:** M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen 518119, China FSC UK Issuance (26-03-2018)	Tianck Guidewire PTFE Coated Guidewire Class-D Shelf life: 3 years Codes as per FSC	Guidewires are mainly used to guide peripheral vessels and assist the catheter to reach the exact position of the arteries and veins.	**Approved.** Firm shall submit valid QMS Certificate.
40.	-do-	**Legal Manufacturer:** M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen 518119, China FSC UK Issuance (26-03-2018)	Tianck Disposable Mnifold Disposable Manifold Class-B Shelf life: 3 years Codes as per FSC	With a high-pressure injection pump, disposable manifolds inject medical liquid or contrast medium for patients through various passageways.	**Approved.** Firm shall submit valid QMS Certificate.
41.	-do-	**Legal Manufacturer:** M/s Tianck Medical Co., Ltd., Building C, No.16 Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen 518119, China FSC UK Issuance (26-03-2018)	Tianck Hemostasis Valve Set Disposable Hemostasis Valve Set Class-B Shelf life: 3 years Codes as per FSC	Used for connecting guide catheter in clinical surgery and assisting guidewire to enter human body in PTCA.	**Approved.** Firm shall submit valid QMS Certificate.
42.	M/s UDL Distribution (Pvt) Ltd 1-D-13, Sector	**Legal Manufacturer:** Teleflex Medical. 3015 Carrington	Weck Hem-o-lok Ligating Clips Class-C	Weck Hem-o-lok Ligating Clips are intended for use in procedures	**Approved.** Firm shall submit Full

	30, Korangi Industrial Area, Karachi. (ELI-00073)	Mill Blvd Morrisville, NC USA 27560 **<u>Manufacturing Site:</u>** Hudson Respiratory Care Tecate S. De R.L. DE C.V. (A Teleflex Medical Company) Prolongacion Mision Eusebio Kino No. 1316. Rancho EI Descanso TECATE. Baja California Mexico C.P. 21478. (FSC USFDA valid till 19-06-2021)	Shelf Life: 5 Years Codes: 544220, 544230, 544233, 544240, 544243	involving ligation of vessels or tissue structures.	Quality Assurance Certificate and MRP of device.
43.	-do-	**Legal Manufacturer:** Teleflex Medical 3015, Carrington Mill Blvd, Morrisville, NC USA 27560. **Name of Owner** Teleflex Medical 2917, Weck Drive Research Triangle Park, NC 27709, USA **Multiple Sites:** 1. Teleflex Medical de Mexico, S.de R.L de C.V AvE. Industrias No 5954, Parque Industrial Finsa, NUEVO LAREDO Tamaulipas, MEXICO 88275 **2.** Hudson Respiratory Care Tec ate S. DER.L. de C.V (A	**Pleur-Evac Chest** Drainage Unit. Class- B. Shelf life: 05-years. Codes & Sizes as per FSC.	**Chest** Drainage Unit is used to evacuate air and /or fluid from the chest cavity or mediastinum.	**Approved.** Firm shall submit valid ISO:13485 of all manufacturing sites involved in manufacturing of subjet medical device.

		Teleflex Medical Company). Prolongacion Mission Eusebio Kino No 1316, Rancho El Descanso, Tecate, B.C., C.P., 21478, Mexico			
44.	-do-	**Legal Manufacturer & mfg. site:** Teleflex Medical 3015 Carrington Mill Blvd Morrisville NC, USA 27560. **Multiple Sites:** Hudson Respiratory Care Tec ate S. de R.L. de C.V (A Teleflex Medical Company). Prolongacion Mission Eusebio Kino No 1316, Rancho El Descanso, Tecate, B.C., C.P., 21478, Mexico Symmetry Medical Inc. Manchester 253 Abby Rd Manchester, NH USA03103. TECOMET, INC 5307, 95TH Ave KENOSHA, WI USA, 53144 KOSCHER WUERTZ GMBH, Einsteinstrasse 7, Spaichingen, Baden-Wuttemberg Germany 78549 Nedical Specialities Inc. 4720 Industry Ln	**Weck Horizon** Ligating Clips. Class- D. Shelf life: 05-years. Codes & Sizes as per FSC.	Weck ligation clips are intended for use in procedures involving vessels or anatomic structures.	**Approved.** Firm shall submit valid ISO:13485 of all manufacturing sites involved in manufacturing of subjet medical device.

		Ste A, Durham NC, USA 27713.			
45.	Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi (ELI-00240)	**Legal Manufacturer:** M/s Vesismin Health (Vesismin S.L.,) Carrer de Lluca.28, 5th Floor, 08028, Barcelona, Spain FSC Spain Issuance Date (04-07-2017)	NDP Air Total + Green CE Class-B Shelf Life: 2 Years Codes/model as per FSC	Indicated for terminal disinfection of critical areas, the main applications are operation theaters, ICUs, Isolation rooms, ambulance, air conditioning ducts, clean rooms, labs, cold storage rooms, silos, spa, public transportation etc.	**Approved.** Firm shall submit valid Letter of Authorization and Full Quality Assurance Certificate.
46.	M/s. Fresenius Medical care Pakistan Pvt Ltd., Tamc First, Floor, 27c III, M.M Alam Road Gulberg III Lahore (ELI-00315)	**Legal Manufacturer:** Fresenius Medical Care AG&Co. KGaA, 61346 Bad Homburg Germany **Manufacturing Site:** Fresenius Medical Care Deutsshland GmbH Scheweinfurt Palnt 9, 97424 Scheweinfurt, Germany FSC: Germany Date of issue: 13.05.2019	MultifiltratePRO (Acute Hemodialysis Machine) Class: C Service Life: N/A. Code: M205001 Accessories (F4003200, F00007585	Acute Hemodialysis Machine is intended to be used, for treatment, in renal failure patients.	**Approved.** Firm shall submit valid Full Quality Assurance Certificate.
47.	M/s Cardiac Care 848, -C, Shamman-I, Lahore. ELI-00070	**Legal Manufacturer:** EUROSETS srl STRADA STATABLE 12, 143 41036 MEDOLLA (MO) Italy. FSC: Italy : Date of issue: 23.03.2018	VENICE Chest Drain Single Class: B Shelf Life: 3 years Codes: EU3601-EU3601/S	Multi-chamber thoracic drainage device is intended for use in Post cardiac/ thoracic surgery.	**Approved.**
48.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden,	**Legal Manufacturer:** Cardioline S.p.A Via Linz 151-	Recorder-Walk 200b Software-Cube abpm	The device is a blood pressure Holter recorder lasting 24 hours or	**Approved.** Firm shall submit original

