

DECISIONS OF THE 24th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 19-11-2020

1. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

S.No	Name of Establishment	Director/Proprietor/partners	Cold Chain (Yes/No)	Recommendations by the panel.
1.	M/s Bain Medical (SMC-Pvt) Ltd, Shop No. 2, Ground Floor, Plot 58-C, Street No. 24, Touheed Commercial Area, Phase 5, D.H.A. Karachi. Godown Address: Same as above.	1. Mr. Li Yin 2. Mr. Fawad Hussain	No	Approved.
2.	M/s Health Care Products, 237/A, Block 2, P.E.C.H.S., Shahrah-e-Quaideen, Karachi. Godown Address: Same as above.	Mr. Raheel Taufiq Feroz Mr. Rizwan Nazim Feroz. Mr. Ayaz Feroz. Mrs. Shama Nazim. Mrs. Afroze Mumtaz	No	Approved.
3.	M/s Truworth Distributors (SMC-Private) Limited, Shop No. 3,4,5 Basement, Shah Mohmand Plaza, E-11/1, Islamabad. Godown Address: Same as above.	Mr. Masood Anwar	No.	Approved for storage of room temperature medical devices without cold chain facility.
4.	M/s Neotech Pharmaceuticals, Flat No. 1, Plot 2-C, Bilal Market, Street 73, G-9/3, Islamabad. Godown Address: Same as above.	Almas Ali Khan	No.	Approved for storage of room temperature medical devices without cold chain facility.

5.	M/s Amin Agencies, Head Office. Office No. 310, 3 rd Floor, ISE Towers, Islamabad. Godown Address: CB-6349, First Floor, Amar Pak Plaza, Opposite Al-Shifa Eye Trust Hospital, Jhelum Road, Rawalpindi.	Mr. Muhammad Sajid	No.	Approved for storage of room temperature medical devices without cold chain facility.
6.	M/s A & S Enterprises, Office No. 4, 1 st Floor, Al- Azeem Arcade, Main Road, Pakistan Town, Phase 2, Islamabad. Godown Address: Same as above.	Usama Khalid Ansari	No.	Approved for storage of room temperature medical devices without cold chain facility.
7.	M/s Pak Engimed, 4 th Floor, Khyber Plaza 2, G-15 markaz, Islamabad.	Naeem Latif Hamza Naeem Latif	No.	Rejected due to the reason that company i.e. M/s Pak Engimed was not present on the address. Another company present there informed that M/s Pak Engimed has changed their address and previously also they were on 2 nd floor and not 4 th floor. When the owner was contacted, he told that they have shifted elsewhere and accepted that they have not informed DRAP.
8.	M/s Amson Vaccines & Pharma (Pvt) Ltd, Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.	Shamim Ahmed Khan Abbas Khan Syed Saleem Asghar	No.	The Board acceded to the request of the firm for postponement of inspection. The firm shall inform the MDMC Division when they are ready for inspection.

9.	M/s Haskan Pharma (Pvt) Ltd, Office No. 1, First Floor, Plaza No. 49, Walayat Complex, Bahria Town, Phase 7, Rawalpindi.	Saad Akhtar Hasan Khan Waqas Akhtar Hasan Khan	No.	The Board acceded to the request of the firm for postponement of inspection. The firm shall inform the MDMC Division when they are ready for inspection
10.	M/s Sadiq Dental Suppliers, Shop No.14 & 15, Al-Khair Plaza, Khyber Bazar, Peshawar, Khyber Pakhtunkhwa	Aamir Sadiq Usman Sadiq Bangash	No.	Approved.

2. SITES VERIFICATION FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

M/s Twenty Four Degree North Pharma, Khokhar Bhuddu Road, Khangoora, Tehsil Kamoke, District Gujranwala has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Khokhar Bhuddu Road, Khangoora, Tehsil Kamoke, District Gujranwala.

Decision: The Board approved the site for manufacturing of medical devices of M/s TwentyFour Degree North Pharma, Khokhar Bhuddu Road, Khangoora, Tehsil Kamoke, District Gujranwala.

3. POST LICENSE VARIATIONS.

3.1.

M/s Allmed Solutions, A-21/3, KDA Scheme-1(Ext), Opposite National Stadium, Karachi has requested for approval of proposed change of their technical person in ELI-00029 as per detail given below: -

Existing Technical Person	Proposed Technical Person
Mr. Muhammad Fahad Ali Khan, CNIC No.42201-3678811-3	Ms. Naveen Anam, CNIC No. 42301-4094315-0 (Pharm-D)

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

Previous Technical Person	New Approved Technical Person
Mr. Muhammad Fahad Ali Khan, CNIC No.42201-3678811-3	Ms. Naveen Anam, CNIC No. 42301-4094315-0 (Pharm-D)

3.2.

M/s National Enterprises, Office No.409, 4th Floor, Al-SEhat Center, Annexe Regent Plaza, Shahrah-e-Faisal, Karachi has requested for approval of proposed change of their technical person in ELI-00043 as per detail given below:-

Existing Technical Person	Proposed Technical Person
Ms. Asia Iqbal CNIC No.42301-9205017-8	Ms. Faiza Khan CNIC No.42201-2730146-0 (Pharm-D)

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

Existing Technical Person	Proposed Technical Person
Ms. Asia Iqbal CNIC No.42301-9205017-8	Ms. Faiza Khan CNIC No.42201-2730146-0 (Pharm-D)

4. REGISTRATION OF MEDICAL DEVICES TO BE IMPORTED FROM TAIWAN.

It is submitted that the cases of below mentioned firms for registration of following medical devices were considered in different meetings of MDB and MDB deferred the cases for seeking clarification of foreign inspection in Taiwan from Foreign Office:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decisions
1.	M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi	Manufacturer: M/s Bionime Corporation Daoing Factory, No. 100, Sec 2, Daqing St. Taichung City 40242, Taiwan	EvoCheck Blood Glucose Monitoring System Class C Shelf Life: 2 Years	Blood Glucose Meter	Deferred. The Board referred the matter to Foreign Office for seeking clarification of foreign

	(ELI-00055)	(FSC China Issuance Date 02-11-2021) Fee submitted Rs.50,000/-			inspection in Taiwan. Meanwhile the firm has now provided CE mark documents and TGA.
2.	-do-	Manufacturer: M/s Bionime Corporation Daoing Factory, No. 100, Sec 2, Daqing St. Taichung City 40242, Taiwan (FSC China Issuance Date 02-11-2021) Fee submitted Rs.50,000/-	EvoCheck Blood Glucose Test Strips Class C Shelf Life: 24 Months	Blood Glucose Test Strip	Deferred. The Board referred the matter to Foreign Office for seeking clarification of foreign inspection in Taiwan. Meanwhile the firm has now provided CE mark documents and TGA Australia.
3.	M/s Aftab Life Care Impex, 1 st Floor Al-Falah Chambers, Tilak Road Hyderabad. (ELI-00357)	Manufacturer: EPS Bio Technology Corp. No. 8 R&D Rd III, Hsinchu Science Park, Hsinchu County, Taiwan, ROC 30077. (FSC issued by Ministry of Health and Welfare, Republic of China (Taiwan) on 18-07-2017 attested by Jordanian commercial office- Taipei)	EASYMAX® Mini Self-Monitoring Blood Glucose System. Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for the quantitative measurements of glucose in fresh capillary whole blood and venous blood from fingertip, palm and forearm.	Deferred for clarification from M/O Foreign Affairs whether product of Taiwan can be registered or not. Now the firm has provided the FSC of Belgium issued on 19-02-2020 alongwith Declaration of Conformity.
4.	-do-	Legal Manufacturer: EPS Bio Technology Corp No. 8 R&D Rd III, HsinchuScien Park, Sinchu, Taiwan	EASYMAX® Blood Glucose Test Strip. Shelf Life: 24 Months Sizes & Codes: EasyMax Blood Glucose Test Strips	The strips are intended for the quantitative measurement of glucose in fresh venous blood and capillary whole	Deferred for clarification from M/O Foreign Affairs whether product of

		30077 ROC. (FSC Taiwan Valid till23-09-2021)	:25 pcs, 50 pcs (25 pcs x 2) Rs.50,000/- Class C	blood sample using EASYMAX® blood glucose monitoring System.	Taiwan can be registered. Now the firm has provided the FSC of Belgium issued on 19- 02-2020 alongwith Declaration of Conformity.
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In the light of decision of MDB, the case was referred to Ministry of Foreign Affairs to provide the following information/clarification with reference to above mentioned case for further processing for inspection of manufacturer in Taiwan vide letter No.F.13-4/2020-MD (M-19) dated 2nd October, 2020:-

- (i) whether the product can be imported into Pakistan through legal channel from Taiwan by an importer? and
- (ii) whether an inspection team of DRAP can officially visit Taiwan or not?