	Block 3, MCHS, Shaheed-e-Millat Road, Karachi (ELI-00274)	38121 Trento (TN) Italy. (FSC Italy issuance 12-01-2018)	Class B Shelf Life: 5 Years Codes not mentioned	more designed to perform ambulatory monitoring tests during 24 hours or more.	Letter of Authorization and Free Sale Certificate.
49.	-do-	**Legal Manufacturer:** Cardioline S.p.A Via Linz 151- 38121 Trento (TN) Italy. (FSC Italy issuance 12-01-2018)	Cubestress System Stress Test System Class B Shelf Life: 5 Years Codes not mentioned	Stress Test System	**Approved.** Firm shall submit original Letter of Authorization and Free Sale Certificate.
50.	-do-	**Legal Manufacturer:** M/s Dirui Industrial Co. Ltd., No.95 Yunhe Str. New & High-Tech Development Zone, Changchun, China FSC China Valid Till (13-04-2021)	Kit for Urine sediment analyzer Class B Shelf Life: 8 Months Sizes & Codes as Per FSC	Copies of legal documents are provided; original documents are in attestation process.	**Deferred** for provision of FSC of any reference country or CE marked documents and brand name.
51.	**-do-**	**Legal Manufacturer & mfg. site:** M/s Cardioline S.p.A. 38121 Trento (TN), Via Linz, 151, Italy FSC Italy Issuance Date (12-01-2018)	**Cubeholter WS.** (Software system with Recorder Walk 400h, and Clickholter) **Class: B.** Shelf Life: 05-Years. Codes & Sizes as per FSC. Apply separately for other product.	It is a software that manages Holter ECG data, acquired by means of Walk400h and Clickholter recorders, with sampling rates from 250 to 1000Hz and recording duration from 1 to 7 days.	**Approved.** Firm shall submit original Letter of Authorization and Free Sale Certificate.
52.	-do-	**Legal Manufacturer & mfg. site:** M/s Cardioline S.p.A. 38121 Trento (TN), Via Linz, 151, Italy	ECG100+ ECG200+ **(Electro-cardiograph**. **Class: B.** Shelf Life: 05-Years. Codes & Sizes as	The device is a 12-lead, fully diagnostic electrocardiograph which displays, acquires, print and stores ECG tracings for adults and	**Approved.** Firm shall submit original Letter of Authorization and Free Sale Certificate.

		FSC Italy Issuance Date (12-01-2018)	per FSC. Apply separately for other product.	children. It also calculates the main overall ECG parameters. The device is equipped with full connectivity: USB (Standard), LAN (Standard) and WiFi (Optional)	
53.	M/s. Chemical House 6-C Sikandar Malhi Road, Canal park, Gulberg II, Lahore. ELI-00156	**Legal Manufacturer** Bio-Rad 3 Boulevard Raymond Poincare, 92430 Maranes-la,Conquette, France FSC- France Date of issue 15.3.2019	Monolisa Anti HCV Plus version-3 Assay (EIA Microplate Format) Class D Shelf Life: 18 months Codes: 72340 (96 tests) 72341 (480 tests)	Monolisa Anti-HCV Plus version 3 is indirect qualitative enzyme immunoassay for the detection of infection caused by hepatitis C virus based on the detection of anti-HCV antibodies in serum or human plasma.	**Approved.**
54.	M/s Biogenics Pakistan (Pvt.) Ltd. 201, Fortuner Center, Shahrah-e-Faisal, Karachi. (ELI-00085)	**Manufacturer:** Innolatex SDN.BHD. Lot 591 & 594, Persiaran Raja Lumu, Pandamaran Industrial Estate, 42000 Port Klang Selangor Darul Ehsan, Malaysia. (FSC valid for 2 years issuance date 02-02-2021)	Hamdam Gold Rubber Latex Condom Class-C Shelf Life: 5 Years. Hamdan Gold GC4398075116	Hamdam gold are an effective form of contraception? If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many others sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	**Approved** on the basis of CE marked documents.
55.	-do-	**Manufacturer:** Innolatex SDN.BHD. Lot 591 & 594, Persiaran Raja Lumu, Pandamaran Industrial Estate, 42000 Port Klang Selangor Darul Ehsan, Malaysia.	Voyager Rubber Latex Condom Class C Shelf Life: 5 Voyager GC4398075116	Hamdam gold are an effective form of contraception? If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many others sexually transmitted diseases, including	**Approved** on the basis of CE marked documents.

		(FSC valid for 2 years issuance date 02-02-2021)		chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	
56.	M/s T&Y Care Pharma (Pvt) Ltd, Office NO, 19, Second Floor, Alhameed Mall Sector G-11, Markaz, Islamabad. ELI:00644	**Legal Manufacturer:** M/s Zhejiang Yuantong Medical Appliances Co. Limited, East of Xinqiao Shuangxin Road, Xinshi Town Dqing County Huzhou city Zhejiang Province, China FSC: China Valid Till: 07-11-2022.	TY-Ject Suction Catheter (Suction Catheter) Class- B Shelf Life: 5 years Codes & Sizes: AS per FSC	This product has connector and tubing it used in suction of mucus secrete or blood adhered on the mucosa of respiratory passage. Short term use.	**Approved** on the basis of CE marked documents.
57.	-do-	**Legal Manufacturer:** M/s Zhejiang Yuantong Medical Appliances Co. Limited, East of Xinqiao Shuangxin Road, Xinshi Town Dqing County Huzhou city Zhejiang Province, China FSC: China Valid Till: 2022.11.07	TY-Ject Nebulizer Mask (Nebulizer Mask) Class- B Shelf Life: 5 year Codes & Sizes: AS per FSC	Nebulizer mask	**Approved** on the basis of CE marked documents.
58.	-do-	**Legal Manufacturer:** M/s Zhejiang Yuantong Medical Appliances Co. Limited, East of Xinqiao Shuangxin Road, Xinshi Town Dqing County Huzhou city Zhejiang Province, China FSC: China	TY-Ject Nasal Oxygen Cannula (Nasal Oxygen Cannula) Class- B Shelf Life: 5 years Codes & Sizes: AS per FSC	Nasal Oxygen Cannula	**Approved** on the basis of CE marked documents.

		Valid Till: 2022.11.07			
59.	-do-	**Legal Manufacturer:** M/s Zhejiang Yuantong Medical Appliances Co. Limited, East of Xinqiao Shuangxin Road, Xinshi Town Dqing County Huzhou city Zhejiang Province, China FSC: China Valid Till: 2022.11.07	TY-Ject Oxygen Mask Class- B Shelf Life: 5 years Codes & Sizes: AS per FSC	Oxygen mask	**Approved** on the basis of CE marked documents.
60.	M/s Business Medical International, Suite # 101 & 102. Trade Center, First Floor, Plot 23/F Commercial Area, Muhammad Ali Cooperatrive Housing Society, Karachi (ELI-00262)	**Legal Manufacturer:** M/s MANI Inc. 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 3213231 Japan. FSC Japan issuance date: 04-07-2019	MANI Silk Ophthalmic Sutures Class-C Shelf life: 5 Years Codes not provided	The product is used to close or ligate tissue or to fasten a medical device to tissue.	**Approved.** Firm shall submit vali Full Quality Assurance Certificate and notarized Letteer of Authorization.
61.	-do-	**Legal Manufacturer:** M/s MANI Inc. 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 3213231 Japan. FSC Japan issuance date: 04-07-2019	MANI Polyglycolic acid Ophthalmic Sutures Class-C Shelf life: 5 Years Codes not provided	The product is used to close or ligate tissue or to fasten a medical device to tissue.	**Approved.** Firm shall submit vali Full Quality Assurance Certificate.
62.	-do-	**Legal Manufacturer:** M/s MANI Inc. 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 3213231 Japan.	MANI Nylon Ophthalmic Sutures Class-C Shelf life: 5 Years Codes not	The product is used to close or ligate tissue or to fasten a medical device to tissue.	**Approved.** Firm shall submit vali Full Quality Assurance Certificate.

		FSC Japan issuanc04-07-2019	provided		
63.	-do-	**Legal Manufacturer:** M/s MANI Inc. 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 3213231 Japan. FSC Japan issuanc04-07-2019	MANI Polyester Ophthalmic Sutures Class-C Shelf life: 5 Years Codes not provided	The product is used to close or ligate tissue or to fasten a medical device to tissue.	**Approved.** Firm shall submit vali Full Quality Assurance Certificate.
64.	-do-	**Legal Manufacturer:** M/s MANI Inc. 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 3213231 Japan. FSC Japan issuanc04-07-2019	MANI Polypropylene Ophthalmic Sutures Class-C Shelf life: 5 Years Codes not provided	The product is used to close or ligate tissue or to fasten a medical device to tissue.	**Approved.** Firm shall submit vali Full Quality Assurance Certificate.
65.	M/s IBS Pharmaceuticals & Generl Order Supply Business. Haji Gulam Saeed Medicine Market Namak Mandi Peshawar Gulab Khana Peshawar. ELI: 00604	**Legal Manufacturer:** M/s Bionen S.A.S di Barbara Nencioni & Co., Via P. Petrocchi, 42/1- 50127, Florence, Italy FSC: Italy Date of issue: 16.04.2019	Bionen Needle Electrodes for EMG Needle (Needle Electrodes for EMG) Class-B Shelf Life: 5 years Codes as per FSC	The Disposable Concentric Needle Electrode is used for electromyography (EMG) recording for examination of the peripheral neuromuscular system, by registration of the electrical activity from the muscles The BOTOX Injection Needle Electrode is intended to be inserted in the muscle while recording electromyography activity and proximally connected to electromyography recording equipment.	**Approved.**

<table>
<tr>
<td>66.</td>
<td>Platinum Corporation, F-10/7/6, Near Arfeen Masjid, Barrage Colony, Sukkur
(ELI-00443)</td>
<td>Legal Manufacturer:
M/s Yangzhou Medline Industry Co., Ltd., 108, Jinshan Road, Economic Development Zone, Yangzhou China

FSC China Valid Till (28-08-2021)</td>
<td>Sterile Disposable Syringe with Needle

Class-B

Shelf Life: 5 years

Codes & Sizes as per FSC
(3ml, 5ml, 10ml, 20ml)</td>
<td>Sterile Disposable Syringe with Needle</td>
<td>Deferred for provision of FSC of any reference country or CE marked documents and brand name.</td>
</tr>
<tr>
<td>67.</td>
<td>M/s Imtiaz Brothers
Suit 7B, 2nd Floor, Abrar Business Center, 25-Main Wahdat Road, Lahore.

ELI-00133</td>
<td>Legal Manfacturer:
M/s Zeon Medical Inc. Japal 1-6-2, Marunouchi, Chiyoda-ku, Tokyo 100,0005, Japan.

FSC Japan
Date of issue: 06-08-2019</td>
<td>XEMEX IABP Balloon Plus (Intra-Aortic Balloon Catheter)

<table>
<tr><th>Balloon Volume</th><th>Catheter O.P</th><th>Balloon Length</th></tr>
<tr><td>25ml</td><td>7.0F (2.33 mm)</td><td>180mm</td></tr>
<tr><td>30ml</td><td>7.0F (2.33 mm</td><td>210mm</td></tr>
<tr><td>35ml</td><td>7.0F (2.33 mm</td><td>243mm</td></tr>
<tr><td>30ml</td><td>8.0F (2.66 mm</td><td>210mm</td></tr>
<tr><td>35ml</td><td>8.0F (2.66 mm</td><td>214mm</td></tr>
<tr><td>40ml</td><td>8.0F (2.66 mm</td><td>243mm</td></tr>
<tr><td>35ml</td><td>8.0F (2.66 mm</td><td>162mm</td></tr>
<tr><td>40ml</td><td>8.0F (2.66 mm</td><td>182mm</td></tr>
</table>

Class: D

Shelf Life: 3 years</td>
<td>The XEMEX IABP Balloon Plus is a balloon catheter set, used for balloon pumping in the aorta to assist heart function in cardiogenic shock or low cardiac output syndrome cases. This device is disposable and reuse is prohibited. This device can only be used for MAQUET'S Consoles and TELEFLEX's consoles.</td>
<td>Approved.</td>
</tr>
<tr>
<td>68.</td>
<td>M/s Ophthalmo-Tec
Haji Fazal Ellahi Building opp, Women College ShahRah-e-Liaquat Karachi.

(ELI- 00310)</td>
<td>Legal Manufacturer:
FSSB Chirurgische Nadeln GmbH Allmendweg 2 79798 Jestetten / Germany</td>
<td>FSSB Surgical Sutures

FSSB Polypropylene Blue

Class D</td>
<td>Surgical sutures for different surgeries, Consistent of needles attached to thread, Sterile packed.</td>
<td>Approved.</td>
</tr>
</table>

		(FSC Germany issuance 31-07-2020)	Shelf Life: 5 Years Codes as per FSC		
69.	-do-	**Legal Manufacturer:** FSSB Chirurgische Nadeln GmbH Allmendweg 2 79798 Jestetten / Germany (FSC Germany issuance 31-07-2020)	FSSB Surgical Sutures FSSB Polyglycolic Acid (PGA) Class D Shelf Life: 5 Years Codes as per FSC	Surgical sutures for different surgeries, Consistent of needles attached to thread, Sterile packed.	**Approved.**
70.	M/s DIGITAL IMAGING SYSTEMS, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore-54000, Pakistan, ELI-00094	**Legal Manufacturer:** St. Jude Medical 14901 DeVeau Place Minnetonka, MN, USA 55345 FSC US FDA Valid till: 10.12.2020	Pacel Bipolar Pacing Catheter Class: D Shelf Life 3 years Codes: 401765, 401766, 401767, 401768 401769, 401770, 401771, 401772 401773, 401774, 401775, 401776	St. Jude Medical Pacel™ Bipolar Cardiac Pacing Catheters are intended for use in intracardiac pacing and/or ECG recording.	**Approved.** Firm shall submit valid FullQuality Assurance Certificate and Design Examination Certificate.
71.	-do-	**Legal Manufacturer:** St. Jude Medical 14901 DeVeau Place Minnetonka, MN, USA 55345 FSC US FDA Valid till: 10.12.2020	Pacel Flow Directed Pacing Catheter Class: D Shelf Life: 18 months Codes: 401761- 401762- 401763- 401764	St. Jude Medical Pacel™ Flow Directed Pacing Catheters are indicated for use in temporary, transvenous right ventricular pacing	**Approved.** Firm shall submit valid FullQuality Assurance Certificate and Design Examination Certificate.
72.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town,	**Legal Manufacturer:** Nano-Ditech Corporation 259 Prospect Plains Rd, BLdg K	Nano-Check ™ AMI c Tnl Test Nano-Check ™ AMI c Tnl Test Class C	The Nano-Check ™ AMI cTnl test is a rapid immunoassay for the qualitative determination of	**Approved.**

	Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209	Cranbury, USA FSC USA Valid till 2.6.2024	Shelf Life: 15.8 months Codes as per FSC	Cardiac Troponin 1 (cTnI) in human whole blood, serum and plasma specimens at cutoff centration of 0.5ng/ml, as an aid in the diagnosis Acute Myocardial Infarction (AMI). Test results should be interpreted by the physician in conjunction with other test results and patient clinical findings.	
73.	-do-	**Legal Manufacturer:** Nano-Ditech Corporation 259 Prospect Plains Rd, BLdg K Cranbury, USA FSC USA Valid till Valid till 2.6.2024	Nano-Check ™ NT-proBNP Test Class B Shelf Life: 15 months Codes as per FSC	Nano-Check ™ NT-proBNP test is use for the determination of NT-proBNP in a whole blood, serum or plasma specimens at the cutoff concentrations of 125 pg./ml for patients younger than 75 years and 450 pg./ml for patients 75 years and older. The test is used as an aid in the diagnosis of patients suspected of hacing CHF.	**Approved.**
74.	-do-	**Legal Manufacturer:** Nano-Ditech Corporation 259 Prospect Plains Rd, BLdg K Cranbury, USA FSC USA Valid till Valid till 2.6.2024	Fluoro-Check ™ AMI 3 IN 1 Test Fluoro-Check ™ AMI 3 IN 1 Test Class: C Shelf Life: 15 months Codes as per FSC	The Fluoro-Check ™ AMI 3 IN 1 test is a time rsolved fluorescence immunoassay for the quantitative determination of CTnL, CK0MB and Myoglobin in human whole blood, serum, and plasma specimen as an aid in the diagnosis of acute myocardial	**Approved.**

				infarction (AMI) and cardiac muscle damage in the emergency room and physician's office. The Fluoro-Check ™ AMI 3 In 1 Test can monitor the rise and fall for cTnl, MyoandCK-MB when used in conjunction with fluoro-Checker ™ TRF reader. Test results should be interpreted by the physician along with other test results and patient clinical symptoms findings.	
75.	M/s Batla Impex, SH.40, Namco Centre, Cambell Street, Karachi. (ELI-00170)	**Legal Manufacturer:** Haiyan Kangyuan Medical Instrument Co., Ltd Songpondong Rd., Shengdang Town, Haiyan.China (FSC China validity 08 -07-2019) FSC MHRA issuance 27-09-2019	Golden+ Endotracheal Tubes Endotracheal Tubes Class B Shelf Life: 5 Years Sizes & Codes as Per FSC	A Tracheal Tube is a catheter that is inserted into the trachea for the primary purpose of establishing and maintaining a patent airway and to ensure the adequate exchange of oxygen and carbon dioxide.	**Approved.** Firm shall submit valid FSC of country of origin.
76.	**M/s Chemical House**, 6-C Sikander Malhi Road, Canal park, Gulberg II, Lahore. **ELI:- 00156.**	**Legal Manufacturer & mfg. site:** AJ Roboscreen GmbH Hohmannstrasse 7m 04129, Leipsig, Germany. FSC: Germany Dated of issue 21st October, 2019.	Robe Gene HDV RNA Quantification Kit 2.0 Class-D. Shelf Life: 06- months.	The Robo HDV RNA Quantification Kit 2.0 is intended for real-time PCR quantification of Hepatitis D Virus (HDV) RNA is human EDTA plasmaor serum smaples using theINSTANT Virus RNA/DNA Kit (ANalytik Jena). Two kit versions	**Approved.**

				are available: lo profile strips 0.1 ml (white) for Light Cycler® 480 and 7500 Fast real-time PCR systems and regular profile tubes 0.2 ml (clear) for application on Rotor-Gene ™ 300/6000/0 respectively.	
77.	-do-	**Legal Manufacturer & mfg. site:** AJ Roboscreen GmbH Hohmannstrasse 7m 04129, Leipsig, Germany FSC: Germany Dated of issue 23rd October, 2019.	**ROBO-GENE HBV DNA** (PCR Quantification Kit 3.0) Class D Shelf Life: 06- months.	The Robo HBV DNA Quantification Kit 3.0 is intended for real-time PCR quantification of Hepatitis D Virus (HDV) RNA is human EDTA plasmaor serum smaples. For specimen purification the manual method (INSTANT Virus RNA/DNA Kit) as well as the automated method (Instant Virus RNA/DNA Kit) is validated on the following real-time PCR devices: TOWER 3, CFX96; Light Cycler® 480; 750 Fast and Totor-Gene ® 3000/6000/Q.	**Approved.**
78.	**-do-**	**Legal Manufacturer & mfg. site:** AJ Roboscreen GmbH Hohmannstrasse 7m 04129, Leipsig, Germany FSC: Germany Dated of issue 21st Oct. 2019.	**ROBO-GENE HCV RNA** (PCR Quantification Kit 3.0) Class: D Shelf Life: 06th month	The Robo-Gene HCV RNA Quantification Kit 3.0 is intended for real-time PCR quantification of Hepatis C virus (HCV) RNA IN human EDTA-or citrate plasma and serum samples. For specimen	**Approved.**

				purification the manual method (INSTANT Virus RNA/DNA Kit) as well as the automated method (INSTANT VIRUS RNA/DNA KIT) is validated on the following real-time PCR devices: q TOWER 3, CFX96; Light Cycler® 480; 750 Fast and Totor-Gene ® 3000/6000/Q.	
79.	**M/s Intek Corporation**, Office No, 30, Al Amin Plaza, the Mall, Rawalpindi. **ELI-00034.**	**<u>Legal Manufacturer:</u>** TERUMO CORPORATION 44-1, 2-Chome, Hatagaya, Shibuya-Ku, Tokyo 151-0072 JAPAN. **Manufacturing Site:**Terumo corporation ashitaka factory Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan FSC: JAPAN. Date of issue: 14-07-2017.	**Radifoucus Glidewire Advantage** (Glidewire catheter) Class-D Shelf Life. 24 months.	The Glidewire advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures, except for central circulatory system.	**Approved.**
80.	-do-	**<u>Legal manufacturer:</u>** Terumo corporation 44-1, 2-chome, hatagaya, shibuya-ku, Tokyo 151-0072 japan **Manufacturing Site** Terumo corporation ashitaka factory	**Runthrough NS** (PTCA Guide wire) Class- D Shelf Life: 03 years	The RUNTHROUGH NS is indicated to be used to guide dilatation catheters to a lesion for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood	**Approved.**

		Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan FSC:- Japan Date of Issue: 14-02-2020.		flow in a stenotic lesion in coronary vessels.	
81.	-do-	**Legal Manufacturer:** Terumo corporation 44-1, 2-chome, hatagaya, shibuya-ku, Tokyo 151-0072 JAPAN **Manufacturing Site:** Terumo corporation ashitaka factory Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan FSC: Japan Date of Issue: 14-01-2020.	**Finecross MG** (Coronary Micro-Guide Catheter) Class-D Shelf Life: 02 years	Finecross MG is intended to be percutaneously introduced into blood vessels and support a guide wire in crossing the localized stenotic lesion of the coronary artery while performing PCI (percutaneous coronary intervention) & also intended for injection of radiopaque contrast media for the purpose of angiography.	**Approved.**
82.	**M/s. Novatek** P-20, 1st floor, office No. 01, Chenab Market, Susan road, Faisalabad. **ELI-00454.**	**Legal Manufacturer & mfg. site:** Life Vascular Devices Biotech S.L. Camí de Can Ubach, 11 (Pol. Ind. Les Fallulles) 08620 Sant Vicenç dels Horts (Barcelona – Spain) FSC: Spain.	**iVascular** Navitian Coronary microcatheter. Class D Shelf Life: 03 Years	Over the wire microcatheter with hydrophilic coating	**Approved.** Firm shall submit original Letter of Authorization.
83.	-do-	**Legal Manufacturer & mfg. site:** Life Vascular Devices Biotech S.L. Camí de Can	**iVascular** Capturer Thrombus extraction catheter. Class D Shelf Life	Rapid exchange thrombus extraction catheter with hydrophilic coating	**Approved.** Firm shall submit original Letter of Authorization.

		Ubach, 11 (Pol. Ind. Les Fallulles) 08620 Sant Vicenç dels Horts Barcelona – Spain. FSC: Spain.	03-Years		
84.	-do-	**Legal Manufacturer & mfg. site:** Life Vascular Devices Biotech S.L. Camí de Can Ubach, 11 (Pol. Ind. Les Fallulles) 08620 Sant Vicenç dels Horts. Barcelona – Spain. FSC: Spain.	**iVascular NC xperience** Coronary balloon dilatation catheter. Class D Shelf Life: 03-Years	Rapid exchange balloon dilatation catheter with hydrophilic coating	**Approved.** Firm shall submit original Letter of Authorization.
85.	-do-	**Legal Manufacturer & mfg. site:** Life Vascular Devices Biotech S.L. Camí de Can Ubach, 11 (Pol. Ind. Les Fallulles) 08620 Sant Vicenç dels Horts, Barcelona – Spain. FSC: Spain.	**iVascular xperience** Coronary balloon dilatation catheter. Class D Shelf Life: 03 Years.	Rapid exchange balloon dilatation catheter with hydrophilic coating	**Approved.** Firm shall submit original Letter of Authorization.
86.	**M/s Moon enterprises**, 5/6 Rabani Road Old Anarkali Lahore **ELI-00356.**	**Legal Manufacturer & mfg. site:** ANTITOXIN GmBH Industries 88 69245 Bammental Germany FSC: Germany Date of Issue 18.09.2018.	**ImuMed** (ABO-SYSTEM) Anti-A monoclonal IgM Anti-A monoclonal IgM Code 01.001-01.003 Class- D. Shelf Life: 05-Years.	Monoclonal Agglutinating anti-A, anti-B test sera are produced from cell culture supernatants of murine cell lines. The testsera are used to determine whether human red blood cells possess orlack the corresponding blood group antigens Aor B. the testsera are intended to be used by qualified and technical personnel only.	**Deferred** for provision of valid ISO:13485, Full Quality Assurance Certificate, QC detail and CoA of the subject product.
87.	M/s Hospital Services &Sales, 13-C Annex, Block 6, PECHS,	**Legal Manufacturer:** M/s Guangdong Haiou Medical	Haiou Retractable Auto Disable Syringes for Fix Dose	Retractable Auto Disable Syringe	**Approved.**

	Karachi (ELI-00081)	Apparatus Co. Ltd., Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China FSC China Valid Till (02-12-2020) WHO Pre-Qualified	Immunization 0.1ml,0.2ml, 0.3ml,0.4ml, 0.5ml,& 1ml Class: B Shelf Life: 5 years		
88.	**M/s deKhon,** 11-C Old FCC, Ferozpure Road, Gulberg-III, Lahore. **ELI-000317.**	**Legal Manufacturer** TRB Chemedica Ag Otto-Lilienthal-Ring 26, D-85622 Feldirchen/Munchen, Germany Production Facility (Vismed Multi) Pharma Stulln GmbH WerksstraBe 3 92551 Stulln, Germany Pharmaster Z I ErsteinKrafft 67150 Erstein France. FSC: France.	**Vismed Multi ®.** (Sodium Hyaluronate 0.18%) Class: C. Shelf Life: 36 months.	It contains a highly purified specific fraction of sodium salt of hyaluronic acid produced by bacterial fermentation and is therefore free from animal protiens.	**Approved.**
89.	M/s Zam Zam Corporation Suit # 205-206, 2nd floor, 6-CL-10, Beaumont Plaza, Karachi ELI-00412	**Manufacturer:** Shanghai Pudong Jinhuan Medical products Co. Ltd.25 Lianzhen RD, Pudong New Area, Shanghai, 201204, P.R China FSC China copy valid till 13-11-2021	OriginO PGA suture Class D Shelf life: 5 years Codes & Sizes as per FSC	Absorbable synthetic suture composed of polymer made from polyglycolic acid indicated for use in general soft tissue approximation and/or ligation including ophthalmic surgery. Sterile, single-use	**Approved.** Firm shall submit original and Embassy attested FSC
90.	-do-	**Manufacturer:** Shanghai Pudong	OriginO Silk suture	Non-absorbable surgical suture	**Approved.**