In response Ministry of Foreign Affairs has informed that as per Policy Guidelines on Taiwan, it is hereby clarified that there is no change in Pakistan's policy towards Taiwan. Pakistan does not recognize Taiwan as a State but as an integral part of the People's Republic of China. Accordingly Pakistan does not have any diplomatic/consular relations with Taiwan. Similarly, no official contact, of any type, is maintained with Taiwan. According to Policy Guidelines on Taiwan, there are no restrictions on trade with Taiwan subject to following conditions:-

- Trade is conducted strictly on un-official basis and through private sector only.
- No direct contacts to be made with the Taiwan authority agencies.
- No Pakistan government functionary can visit Taiwan.
- No Taiwan authority functionary can visit Pakistan.
- Government/ official investment from Taiwan is not allowed into Pakistan.
- Exchange of delegations(s) is not allowed.
- Holding of trade exhibitions, establishment of display is not allowed.
- No publicity is given to Pakistan's trade or commercial contacts with Taiwan.
- Private businessmen can, technically, interact with Taiwan parties.

It is further submitted that following medical devices have been registered under Medical Devices Rules, 2017 on the basis of CE mark documents provided by the firm:-

Sr. No	Company Name	Manufacturer Name	Medical Device Name/ Class	Registration No.	Date of Issuance
1	M/s Cardiac Care 848-C Shadman -1, Lahore.	M/s. Pasific Hospital Supply Co., Ltd 4F, No. 160, Daye Road,Beitou District 112 Taipei Taiwan (ROC)	PAHSCO Chest Drainage Bottle (Chest Drainage Device) [H03180 1800ml] Class B	MDIR-0001344	18-02-20
2	M/s Cardiac Care 848-C Shadman -1, Lahore Godown: Same as above	M/s Pacific Hospital Supply Co, Ltd 4F, No. 160, Daye Road, Beitou District, 122 Taipei, Taiwan (ROC)	PAHSCO FEEDING TUBE (Pediatric) Class B	MDIR-0001647	12-08-20
3	M/s Cardiac Care 848-C Shadman -1, Lahore Godown: Same as above	M/s Pacific Hospital Supply Co, Ltd 4F, No. 160, Daye Road, Beitou District, 122 Taipei, Taiwan (ROC)	PAHSCO Stomach Tube Class B	MDIR-0001648	12-08-20

Submitted for consideration of MDB regarding the products applied for registration/enlistment and already registered medical devices please.

Decision: The Board considering the Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs rejected the request of M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055) and M/s Aftab Life Care Impex, 1st Floor Al-Falah Chambers, Tilak Road Hyderabad, (ELI-00357) for registration of their products at serial no. 1-2 and 3-4 respectively. Further decided to issue show casuse notice to M/s Cardiac Care 848-C Shadman -1, Lahore for cancellation of their registered products, namely, PAHSCO Chest Drainage Bottle (Chest Drainage Device) [H03180 1800ml] Class B, (MDIR-0001344), PAHSCO FEEDING TUBE (Pediatric)Class B, (MDIR-0001647) and PAHSCO Stomach Tube Class B (MDIR-0001648).

5. ROUTINE GMP INSPECTION OF M/S PAK DISPOSABLE SYRINGES (PVT) LIMITED, GADOWN AMAZAI, SWABI.

Decision: The Board discussed the matter and decided to stop the production of the firm for one month and directed the firm to inform the Division about rectification of the above mentioned deficiencies and thereafter facility will be re-inspected by the panel constituted by Chairman, MDB.

6. DEFERED 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 to provision of document as mentioned against each. Now the firms have provided the requisite documents and were submitted for consideration of MDB.

Decision: The Board considered and decided as mentioned below:-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	Manufacturer: ev3, Inc. 4600 Nathan LN, North Plymouth, MN USA 55442 (FSC US FDA valid till 27-01-2021)	Trailblazer™ Support Catheter (Intravascular Guiding Catheter) Class B Shelf Life: 3 Years Codes as per US FDA CFG NO.4376-1-2019 Dated 27-01-2021 Fee submitted: Rs. 50,000/-	Percutaneous, single lumen catheters designed for use in the peripheral vascular system. Intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents. Sterile, single-use	Approved
2.	-do-	Manufacturer: Micro Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA USA,	Concerto™ PGLA Fiber Helix (Concerto™ Detachable Coil System) Class D	Non-neurovascular Embolization Coil indicated for arterial and venous	Approved

		92618 (FSC US FDA valid till 23-07- 2021)	Shelf Life: 3 Years Codes: PV-12-30-Helix PV-14-30-Helix PV-16-40-Helix PV-18-40-Helix PV-20-50-Helix Fee submitted: Rs.50,000	embolizations in the peripheral vasculature	
3.	-do-	Manufacturer: Microtherapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA (FSC Netherlands valid till 04-03- 2021)	Onyx™ Liquid Embolic System (Neurovascular Embolization Plug) Class D Shelf Life 3 Years Codes: 105-7200-060 105-7200-080 Fee submitted: Rs.50,000	Non-adhesive liquid embolic agent indicated for embolization of lesions in the peripheral and neurovasculatu re, including arteriovenous malformations and hypervascular tumors. Sterile, single-use	Approved
4.	-do-	Legal Manufacturer Ev3,Inc. 4600 Nathan LN, North Plymouth, MN USA 55442 Manufacturing Site: Lake Region Medical, 340 Lake Hazeltine Dr Chasaka, MN USA 55318 (FSC US FDA valid till 13-12- 2020)	Nitrex™ Guidewires (coronary and peripheral vasculature use) Class D Shelf Life 3 Years Codes: N140801 N141802 N143001 N180601 N180603 N180801 N180802 N181804 N181805 N181806	Nitinol guidewires for use in the peripheral and coronary vasculature. Sterile, single- use	Approved