		Jinhuan Medical products Co. Ltd.25 Lianzhen RD, Pudong New Area, Shanghai, 201204, P.R China FSC China copy valid till 13-11-2021	Class C Shelf life: 5 years Codes & Sizes as per FSC	composed of braided multifilament of silk indicated for use in general soft tissue suturing and ligation. Sterile, single-use	Firm shall submit original and Embassy attested FSC
91.	-do-	**Manufacturer:** Shanghai Pudong Jinhuan Medical products Co. Ltd.25 Lianzhen RD, Pudong New Area, Shanghai, 201204, P.R China FSC China copy valid till 13-11-2021	OriginO Nylon suture Class C Shelf life: 5 years Codes & Sizes as per FSC	Non-absorbable surgical suture composed of monofilament of polyamide nylon 6 indicated for use in general soft tissue suturing and ligation. Sterile, single-use	**Approved.** Firm shall submit original and Embassy attested FSC
92.	-do-	**Manufacturer:** Shanghai Pudong Jinhuan Medical products Co. Ltd.25 Lianzhen RD, Pudong New Area, Shanghai, 201204, P.R China FSC China copy valid till 13-11-2021	OriginO Polypropylene suture Class C Shelf life: 5 years Codes & Sizes as per FSC	Non-absorbable surgical suture composed of monofilament polypropylene indicated for use in general soft tissue suturing and ligation. Sterile, single-use.	**Approved.** Firm shall submit original and Embassy attested FSC

Item No.XV. <u>RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).</u>

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s A.Feroz & Co., Medicine Street No. 1, Marriot Road Karachi (ELI-00066)	**<u>Legal Manufacturer:</u>** M/s Jiangsu Kanghua Medical Equipment Co. Ltd., Sanhekou, Changzhou, Jiangsu,	Star Fine Disposable Insulin Syringes Class-B	Sterile, single-use syringe for insulin administration	**Approved.**

	Renewal	China P.C: 213115. FSC China valid till 09-10-2020 FSC Germany issuance 02-02-2020	Shelf Life: 5 years Size: 1ml		

Item No.XVI. <u>ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).</u>

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070	**Manufacturer:** FIAB SpA Via Paolo Costoli 4, 50039 VICCHIO- Florence, Italy FSC Italy issued on 12-4-2018	**FIAB Disposable ECG Electrodes** Class A Shelf Life: 36 months Codes: F9060 F9060P	Designed for surface recording of cardiac activity through the use of any kind of electrocardiograph monitoring device. Non sterile, single use	**Approved.**
2.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109	Manufacturer: M/s Hologic Inc.10210 Genetic Centre Drive, San Diego, CA 92121, USA FSC Belgium issued on 08-09-2020	Hologic Panther® System Code: 303095 Class A Shelf Life: N/A	An integrated nucleic acid testing system which fully automates all steps necessary to perform Aptima® Assays from sample processing through amplification, detection and data reduction	**Approved.** Firm shall submit valid Letter of Authorization, ISO 13485 and MRP.
3.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** M/s Abbott Ireland Diagnostics Division, Finiskin Business Park, Sligo, Ireland. FSC Ireland valid till 1-07-2024.	Alinity s Concentrated Wash Buffer Class-A Shelf Life: 11 Months Codes: 06P1388	The Alinity s Concentrated Wash Buffer is pumped to sample and reagent pipettor assemblies and wash zones during assay processing to discard unbound analyte from the reaction mixture in reaction vessels on the Alinity system.	**Approved.**

4.	M/s. Chemical House 6-C Sikandar Malhi Road, Canal park, Gulberg II, Lahore. ELI-00156	**Legal Manufacturer** Bio-Rad 3 Boulevard Raymond Poincare, 92430 Maranes-la,Conquette, France FSC- France Date of issue 15.3.2019	Evolis Twin Plus Microplate Analyzer Class-A Shelf Life: N/ A Code: 93501	Fully automated microplate analyzer including functions such as sample preparation, test performance, photometric measurement and data evaluation.	**Approved.**
5.	M/s Schazoo SPL Consumer Healthcare 71B/C2, Gulberg 3, Lahore ELI: 00095	**Legal Manufacturer:** M/s Shenzhen Yilifang Biotech Co., Ltd, 01 Area F9 Building B, No 16 Baoshan Road, Langwei village, six community, Pingshan Office, Pingshan new district, Shenzhen, Guangdong Province. P.R China FSC China valid till 02-03-2023	MagPure Viral Nucleic Acid Isolation kit Class-B Shelf Life: 1 year Codes as per FSC	MagPure Viral Nucleic acid isolation Kit uses magnetic bead technology to provide a simple and straight-forward solution to extract virus nucleic acids. The MagPure Extraction Kit is ideally suited for the extraction of RNA from patient samples suspected of COVID-19 infection.	**Deferred** for provision of FSC of reference country or CE marked document issued by CAB notified NANDO data base.

Item No.XVII. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and deferred for provision of document. Now the firm has submitted documents :-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision
1.	M/s Abdullah Traders, 3 Green Town, Ghous-ul-Azam Road, Multan ELI-00444	Legal Manufacturer: M/s Nuclear Laser Medicine s.r.l Via Cascina Conighetto snc-20049 Settala, Milan, Italy	Nuclear Laser Medicine s.r.l SARS CoV-2 Real Time (Kit) Class C Codes: AA1571/96	For the determination of SARS-Cov-2 virus in nasopharyngeal and oropharyngeal swabs, sputum and bronchoalveolar lavages samples by real time RT-PCR technique. For professional use only	**Approved.**

		Manufacturing site: M/s Nuclear Laser Medicine s.r.l Viale Delle Industrie, 3-20049 Settala, Milan, Italy. FSC Italy issued on 09-04-2021	(96 tests) Shelf Life: 18 months Fee submitted: Rs. 50,000/-		
2.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 19-07-2018)	Alinityi SCC Kit Class C Sizes & Codes as Per FSC Alinityi SCC Calibrators 09P3301 Shelf Life: 24 Months Alinityi SCC Controls 09P3310 Shelf Life: 24 Months Alinityi SCC Reagent Kit (2x100 tests) 09P3322 Shelf Life 12 Months.	The Alinityi SCC assay is used for the quantitative determination of squamous cell carcinoma antigen (SCC Ag) in human serum and plasma on the Alinityi analyzer.	**Approved.**
3.	M/s United International, GNB-F 18/A Ground Floor, F-Block, Mehar Sons Estate, Karachi. (ELI-00061)	**Legal Manufacturer:** Juye Forna Medical Instrument Co. Ltd No. 173. Yongfeng Street, Juye County, Heze, Shangdong, China. (FSC China validity 17-03-2021)	JAZZ Plus IV Cannula with wings Intravenous (IV) Catheter Class B Shelf Life: 5 Years Sizes: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	IV Cannula	**Approved** on the basis of CE marked document.

4.	**M/s. Safe Health** Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi.	**Legal Manufacturer** : M/s Guangdong Intmed Medical Appliance Co., Ltd., South Shunhe Road Europe Industry Park, Shunde, District, Foshan City, Guangdong, China. FSC China Valid Till (30-06-2022) FSC of Ireland provided.	**Disposable Syringes with Needle** (30ml & 50ml) Codes & Sizes as per FSC **Class-B.** **Shelf-life:** 03-years.	**Disposable Syringes**	**Approved.**
5.	-do-	**Legal Manufacturer** M/s Guangdong Intmed Medical Appliance Co., Ltd., South Shunhe Road Europe Industry Park, Shunde, District, Foshan City, Guangdong, China. FSC China Valid Till (30-06-2022) FSC of Ireland provided.	**Disposable Syringes with Needle** (1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml) **Class-B.** **Shelf-life:** 03-years. Codes & Sizes as per FSC	**Disposable Syringes**	**Approved only 1 ml, 10 ml and 20 ml**
6.	-do-	**Legal Manufacturer** M/s Bao Health Medical Instrument Co., Ltd., 2nd Floor	**Bao Helath** (Ostomy Care Bag) **Class-B.** **Shelf-life:** 03-years.	Ostomy Care Bag	**Approved** on the basis of CE mark documents.

		of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang, Zhejiang, P.R. China FSC China Valid Till (28-08-2021	Codes & Sizes as per FSC.		
7.	**M/s. Popular International** (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091)	**Legal Manufacturer:** M/s Covidien LLC a Medtronic Company, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** M/s Covidien Energy Based Devices 5920 Longbow Drive Boulder, CO 80301, USA FSC USA Valid Till (21-07-2021)	**Valleylab LS10 Generator.** **Class:C** Service life: 03-years. Shlef Life: 07-Years. Codes & Sizes as per FSC	The platform is intended for open and laparoscopic surgical procedures and includes: TissueFect™ sensing technology across all modalities.	**Approved.**
8.	-do-	**Legal Manufacturer:** M/s Covidien LLC a Medtronic Company, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** M/s Covidien Medical Products (Shanghai) Manufacturing LLC 10 Bldg. No. 789 Puxing	**Ligasure Sealer/Divider** (Open Laparoscopic, allow to grasp, cut, dissect, and reliably seal tiss ue vessels sticking and jaw cleanings. **Class: C** Service life: 04-years. Shlef Life: 07-Years. Rs.50,000/- Codes & Sizes as per FSC	Open Laparoscopic, allow to grasp, cut, dissect, and reliably seal tissue vessels sticking and jaw cleanings	**Approved.**

		Road Shanghai, China FSC USA Valid Till(21-07-2021)			
9.	-do-	**Legal Manufacturer:** M/s Covidien LLC a Medtronic Company, 15 Hampshire Street Mansfield, MA 02048, USA. **Manufacturing Site:** M/s Covidien Energy-based Devices 5920 Longbow Drive Boulder, CO 80301 USA. M/s Kirwan Surgical Products LLC. 180 E\nterprise Dr Marshfield MA 02050 USA. FSC USA Valid Till(21-07-2021)	**Valleylab FT10** Energy Platform. **Class C** Service life: 04-years. Shlef Life: 07-Years. **Rs. 50,000/-** Codes & Sizes as per FSC	Energy Platform	**Approved.**
10.	**M/s Save on Health Care** 101-B, Punjpeer Road Lalpul Mughalpura Lahore ELI: 00027.	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany	**HITECARE** Laryngeal Mask Class-B. Shlef Life: 02-Years. Codes & Sizes as per FSC. Rs.25,000/-	Laryngeal Mask	**Approved.**

		FSC: Germany Date of Issue: 10.11.2019.			
11.	-do- ELI: 00027. 1151-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	**HITECARE** Aerosol Mask Class-B Rs.25,000/- Shelf Life: 02-years. Codes & Sizes as per FSC.	Aerosol Mask	**Approved.**
12.	-do- ELI: 00027. 1152-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	**HITECARE** (Oxygen Mask) Class-B Shelf Life: 02-years Rs.25,000/- Codes & Sizes as per FSC.	Oxygen Mask	**Approved.**

13.	-do- ELI: 00027 1005-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	**HITECARE** Breathing Circuit Adult & Peads. Class-B Shelf Life: 02-years. Codes & Sizes as per FSC. Rs.25,000/-	Breathing Circuit Adult & Peads	**Approved.**
14.	-do- ELI: 00027 1146-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	**HITECARE** (HME filter viral & bacterial adult with connector) Class- B Rs.25,000/- Shelf Life: 02-years. Codes & Sizes as per FSC.		**Approved.**
15.	-do- ELI: 00027 1153-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703	**HITECARE** (Reinforced Endotracheal Tube) Class B		**Approved.**

		Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	Shelf Life: 02-years. Codes & Sizes as per FSC. Rs.25,000/-		
16.	-do- ELI: 00027 1154-(P)	**Legal Manufacturer & mfg. site:** Hitec Medical Co., Ltd No, 703 Hengnan RD 1328 Minhang district 201114 Shanghai Peoples Republic of China. **Authorized Representative:** Shanghai International Holding Corp, GmbH (Europe) EiffestraBe 80 20537 Hamburg, Germany FSC: Germany Date of Issue: 10.11.2019.	**HITECARE** (Connecting tube with yankauer handle) Class-B Shelf Life: 02-years. Codes & Sizes as per FSC. Rs.25,000/-		**Approved.**

Item No.XVIII. <u>APPROVED SUBJECT TO CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and approved for provision of certain document. Now the firm has submitted documents :-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision
1.	M/s AB Enterprises, 192 block 7/8, K.M.C.H.S, Karachi ELI-00292	**Legal Manufacturer:** M/s Shengguang Medical Instrument Co., Ltd East of Longshan Road, Pingddingshan City, Henan Province. FSC China issuance 22-11-2018 valid for 5 years FSC Germany issuance	AB Auto destructive syringe Class-B Shelf life: 5 years Codes/ sizes: 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Auto-destructive syringes	**Approved.**
2.	-do-	**Legal Manufacturer:** Heze Yinuo Medical Industry Co. Ltd, Dingtao County, Economic development Zone, Heze City, Shangdong, China. FSC China issuance 03-12-2021 FSC MHRA issuance 25-02-2020	AB Safety syringe Retractable syringes Class-B Shelf life: 5 years Codes/ sizes: 0.1ml, 0.2ml, 0.3ml, 0.5ml, 1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml.	Auto-destructive syringes	**Approved.**

Item No.XIX. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).

S.	Name of Firm	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision

#	(s)/Importer				
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA FSC Germany issued on 27-04-2021	Alinity m SARS-CoV-2 Kit Class C 1. Alinity m SARS-CoV-2 AMP Reagent Kit Code: 09N78-090 Shelf life: 12 months 2. Alinity m SARS-CoV-2 CTRL Kit Code: 09N78-080 Shelf life: 12 months	Real-time Reverse Transcriptase (RT) polymerase chain reaction (PCR) test intended for qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal swabs collected by healthcare provider from patients who are suspected of COVID-19 infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history andepidemiologic al information. The assay is intended for use by qualified and	**Approved.**

				trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.	
2.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah-e-Faisal Karachi (ELI-00010)	Manufacturer: Bioneer Corporation, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon 34302, Republic of Korea Export Only certificate of Korea issued on 1-2-2021 FSC Germany valid till 24-2-2022	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit Size: 100 Tests Code: SCVM-2112 Class C Shelf life: 12 months	An invitro diagnostic kit that helps to diagnose COVID-19 infections. This kit is designed for the detection of SARS-CoV-2 nucleic acids (E gene, RdRp gene and N gene) from a COVID-19 suspected individual's specimens (such as sputum, nasopharyngeal swab and oropharyngeal swab) through real-time polymerase chain reaction	**Approved.** Firm shall submit original Letter of Authorization

Item No.XX. **<u>REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)</u>**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014).	Medi Paraffin Gauze (Paraffin Gauze Dressing Tulle (B.P 1988) Shelf life 05 years. Class B	used in skin burn and injuries etc	**Deferred** for product specific inspection.