			N183001 N183002 Fee submitted: Rs.50,000		
5.	-do-	<p>Legal Manufacturer:</p> <p>Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432, USA</p> <p>Manufacturing Site: Medtronic Ireland, Parkmore Business Park west, Galway, Ireland.</p> <p>(FSC Ireland Valid 16-08-2022)</p>	<p>Talent™ Endoluminal Occluder System</p> <p>Class C</p> <p>Codes: OCL08 OCL10 OCL12 OCL14 OCL16 OCL18 OCL20 OCL22 OCL24</p> <p>Shelf Life: 2 Years</p> <p>Fee submitted: Rs.50,000</p>	<p>Intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure. It is to be used as an accessory to an aorto-uni-iliac stent graft device. Sterile, single-use</p>	Approved
6.	M/s Cor-Med 2 nd Floor 38/62 Rahman Plaza Bank Road Saddar, Rawalpindi. ELI-00226	<p>Legal Manufacturer:</p> <p>MERIT MEDICAL SYSTEMS, INC. 1600 West Merit Parkway South Jordan UT 84095, USA</p> <p>Manufacturing Site:</p> <p>MERIT MEDICAL IRELAND, LTD, Parkmore Business Park West, Galway, Ireland 0000</p> <p>FSC US FDA valid</p>	<p>basixCOMPAK™ Inflation Device</p> <p>Class: B</p> <p>Code: IN4130</p> <p>Shelf Life: 3 years</p>	<p>Used to inflate and deflate an angioplasty balloon or other interventional device and to measure the pressure within the balloon.</p>	Approved

		till 27 th February, 2021			
7.	-do-	<p>Legal Manufacturer: MERIT MEDICAL SYSTEMS, INC. 1600 West Merit Parkway South Jordan UT 84095, USA</p> <p>Manufacturing Site: Merit Medical Systems, Inc. 14646 Kirby Drive, Houston, TX, USA, 77047</p> <p>FSC US FDA valid till 27th September, 2020</p>	<p>ReSolve Locking Drainage Catheter</p> <p>Class: C</p> <p>Codes: RLC-6-038 RLC-7-038 RLC-8-038 RLC-10-038 RLC-12-038 RLC-14-038 RLC15-6-038MB RLC15-7-038MB RLC15-8-038MB RLC15-10-038MB RLC15-12-038MB RLC15-14-038MB RLC-6-038MB RLC-7-038MB RLC-8-038MB RLC-10-038MB RLC-12-038MB RLC-14-038MB RLC40-6-038MB RLC40-7-038MB RLC40-8-038MB RLC40-10-038MB RLC40-12-038MB RLC40-14-038MB</p> <p>Shelf Life: 3 years</p>	It is intended for percutaneous drainage of fluid from body cavities. Sterile, single use	Approved
8.	-do-	<p>Legal Manufacturer: MERIT MEDICAL, USA 1600 West Merit Parkway South Jordan UT 84095, USA</p> <p>Manufacturer Site: Biosphere Medical SA, Parc des Nations-Paris Nord 2, 383 rue de la Belle, Etoile, 95700 Roissy EN France, Roissy, Val-doise FRANCE 95700</p> <p>FSC US FDA valid till 05-04-2020</p>	<p>Bearing nsPVA® Embolization Particles</p> <p>Class C</p> <p>Codes: V100EP V200EP V300EP V400EP V600EP V800EP V1100EP</p> <p>Shelf Life: 3 years</p>	Used for embolization of peripheral hypervascularized tumors including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Sterile, single-use	Approved

9.	M/s Eastern Medical Care (Pvt) Ltd, 7A Block N, Model Town Extension, Lahore ELI-00130	Manufacturer: AMTEC CO., LTD. 1-27-9 Edobori Nishi-Ku, Osaka 550-0002, Japan FSC Netherlands valid till 21-08-2021	Citrix-LA (organic acid-based disinfectant) Class C Size: 5L Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Liquid disinfectant mainly composed of citric acid, malic acid and lactic acid used for heat disinfection of fluid pathways of hemodialysis machines	Approved
10.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	Legal Manufacturer/Manufacturing site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 03-04-2021)	Dermabond™ Mini Topical Skin Adhesive Class B Shelf Life: 2 years Code: AHVM12 Fee submitted: Rs. 25,000/-	Intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. Sterile, single-use	Approved.
11.	-do-	Legal Manufacturer/Manufacturing site: Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 08-06-2022)	Surgicel® SNoW™ Absorbable Hemostat (oxidized regenerated cellulose) Class D Shelf Life: 2 years Codes: 2081 2082 2083	Used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial haemorrhage when ligation or other conventional methods of control are impractical or	Approved

			Fee submitted: Rs. 50,000/-	ineffective. Sterile, single-use	
12.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: Sentinel Ch. S.p.A Via Robert Koch, 2 20152 Milano, Italy. (FSC Italy Issue 18-6-2018)	Lithium (Kit) Class C Code: 8L25-30 Shelf Life: 24 Months Fee submitted: 50,000/-	Multigent lithium assay is intended for the quantitation of lithium in serum of plasma using the architect systems	Approved.
13.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (EXPORT ONLY certificate USFDA Valid Till 13-05- 2020)	Abbott RealTime CT/NG Kit Class C i) Abbott RealTime CT/NG Control Kit Code: 2G28-80 Shelf Life: 18 Months ii) Abbott RealTime CT/NG Amplification Reagent Kit (4x48 Tests) Code: 2G28-91 Shelf Life: 18 Months Rs.50,000/- (Challan:0580489)	An invitro PCR assay for direct qualitative detection of the plasmid DNA of C. trachomatis and the genomic DNA of N.gonorrhoeae in female endocervical or vaginal swab specimens , male urethral swab specimens, or in male and female urine specimens	Approved
14.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (EXPORT ONLY certificate USFDA Valid Till 13-05-	Abbott RealTime CMV Kit Class C i) Abbott RealTime CMV Calibrator Kit Code: 5N23-70 Shelf Life: 18 Months	An invitro PCR assay for quantitation of cytomegalovirus (CMV) DNA in human plasma or whole blood.	Approved.

		2020)	<p>ii) Abbott RealTime CMV Control Kit Code: 5N23-80 Shelf Life: 18 Months</p> <p>iii) Abbott RealTime CMV Amplification Reagent Kit Code: 5N23-90 Shelf Life: 18 Months</p> <p>Rs.50,000/- (Challan:0580491)</p>		
15.	-do-	<p>Legal Manufacturer: M/s. Abbott Laboratories 1921 Hurd Dr, Irving, Tx USA 75038 (Address also known as); Abbott Laboratories Diagnostics Division 100 Abbott Park, IL USA 6004.</p> <p>(FSC USA Valid from 04-03- 2019 to 03-03- 2021)</p>	<p>Urine/CSF Protein Reagent Kit Code: 7D79-21 No. of tests: 2244 Shelf Life: 24 months (2°C - 25°C)</p> <p>Urine/CSF Protein Reagent Kit Code: 7D79-31 No. of tests: 209 Shelf Life: 24 months (2°C - 25°C)</p> <p>Urine /CSF Protein Calibrator Code: 1E71-02 Shelf Life: 24 months(2°C - 8°C) Class B Shelf Life: 24 months(2°C - 25°C)</p> <p>Rs.25,000/-</p>	The Urine/CSF protein (Upro) assay is used for the quantitation of protein in human urine or cerebrospinal fluid (CSF). CSF protein measurement is used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous system.	Approved
16.	-do-	<p>Legal Manufacturer: Abbott Ireland Diagnostics Division LisnamuckLongfo</p>	<p>Alinity i 25-OH Vitamin D Alinity B12</p> <p>Alinity i 25-OH Vitamin D Alinity B12</p>	Alinity I 25-OH Vitamin-D Assay is a chemiluminescent assay for the quantitative determination	Approved

		rd Co. Longford Ireland. (FSC Ireland issue 03-09-2023)	Class B Alinityi 25-OH Vitamin D: 15 Months Alinityi B12: 11 Months	of vitamin B12 in human serum and plasma on the Alinity I System. Alinity I B12 Assay is a chemiluminescent Microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum and plasma on the Alinity I System.	
17.	M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg-II Lahore ELI: 00150	Legal manufacturer Soluscope SAS 100 Rue du Fauge -Z.I.LesPaluds 13400 Aubange-France FSC: France Date of issue: 10.07.2019	SOLUSCOPE EZ (Cleaner for Endoscope) Code: SL-V1-PA SOLUSCOPE SERIE 1 Class: A Shelf Life: 36 months	Cleaner for Endoscope	Approved
18.	-do-	Legal Manufacturer Dragerwerk AG & Co, KGaAMoislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany. FSC: Germany Date of issue: 15-10-2019	Ergo Star Tracheal Tube Adapter Class B Shelf Life: 3 years Codes & sizes: CM 40, CM 45, CM 50, CM 55, CM 60, CM 90, CM 95	Airway connector for conduction of respiratory gases between the breathing system and the patient interface of a mechanically ventilated patient.	Approved

19.	-do-	<p>Legal Manufacturer</p> <p>MIMP Mammendorfer Institute fur Physik un Medizin GmbH Oskar-von- Miller Str. ^ 82291 Mammendorf, Germany</p> <p>FSC: Germany</p> <p>Date of issue: 20- 04-2020.</p>	<p>EZ Pad MRI</p> <p>Class-A</p> <p>Service Life: 10 years</p> <p>Codes & sizes: 5300202 (S) 5300203 (L)</p>	<p>Single use</p> <p>ECG Electrodes intended to be used for ECG monitoring during MRI examinations of patients.</p>	Approved
20.	-do-	<p>Legal manufacturer</p> <p>Soluscope SAS 100 Rue du Gauge -ZI, les Paluds 13400 AUBAGNE France</p> <p>FSC: France</p> <p>Date of issue: 10- 07-2019</p>	<p>SOLUSCOPE GTA</p> <p>(Disinfectant)</p> <p>Class- C</p> <p>Shelf Life: 35 months</p> <p>Codes & sizes: SL-V1-GTA SOLUSCOPE SERIE 1</p>	<p>Cleaner for Endoscope</p>	Approved
21.	-do-	<p>Legal manufacturer</p> <p>Soluscope SAS 100 Rue du Fauge -Z.I.LesPaluds 13400 Aubange- France</p> <p>FSC: France</p> <p>Date of issue: 10.07.2019</p>	<p>Soluscope SERIE 1 (Endoscope Washer/Disinfecto r)</p> <p>Code & Sizes: Not mentioned</p> <p>Class- C</p> <p>Shelf Life: 35 months</p>	<p>Endoscope Washer/Disinfe ctor</p>	Approved
22.	-do-	<p>Legal Manufacturer</p> <p>Dragerwerk AG &Co, KGaAMoislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site:</p>	<p>Drager Water Lock 2</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Codes & sizes: Not mentioned</p>	<p>Disposable water trap for separating water from the sample line of suctioning patient monitor. For protection of</p>	Approved

		Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany. FSC: Germany Date of issue: 15-10-2019		the patient-gas measurement module against water, bacteria and viruses.	
23.	-do-	Legal Manufacturer Dragerwerk AG & Co, KGaAMoislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany. FSC: Germany Date of issue: 15-10-2019	Drager Infinity ID Flow sensor Class-B Shelf Life: Reuseable Codes & sizes: 5x	The Flow sensor is a hot wire sensor for measuring volumetric gas flow in Drager anesthesia machines and ventilators	Approved

7. REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland. (FSC Ireland valid 03-09-2023)	Alinityi Folate Alinityi Ferritin Class B Shelf Life: Alinityi Ferritin Reagent kit: 14 months, Calibrators: 17 months, Controls: 17 months Alinityi Folate Reagent kit: 18 months, Calibrators: 18 months, Controls: 12 months Alinityi Folate Manual diluent: 18	Alinityi Folate & Ferritin is a Chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of folate & ferritin in human serum, plasma, and red blood cells on the Alinity I analyzer.	Approved.

			<p>months, Alinityi Folate RBC lysis diluent: 9 months, Alinityi Folate Lysis Reagent: 12 months Sizes & Codes as Per FSC Alinityi Folate Reagent kit: 08P1422 & 08P1432 Alinityi Folate Calibrators: 08P1401 Alinity i Folate Controls: 08P1410 Alinityi Folate Manual diluent: 08P1460 Alinityi Folate RBC lysis diluent: 08P1440 Alinityi Folate Lysis Reagent: 08P1542 Alinityi Ferritin Reagent kit: 07P6520 & 07P6530 Alinityi Ferritin Calibrators: 07P6501 Alinityi Ferritin Controls: 07P6510</p> <p>Rs.25,000/-</p>		
2.	-do-	<p>Manufacturer: Standard Diagnostics, Inc. 65, Borahag1-ro, Giheung-gu, Yongin-si, Gyeonggi-do</p> <p>(FSC Korea issuance 11-08-2017)</p>	<p>SD UroColor SD UroColor Class B Shelf Life: 24 Months Sizes & Codes as Per FSC SD UroColor 10 (10UK10)</p>	<p>SD UroColor are plastic Strips to which are attached several separate reagent areas. Depending on the product being used, SD UroColor provides test for Blood, Bilirubin, UroBilinoge,</p>	<p>Deferred for provision of Free Sale Certificate of any reference country mentioned in Rule 67 or Foreign inspection of manufacturer abroad.</p>

			Rs.25,000/-	Keton, Protein, Nitrite, Glucose, pH, Specific gravity, Leucocytes and Ascorbic acid in Urine.	
3.	-do-	<p>Manufacturer: Standard Diagnostics, Inc. 65, Borahagl-ro, Giheung-gu, Yongin-si, Gyeonggi-do</p> <p>(FSC Korea issuance 11-08-2017)</p>	<p>SD BiolinehCG</p> <p>SD BiolinehCG</p> <p>Class B Shelf Life: 24 Months</p> <p>Sizes & Codes: (30FK10)</p> <p>Rs.25,000/-</p>	SD BiolinehCG is an IV immunochromatographic one step assay designed for qualitative determination of hcg in urine after conception.	Deferred for provision of Free Sale Certificate of any reference country mentioned in Rule 67 or Foreign inspection of manufacturer abroad.
4.	-do-	<p>Legal Manufacturer: BIOKIT, S.A, CAN MALE S/N, - 08186-LICA D'AMUNT, Barcelona Spain</p> <p>Manufacturing Sites: BIOKIT, S.A, Can XICOTA, 08186 LICA D'AMUNT, Barcelona Spain.</p> <p>BIOKIT, S.A, Av Can Montacau, 7 08186 Llica d Amunt, Barcelona Spain.</p> <p>(FSC Spain issue 24-01-2019)</p>	<p>Alinity c RF Reagent Kit</p> <p>Alinity c RF Standard</p> <p>Alinity c ASO Reagent Kit</p> <p>Alinity C ASO Standard</p> <p>Alinity c ASO-RF Control</p> <p>Alinity c ASO-RF Control II</p> <p>Class B</p> <p>Alinity c RF Reagent Kit 13 Months</p> <p>Alinity c RF Standard 14 Months</p> <p>Alinity c ASO Reagent Kit 19 Months</p> <p>Alinity C ASO Standard 60 days</p> <p>Alinity c ASO-RF Control I 20 Months</p> <p>Alinity c ASO-RF Control II 24 Months</p>	The assay is used for quantitative determination of Rheumatoid factor & Antidreptolyc in-O in Human serum on Alinity c analyzer.	Approved.