		Rs.20,000/- Sizes as Applied.		
2.	-do-	Gauze Eye Pad B.P-1988 (Sterilized) Shelf Life: 5 Years. Rs.5000/- Class B	Gauze Eye Pad BP	**Deferred** for product specific inspection.
3.	-do-	Absorbent Ribbon Gauze B.P (Medi Ribbon Gauze B.P) Shelf Life: 5 Years. Rs.5000/- Class B	Absorbent Ribbon Gauze BP	**Deferred** for product specific inspection.
4.	-do-	Gauze Swab Sponges USP-IV (Me Soft Gauze Swab/Sponges). Shelf life: 05 Years Class B Rs.5000/-	Used to absorb blood and other fluids and clean wounds.	**Deferred** for product specific inspection.
5.	M/s Unisa (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak, District Nowshera	UNICAN (Intravenous Cannula) Class B Shelf Life: 05 Years 14G-26G IV Cannula with Wings & with injection port 14G-26G IV Cannula with Wings & Without injection port	Intravenous Cannula	**Approved only UNICAN** IV Cannula with Wings & Without injection port 14G, 16G, 16G, 18G, 20G, 22G, 24G and 26G

		14G-26G IV Cannula with port, snap fit cap & suturable wings 14G-26G IV Cannula with small wings & Heparin Stopper		
6.	M/s Essity Pakistan Limited, A/69, SITE, Manghopir Road, P.O. Box 3659, Karachi (ELM-00008)	Propax® (Combine Dressing) Absorbent Pad Class B Shelf Life: 05 Years 10cm x 10cm 10cm x 20cm	It is consist of absorbent cotton over-wrap with low adherent non-woven net & has an x-ray detectable thread.	**Approved.** Firm shall submit stability studies of claimed shelf life.

Item No.XXI. **RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7).**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore. (ELM-0014)	Absorbent Gauze Roll BPC-1973 (Soft Gauze) Class B Shelf Life: 05 Years Rs.5000/-	They are used to place over a wound before taping, strapping or bandaging up or can be soaked in antiseptic liquid and used to wipe over hand	**Deferred** for product specific inspection Firm shall submit stability study data for claimed shelf life.
2.	M/s Silver Surgical Complex (Pvt) Ltd., C-40/41, Scheme 33, SITE,, Super Highway, Industrial Area, Karachi (ELM-007)	Silver IV Cannula/Catheter with wings injection port cap Class B Shelf Life: 02 Years	IV Cannula/Catheter	**Approved the mew brand name i.e. Green IV cannula with wings and injection port**

		Pervious Reg No. 067476 16G, 18G, 20G, 22G, 24G		

Item No.XXII. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Kolachee International (Pvt) Ltd., Plot No. C-79, (Formal F-675), Unit No.2, Ground Floor, South Avenue Opp Generation School, SITE, Karachi (ELM-0017)	Verra Disposable Surgical Gown Class A Shel Life: 03 Years Rs. 5000/-	Protective Coverings and clothes that aid in maintaining cleanliness and limiting risk of contamination during various types of medical and dental surgeries.	**Approved.**

Item No.XXIII. APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.

Decision: The MDB discussed and approved the issuance of Import Permit (Form-10) to M/s Surgimed Laboratory and Research Center, Surgimed Hospital, 1-Zafar Ali Road, Gulberg-V, Lahore to import following medical devices manufactured by M/s Eryigits Endustriyel Makina VE Tibbi Chlazlar Malat-Ankara, Turkey:-

Sr.No.	Name of Medical Device.	Quantity
1.	SARC-CoV-2 (Covid-19) RT-qPCR Multiplex with One Step PCR Reagent Detection Test.	03 Pcs
2.	Enzymes.	01 Pcs

Item No.XXIV. CANCELLATION OF SOLE AGENCY AGREEMENT

Decision: The representatives of M/s Dora Enterprises did not appear before the MDB. Therefore, the Board cancelled the registration of products namely DORA Disposable A.V. Fistula Needle Sets (Regn. No. MDIR-0000599), DORA Tubing Sets for Hemodialysis (Regn.No. MDIR-0000600) and DORA Hollow Fiber Dialyzer (Regn.No.MDIR-0000601).

Item No.XXV. REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Following applications of M/s Al-Hamd Enterprises, Karachi was discussed in 31st meeting of MDB and deferred till cancellation of Farcocath I.V Cannula registered as drug from registration Board. Now Registration Board has cancelled the registration of above mentioned product:-

S.No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	M/s AL-HAMD Enterprises, FL-11/1/1, Block06, Gulshan-e-Iqbal, Karachi ELI: 00285	**Legal Manufacturer** FARMOMAKE FOR ADVANCE MEDICAL INDUSTRIES (S.A.E) Borg AL-Arab, 4thIndustrial Zone, Block-2, Part 7/16, Alexandria Egypt FSC: Egypt Date of Issue8th November,2016 FSC Germany issuance 08-04-2020	FARCOCATH E I.V CANNULA (Safety Type) Class-B Shelf Life: 5 years Sizes: 14G,16G,18G, 20G,22G, 24G,26G	I.V Cannula to be introduced into a peripheral vein for administering infusion & IV Drugs	**Approved.**
2.	-do-	**Legal Manufacturer:** FARMOMAKE FOR ADVANCE MEDICAL INDUSTRIES (S.A.E) Borg AL-Arab, 4th Industrial Zone, Block-2, Part 7/16, Alexandria Egypt FSC: Egypt Date of Issue: 8th November,2016 FSC Germany issuance 08-04-2020	FARCOCATH E I.V CANNULA (With Stopper Type)) Class-B Shelf Life: 5 years Sizes: 14G,16G,18G, 20G,22G, 24G,26G	I.V Cannula to be introduced into a peripheral vein for administering infusion & IV Drugs	**Approved.**
3.	-do-	**Legal Manufacturer:** FARMOMAKE FOR ADVANCE MEDICAL	FARCOCATH E I.V CANNULA (Injection Fort	I.V Cannula to be introduced into a peripheral vein	**Approved.**

		INDUSTRIES (S.A.E) Borg AL-Arab, 4th Industrial Zone, Block-2, Part 7/16, Alexandria Egypt FSC: Egypt Date of Issue: 8th November,2016 FSC Germany issuance 08-04-2020.	Type) Class-B Shelf Life: 5 years Sizes: 14G,16G,18G, 20G,22G, 24G,26G	for administering infusion & IV Drugs	