			Sizes & Codes as Per FSC Rs. 25,000/-		
5.	-do-	<p>Legal Manufacturer:</p> <p>Sentinel Ch. S.p.A. Via Robert Koch, 2 Milano (MI) 20152, Italy</p> <p>(FSC Italy issue 11-04-2017)</p>	<p>Alinity c Ammonia Ultra Reagents Kit, Alinity c Ammonia Controls</p> <p>Alinity c Ammonia Ultra Reagents Kit, Alinity C Ammonia Controls</p> <p>Class B</p> <p>Shelf Life: Alinity c Ammonia Ultra Reagents Kit ,16 Months Alinity c Ammonia Controls 30 Months at 2-8 °C</p> <p>Sizes & Codes as Per FSC Alinity c Ammonia Ultra Reagents Kit: 08P2220 Alinity c Ammonia Controls: 08P2210</p> <p>Rs. 25,000/-</p>	<p>Alinity c Ammonia Ultra Reagents Kit, used for quantitative determination of Ammonia in human serum on Alinity c analyzer</p>	Approved.
6.	-do-	<p>Manufacturer:</p> <p>Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland.</p> <p>(FSC Ireland valid 03-09-2023)</p>	<p>Architect Folate Folate Lysis Reagent Architect Ferritin.</p> <p>Architect Folate Folate Lysis Reagent Architect Ferritin.</p> <p>Class B Shelf Life: Architect Folate Folate Lysis Reagent: 18 Months Architect Ferritin: 14 Months</p> <p>Sizes & Codes as</p>	<p>The Architect Folate assay is a chemiluminescent assay for the quantitative determination of folate in human serum, plasma, and red blood cell on the Architect I System. The Folate Lysis Reagent is for use with the architect I systems when used for the quantitative determination of</p>	Approved.

			<p>Per FSC Architect Folate Calibrators 1P74-01 Architect Folate Controls 1P74-10 Architect Folate Reagent kits: 1P74-25 & 1P74-35 Architect Folate Manual diluent: 1P74-50 ArchitectFolate RBC lysis diluent: 1P74-40 Architect Folate Lysis Reagent: 3P21-60 Architect Ferritin Calibrators: 7K59-01 Architect Ferritin Controls: 7K59-10 Architect Ferritin Reagent kits: 7K59-30 & 7K59-35 Rs.25,000/-</p>	<p>folate in human red blood cells. The Architect Ferritin assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of ferritin in human serum and plasma.</p>	
7.	-do-	<p>Legal Manufacturer: Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 22-03-2019)</p>	<p>Alinity c Glucose, Creatinine, Urea Nitrogen, Uric Acid, Multiconstituent Calibrator Class B Shelf Life: Alinity c Multiconstituent Calibrator Kit 12 Months Alinity c Creatinine Reagent Kit 15 Months Alinity c Glucose Reagent Kit 13 Months Alinity c Uric Acid Reagent Kit</p>	<p>The Alinity c Creatinine assay is used for quantitation of creatinine in human serum, plasma or urine. The Alinity c Glucose assay is used for quantitation of glucose in human serum, plasma, urine or CSF. The Alinity c Multiconstituent calibrator is used in calibration of Albumin, Calcium,</p>	Approved.

			<p>13 Months Alinity c Urea Nitrogen Reagent Kit 13 Months</p> <p>Sizes & Codes as Per FSC Alinity c Multiconstituent Calibrator Kit 08P6001 Alinity c Creatinine Reagent Kit 07P9920 & 07P9930 Alinity c Glucose Reagent Kit 07P5520 & 07P5530 Alinity c Uric Acid Reagent Kit 08P5620 & 08P5630 Alinity c Urea Nitrogen Reagent Kit 08P1630 & 08P1630</p> <p>Rs. 25,000/-</p>	<p>Cholestrol, Creatinine, Glucose, Iron, Lactic acid, Megnesium, Phosphorus, Total Protein, Triglyceride, Urea Nitrogen and Uric acid assays. The Alinity c Urea nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma or urine. The Alinity c Uric Acid assay is used for the quantitation of uric acid in human serum, plasma or urine.</p>	
8.	-do-	<p>Manufacturer: Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland. (FSC Ireland valid 03- 09-2023)</p>	<p>Architect LH Architect FSH Architect Estradiol Architect Prolactin Architect Progesterone Architect Total B- HCG</p> <p>Class B Shelf Life:</p> <p>Architect LH 15 Months Cal: 12 Months</p> <p>Architect FSH 18 Months Cal & Control 15 Months</p> <p>Architect Estradiol 10 Months</p> <p>Architect Prolactin</p>	<p>The Architect Total B-hcg assay is a Chemiluminesce nt Microparticle Immunoassay (CMIA) for the quantitative and qualitative determination of beta-human chorionic gonadotropin (B-hcg) in human serum and plasmafor the early detection of pregnancy.</p>	Approved.

			12 Months Architect Progesterone 09 Months, Cal & Control 12 Months Architect Total B- Hcg 12 Months Sizes & Codes as Per FSC ARCHITECT LHCalibrators (2P40-01) ARCHITECT LH Reagent Kit (2P40- 25) ARCHITECT FSH Calibrators (7K75- 01) ARCHITECT FSH Controls Kit (7K75-10) ARCHITECT FSH Reagent (7K75-25) ARCHITECT FSH Reagent (7K75-30) ARCHITECT FSH Reagent (7K75-35) ARCHITECT Estradiol Calibrators (7K72- 01) ARCHITECT Estradiol Controls (7K72-10) ARCHITECT Estradiol Manual Diluent (7K72-50) ARCHITECT Estradiol Reagent Kit 1 Diluent (7K72-25) ARCHITECT Estradiol Reagent Kit 1 Diluent (7K72-35) ARCHITECT Prolactin Calibrators (7K76-01) ARCHITECT		
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			Prolactin Calibrators (7K76-10) ARCHITECT Prolactin Reagent Kit (7K76-25) ARCHITECT Prolactin Reagent Kit (7K76-30) ARCHITECT Prolactin Reagent Kit (7K76-35) ARCHITECT Progesterone Calibrators (7K77-01) ARCHITECT Progesterone Controls (7K77-10) ARCHITECT Progesterone Manual Diluent (7K77-50) ARCHITECT Progesterone Reagent Kit (7K77-25) ARCHITECT Progesterone Reagent Kit (7K77-35) ARCHITECT total B-hCG Calibrators (7K78-01) ARCHITECT total B-hCG Controls (7K78-10) ARCHITECT total B-hCG Reagent Kit (7K78-25) ARCHITECT total B-hCG Reagent Kit (7K78-30) ARCHITECT total B-hCG Reagent Kit (7K78-35) Rs.25,000/-		
9.	-do-	Manufactuerer: Abon Biopharm (Hangzhou) Co., Ltd	One Step H. Pylori Test Device (Serum/Plasma) Strep A Rapid Test	One step H. pylori test device is rapid chromatographic	Approved.

		<p>#198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.</p> <p>(FSC Germany issuance 21-03-2019)</p>	<p>Device (Throat Swab)</p> <p>One Step H. Pylori Test Devcie Strep A Rapid Test Device</p> <p>Class B Shelf Life: 24 Months</p> <p>Sizes & Codes as Per FSC: ST-502 Clearview Strep A Cassette 2 HP-302 One Step H.pylori Test Device (Serum/plasma</p> <p>Rs.25,000/-</p>	<p>immunoassay test for the qualitative detection of Antibodies to H. pylori in serum or plasma tO aid in diagnosis of H. pylori infection. Strep A rapid test device is rapid chromatographic immunoassay test for the qualitative detection of Antigen in throat swab to aid in diagnosis of Group A Streptococcal infections.</p>	
10.	-do-	<p>Manufacturer:</p> <p>Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland.</p> <p>(FSC Ireland valid 03- 09-2023)</p>	<p>Architect 25-OH Vitamin-D</p> <p>Architect B12 Reagent kit</p> <p>Architect 25-OH Vitamin-D</p> <p>Architect B12</p> <p>Class B Shelf Life: Architect 25-OH Vitamin-D 15 Months</p> <p>Architect B12 11 Months</p> <p>Sizes & Codes as Per FSC 25-OH Vitamin-D Reagent kits 5P02-25 5P02-30 5P02-35 Calibrator kit 5P02-01</p>	<p>Architect25- OH Vitmin-D Assay is a chemiluminesce nt assay for the quantitative determination of vitamin B12 in human serum and plasma on the architect I System. Architect B12 Assay is a chemiluminesce ntMicroparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum and plasma on the architect I System.</p>	Approved.

			Control 5P02-10 Architect B12 Reagent kit 7K61-25 7K61-35 Architect B12 Calibrators 7K61-01 Architect B12 controls 7K61-10 Rs.25,000/-		
11.	-do-	<p>Manufacturer: AbonBiopharm (Hangzhou) Co., Ltd. # 198,12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.</p> <p>Certificate of Exportability, China Validity 04-02-2019 08-01-2020</p> <p>FSC Germany Validity 21-03-2020</p>	<p>Abon TB Tuberculosis Rapid Test Device (whole blood/ Serum/ Plasma) Tuberculosis Test</p> <p>Class-C</p> <p>Shelf life: 24 months</p> <p>Codes & sizes: ITB-402</p>	<p>TB Tuberculosis Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of anti-TB antibodies in whole blood, serum or plasma specimens.</p>	<p>Approved.</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>
12.	-do-	<p>Legal Manufacturer: AbonBiopharm (Hangzhou) Co., Ltd. # 198,12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.</p> <p>Certificate of Exportability, China Validity 04-02-2019 08-01-2020</p> <p>FSC Germany Validity 21-03-2020</p>	<p>Multi-Drug One Step Screen Test Panel (Urine) Multi-Drug One Step Screen Test Panel Adulteration strip (Urine)</p> <p>Class-B</p> <p>Shelf life: 24 months but ongoing for Cannabinoids</p> <p>Codes & sizes: DUD-124 DUD-134 DUD-144 DUD-154 DUD-164 DUD-174 DUD-184 DUD-194</p>	<p>A rapid one step test for the simultaneous qualitative detection of multiple drugs andmetabolites in human urine DUD-124 (Cocain, Mairjuana) DUD-134 (COC, Amphetamine, Mairjuana) DUD-144 (cocain, Amphetamine, Mairijuana, Benzodiazepines) DUD-154 (MET, THC,</p>	<p>Approved.</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>

			DUD-1104	OPI, BZO, BUP) DUD-164 (COC150, AMP500, MET500, THC, OPI, BZO200) DUD-174 (COC, AMP, THC, MOP, TRA, BAR, BZO) DUD-184 (COC, AMP, THC, OPI, TRA, BZO, K2 cannabinoids) DUD-194 (COC, AMP, MET, MTD, MOP, PCP, THC, BZO, BAR) DUD-1104 (COC, AMP, MET, MTD, MOP, PCP, THC, BZO, BAR, TCA)	
13.	-do-	<p>Legal Manufacturer:</p> <p>Alere San Diego, Inc. 9975 summers Ridge Road San Diego, CA 92121 USA.</p> <p>FSC US FDA validity 08-05-2021</p>	<p>Cholestech LDX System Cholestech LDX System</p> <p>Class-C</p> <p>Shelf life: Stable for more than 12 months when stored at 2-8 °C and 30 days when stored at 30 °C.</p> <p>Codes & sizes: CholestrolLDX TC (10-986) Cholestrol LDX TC.HDL (10-987) Cholestrol LDX TC.GLU (10-988) Cholestrol LDX Lipid Profile (10-989)</p>	<p>Is a small, portable analyzer and test cassette system, the system combines enzymatic methodology and solid phase technology to measure total Cholesterol, HDL cholesterol, triglycerides and glucose in whole blood.</p>	Approved.

			<p>Cholestrol LDX TC.HDL.GLU (10-990) Cholestrol LDX Lipid Profile.GLU (10-991) Cholestrol LDX Lipid Profile.GLU (99021) Cholestrol LDX Multianalyte Control (88769) Cholestrol LDX Multianalyte Control (88773) Cholestrol LDX Calibration Verification (88770)</p>		
14.	-do-	<p>Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P.O. Box 6863 Rodelokka No-0504 Oslo, Norway.</p>	<p>Afinion CRP Afinion CRP Control</p> <p>Codes & Sizes as per FSC. Claimed Shelf- life: CRP Reagent:12 Months CRP Control 36 Months. Class: B Category: IVD-Cluster.</p>	<p>Afinion CRP Reagent kit used for the quantitative determination of C-reactive protein in human whole blood, serum and plasma.The measurement of CRP provides information for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.</p>	<p>Approved subject to provision of valid ISO- 13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP & manufacturing sites are missing.)</p>
15.	-do-	<p>Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P O Box 6863 RodelokkaNo-0504 Oslo, Norway.</p> <p>FSC Norway Valid Till (18-03-2021)</p>	<p>Afinion HbA1C Panel Afinion HbA1C Control</p> <p>Claimed Shelf- life: AfinionHbA1c:24- Months. AfinionHbA1c control:24-Months. Class: B Category:</p>	<p>Afinion HbA1cis an in- vitro diagnostic test for quantitative determination of HbA1cin human whole blood. The measure of HbA1c is recommended as a marker of long-term</p>	<p>Approved subject to provision of valid ISO-13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP &</p>

			IVD-Cluster. Codes & Sizes as per FSC.	metabolic control in person with diabetes mellitus.	manufacturing sites are missing.)
16.	-do-	Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P O Box 6863 Rodelokka No-0504 Oslo, Norway. FSC Norway Valid Till (18-03-2021)	NYCOCARD HbA1c NYCOCARD HbA1c Control Claimed Shelf- life: NYCOCARD HbA1c:07-Months. NYCOCARD HbA1c control:15- Months. Class: B Category: IVD-Cluster. Codes & Sizes as per FSC.	NYCOCARDH bA1c Reagent kit used for the quantitative determination of HbA1c in human whole blood. The measure of HbA1c is recommended as a marker of long-term metabolic control in person with diabetes mellitus.	Approved subject to provision of valid ISO-13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP & manufacturing sites are missing.)
17.	-do-	Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P O Box 6863 Rodelokka No-0504 Oslo, Norway. FSC Norway Valid Till (18-03-2021)	NYCOCARD Albumin NYCOCARD Albumin Control Claimed Shelf- life: NYCOCARD Albumin:14- Months NYCOCARD Albumin:12- Months Class: B Category: IVD-Cluster. Codes & Sizes as per FSC.	NYCOCARD U-Albumin is a rapid in-vitro test for measurement of low albumin concentration in human urine.	Approved subject to provision of valid ISO-13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP & manufacturing sites are missing.)
18.	-do-	Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P O Box 6863 Rodelokka No-0504 Oslo, Norway. FSC Norway Valid Till (18-03-2021)	NYCOCARD CRP Claimed Shelf- life: CRP Reagent:18 Months Class: B Category: IVD-Cluster. Codes & Sizes as per FSC.	NYCOCARD CRP Reagent kit used for the quantitative determination of C-reactive protein in human whole blood, serum and plasma.The measurement of CRP provides information for the detection and evaluation of infection,	Approved subject to provision of valid ISO-13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP & manufacturing sites are

				tissue injury, inflammatory disorders and associated diseases.	missing.)
19.	-do-	<p>Legal Manufacturer: M/s Abbott Diagnostics Technologies AS, Kjelsasveien 161 P O Box 6863 Rodelokka No-0504 Oslo, Norway.</p> <p>FSC Norway Valid Till (18-03-2021)</p>	<p>AFINION ACR AFINION ACR Control</p> <p>Codes & Sizes as per FSC.</p> <p>Claimed Shelf-life: ACR Reagent:09-Months ACR Control:12-Months. Class: B</p> <p>Category: IVD-Cluster.</p>	<p>AFINION ACR is a rapid in-vitro test for QN measurement of albumin, creatinine and albumin/creatinine ratio in human urine.</p>	<p>Approved subject to provision of valid ISO-13485 certificate and revise application form alongwith complete particulars as per MDR-2017 (MRP & manufacturing sites are missing.)</p>
20.	-do-	<p>Manufacturer: Microgenics Corporation 46500 Kato Road, Feromont, CA USA 94538</p> <p>(FSC US FDA Valid till 06-11-2020)</p>	<p>Theophylline (Kit)</p> <p>Class C</p> <p>Theophylline Code: 0506-21</p> <p>Shelf life: 18 months\</p> <p>Fee submitted: Rs. 50,000/- (Challan No. 0580475)</p>	<p>An invitro diagnostic use for the quantitative measurement of theophylline in human serum or plasma on the Architect c systems.</p>	<p>Approved.</p>
21.	-do-	<p>Manufacturer: Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany.</p> <p>(FSC Germany issued on 19-07-2018)</p>	<p>Alinity i EBV VCA IgG Kit</p> <p>Class C</p> <p>Alinity i EBV VCA IgG Calibrator Code: 09P2101 Shelf Life:18 months</p> <p>Alinity i EBV VCA IgG Controls Code: 18 months Shelf Life: 09P2110</p> <p>Alinity i EBV VCA IgG Reagent Kit</p>	<p>CMIA used for the qualitative detection of IgG antibodies to Epstein-Barr Virus(EBV) Viral Capsid Antigen (VCA) in human serum and plasma on the Alinity i analyzer</p>	<p>Approved.</p>

			Code: 09P2122 Shelf Life: 10 months Alinity i EBV VCA IgG Reagent Kit Code: 09P2132 Shelf Life: 10 months Fee submitted: Rs. 50,000/-		
22.	-do-	Legal Manufacturer: B.R.A.H.M.S GmbH Neuendorfstrabe 25 D-16761 Henningsdorf Germany Manufacturing Site: Microgenics corporation 46500 Kato Road, Fremont California 94538 USA. (FSC Germany issued on 17-10-2018)	Alinity c Gentamicin Reagent Kit Class C Code: 08P5520 Shelf Life: 12 Months Fee submitted: Rs. 50,000/-	Used for the quantitative determination of gentamicin in human serum, or plasma on the Alinity c analyzer	Approved.
23.	-do-	Legal Manufacturer: B.R.A.H.M.S GmbH Neuendorfstrabe 25 D-16761 Henningsdorf Germany Manufacturing Site: Microgenics corporation 46500 Kato Road, Fremont California 94538 USA. (FSC Germany issue 15-05-2018)	Alinity c Vancomycin Reagent Kit Class C Code: 08P5220 Shelf Life: 16 Months Fee submitted: Rs. 50,000/-	Used for the quantitative determination of vancomycin in human serum or plasma on the Alinity c Analyzers	Approved.
24.	-do-	Legal Manufacturer: B.R.A.H.M.S GmbH Neuendorfstrabe 25 D-16761 Henningsdorf Germany Manufacturing Site: Microgenics	Alinity c Phenytoin Reagent Kit Class C Code: 08P5420 Shelf Life: 13 Months	Used for in vitro diagnostic use for the quantitative measurement of phenytoin in human serum or plasma on the Alinity c analyzer.	Approved.

		corporation 46500 Kato Road, Fremont California 94538 USA. (FSC Germany issue 17-10-2018)	Fee submitted: Rs. 50,000/-		
25.	-do-	Legal Manufacturer: B.R.A.H.M.S GmbH Neuendorfstrabe 25 D-16761 Henningsdorf Germany Manufacturing Site: Microgenics corporation 46500 Kato Road, Fremont California 94538 USA. (FSC Germany issue 17-10-2018)	Alinity c Amikacin Reagent Kit Class C Code: 09P4420 Shelf Life: 12 Months Fee submitted: Rs. 50,000/-	Used for the quantitative determination of amikacin in human serum or plasma on the Alinity c analyzer	Approved.
26.	-do-	Manufacturer: Abbott GmbH & Co, KG. Max-Planck-Ring 2 65205, Wiesbaden, Germany. (FSC Germany issued on 19-07-2018)	Alinity i CYFRA 21-1 Kit Class C Alinity i CYFRA 21-1 Reagent Kit Code: 09P4022 Shelf Life: 11 Months Alinity i CYFRA 21-1 Controls Code: 09P4010 Shelf Life: 12 Months Alinity i CYFRA 21-1 Calibrators Code: 09P4001 Shelf Life: 12 Months Fee submitted: Rs. 50,000/-	CMIA used for the quantitative determination of human cytokeatin 19 fragments in human serum and plasma on the Alinity i analyzer	Approved.
27.	-do-	Manufacturer: Sentinel CH. S.p.A. Via Robert Koch, 2 -20152, Milano, Italy (FSC Italy issue 18-10-2018)	Alinity c CK-MB Kit Class C Alinity c CK-MB Reagent Kit Code: 09P9522 Shelf Life: 19 Months	Used for the kinetic determination of the CK-MB and CK-BB isoenzymes of creatinine kinase in serum or plasma on the Alinity c	Approved.

			<p>Alinity c CK-MB Reagent Kit Code: 09P9532 Shelf Life: 19 Months</p> <p>Alinity c CK-MB Control Kit Code: 09P9510 Shelf Life: 24 Months</p> <p>Alinity c CK-MB Calibrator Kit Code: 09P9501 Shelf Life: 24 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	analyzer	
28.	-do-	<p>Manufacturer: Abbott GmbH & Co, KG. Max-Planck-Ring 2 65205, Wiesbaden, Germany.</p> <p>(FSC Germany issued on 19-07-2018)</p>	<p>Alinity c Creatinine Kinase Kit</p> <p>Class C</p> <p>Alinity c Creatinine Kinase Kit Code:08P4220 Shelf Life: 09 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	Used for the quantitation of creatine kinase in human serum or plasma on the Alinity c analyzer	Approved.
29.	-do-	<p>Manufacturer: Abbott GmbH & Co, KG. Max-Planck-Ring 2 65205, Wiesbaden, Germany.</p> <p>(FSC Germany issued on 19-07-2018)</p>	<p>Alinity i PIVKA-II Kit</p> <p>Class C</p> <p>Alinity i PIVKA-II Reagent Kit Code: 01R1732 Shelf Life: 17 Months</p> <p>Alinity i PIVKA-II Reagent Kit Code: 01R1722 Shelf Life: 17 Months</p> <p>Alinity i PIVKA-II Controls</p>	CMIA used for the quantitative determination of PIVKA-II in human serum or plasma on the Alinity i analyzer	Approved.

			Code: 01R1710 Shelf Life: 23 Months Alinity i PIVKA-II Calibrator Kit Code: 01R1701 Shelf Life: 23 Months Fee submitted: Rs. 50,000/-		
30.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC USFDA Valid Till 10-05-2020)	PathVysion HER-2 DNA Probe Kit Class C i) PathVysion HER-2 DNA Probe Kit Code: 02J01-030 Shelf Life: 18 Months ii) ProbeChek HER-2/neu Cut-Off Control Slides Code: 02J04-030 Shelf Life: 12 Months iii) ProbeChek HER-2/neu Normal Control Slides Code: 02J05-030 Shelf Life: 12 Months Fee submitted: Rs. 50,000/- (Challan No. 0580494)	Designed to detect amplification of the HER- 2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin- embedded human breast cancer tissue specimens	Approved Before issuance of registration letter, the firm shall provide valid FSC. The firm shall submit separate application for Vysis MYC Spectrum Orange FISH probe kit.
31.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	Abbott RealTime HBV Kit Class C i) Abbott RealTime HBV Calibrator Kit Code: 2G34-70 Shelf Life: 18 Months ii) Abbott	An invitro PCR assay for quantitation of Hepatitis B Virus (HBV) DNA in human plasma or serum from HBV- infected individuals	Approved

			<p>RealTime HBV Control Kit Code: 2G34-80 Shelf Life: 18 Months</p> <p>iii) Abbott RealTime HBV Amplification Reagent Kit Code: 2G34-90 Shelf Life: 18 Months</p> <p>Fee submitted: Rs. 50,000/- (Challan 0580487)</p>		
32.	-do-	<p>Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p> <p>(FSC GERMANY issued on 28-01-2016)</p>	<p>Abbott RealTime HCV Kit</p> <p>Class C</p> <p>i) Abbott RealTime HCV Calibrator Kit Code: 4J86-70 Shelf Life: 18 Months</p> <p>ii) Abbott RealTime HCV Control Kit Code: 4J86-80 Shelf Life: 18 Months</p> <p>iii) Abbott RealTime HCV Amplification Reagent Kit Code: 4J86-90 Shelf Life: 18 Months</p> <p>Fee submitted: Rs. 50,000/- (Challan 0580486)</p>	<p>An invitro reverse transcription-PCR (RT-PCR) assay for quantitation of Hepatitis C Virus (HCV RNA) DNA in human plasma or serum from HCV-infected individuals</p>	Approved
33.	-do-	<p>Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA</p>	<p>Abbott RealTime HCV Genotype II Kit</p> <p>Class C</p>	<p>An invitro reverse transcription-PCR (RT-PCR) assay for determining the</p>	Approved

		(FSC GERMANY issued on 28-01-2016)	<p>i) Abbott RealTime HCV Genotype II Control Kit Code: 8K24-80 Shelf Life: 18 Months</p> <p>ii) Abbott RealTime HCV Genotype II Amplification Reagent Kit Code: 8K24-90 Shelf Life: 18 Months</p> <p>Fee submitted: Rs. 50,000/- (Challan 0580496)</p>	genotype(s) of Hepatitis C Virus (HCV RNA) DNA in plasma or serum from HCV-infected individuals	
34.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSCs USFDA Valid Till 13-09-2019)</p>	<p>i-STAT PT/INR Cartridge (Kit) Class C</p> <p>i) i-STAT PT Control Level 1 Code: 06P17-13 Shelf Life: 365 Days</p> <p>ii) i-STAT PT Control Level 2 Code: 06P17-14 Shelf Life: 365 Days</p> <p>iii) i-STAT PT/INR Cartridge Code: 03P89-24 Shelf Life: 180 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	Prothrombin time test for monitoring patients receiving oral anticoagulation therapy such as Coumadin or warfarin	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>
35.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSCs USFDA Valid Till 13-09-2019)</p>	<p>i-STAT CK-MB Cartridge (Kit) Class C</p> <p>i) i-STAT CK-MB Control Level 1 Code: 06P17-01 Shelf Life: 730 Days</p> <p>ii) i-STAT CK-MB</p>	Invitro diagnostic test for the quantitative measurement of creatinine kinase MB mass in whole blood or plasma samples.	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>

			<p>Control Level 2 Code: 06P17-02 Shelf Life: 730 Days</p> <p>iii) i-STAT CK- MB Control Level 3 Code: 06P17-03 Shelf Life: 730 Days</p> <p>iv) i-STAT CK-MB Calibration Verification Set Code: 06P17-04 Shelf Life: 730 Days</p> <p>v) i-STAT CK-MB Cartridge Code: 03P92-25 Shelf Life: 167 Days</p> <p>Fee submitted: Rs. 50,000/-</p>		
36.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSC USFDA Valid Till 13-09-2019)</p>	<p>i-STAT Kaolin ACT Cartridge (Kit)</p> <p>Class C</p> <p>i) i-STAT ACT Control Level 1 Code: 06P17-15 Shelf Life: 365 Days</p> <p>ii) i-STAT ACT Control Level 2 Code: 06P17-16 Shelf Life: 365 Days</p> <p>iii) i-STAT Kaolin ACT Cartridge Code: 03P87-25 Shelf Life: 180 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Kaolin Activated Clotting Time (ACT) is an invitro diagnostic test that uses fresh, whole blood to monitor high dose heparin anticoagulation frequently associated with cardiovascular surgery</p>	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>

37.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSC USFDA Valid Till 13-09-2019)</p>	<p>i-STAT BNP Cartridge (Kit)</p> <p>Class C</p> <p>i) i-STAT BNP Control Level 1 Code: 06P17-05 Shelf Life: 730 Days</p> <p>ii) i-STAT BNP Control Level 2 Code: 06P17-06 Shelf Life: 730 Days</p> <p>iii) i-STAT BNP Control Level 3 Code: 06P17-07 Shelf Life: 730 Days</p> <p>iv) i-STAT BNP Calibration Verification Set Code: 06P17-08 Shelf Life: 730 Days</p> <p>v) i-STAT BNP Cartridge Code: 03P93-25 Shelf Life: 204 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Intended for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant</p>	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>
38.	-do-	<p>Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSC USFDA Valid Till 13-09-2019)</p>	<p>i-STAT Celite ACT Cartridge</p> <p>Class C</p> <p>Code: 03P86-25</p> <p>Shelf Life: 180 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Celite Activated Clotting Time (ACT) is an invitro diagnostic test that uses fresh, whole blood to monitor anticoagulation therapy</p>	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>
39.	-do-	<p>Manufacturer: M/s Abbott Point of</p>	<p>i-STAT cTnl Cartridge (Kit)</p>	<p>Intended for the quantitative</p>	<p>Approved</p>

		<p>Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064</p> <p>(FSCs USFDA Valid Till 13-09-2019)</p>	<p>Class C</p> <p>i) i-STAT cTnI Cartridge Code: 03P90-25; 06P23-25 Shelf Life: 213 Days</p> <p>ii) i-STAT cTnI Control Level 1 Code: 06P17-09 Shelf Life: 730 Days</p> <p>iii) i-STAT cTnI Control Level 2 Code: 06P17-10 Shelf Life: 730 Days</p> <p>iv) i-STAT cTnI Control Level 3 Code: 06P17-11 Shelf Life: 730 Days</p> <p>v) i-STAT cTnI Calibration Verification Set Code: 06P17-12 Shelf Life: 730 Days</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>measurement of cardiac troponin I (cTnI) in whole blood or plasma</p>	<p>Before issuance of registration letter, the firm shall provide valid FSC.</p>
40.	-do-	<p>Manufacturer: Abbott Molecular Inc. 1300 E. Touhy Ave. Des Plaines, IL USA 60018</p> <p>(FSC Germany issued on 18-05-2020)</p>	<p>Abbott Realtime SARS-CoV-2 Kit</p> <p>Class C</p> <p>Abbott Realtime SARS-CoV-2 Amplification Reagent Kit Code: 09N77-090 Shelf life: 18 monts</p> <p>Abbott Realtime</p>	<p>The Abbott RealTime SARS-COV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-COV-2 in</p>	<p>Approved</p>

			<p>SARS CoV-2 Control Kit Code: 09N77-080 Shelf life: 12 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>nasopharyngeal (NP) and oropharyngeal (OP) swabs from patients who are suspected of COVID-19 by their healthcare provider. Results are for the identification of SARS-COV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal and oropharyngeal swabs during the acute phase of 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</p>	
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				must be combined with clinical observations, patient history and epidemiological information. The Abbott RealTime SARS-CoV-2 assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.	
41.	M/s. Roche Pakistan Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi. (ELI-00009)	Legal & Actual Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. Codes & Sizes as per FSC of Germany.	ROCHE COBAS ®ANTI HAV II IVD-Test kit. Class:C It consists of ROCHE COBAS ® Anti HAV II (100- Tests). ROCHE COBAS ® Anti HAV II (300- Tests). ROCHE COBAS ® Preci-control Anti HAV II (16x1.3ml). Claimed Shelf Life: 18-months ROCHE COBAS ® Anti HAV II while for Preci-control Anti HAV II 15- months.	ROCHE COBAS ® ANTI HAV-II immunoassay for In-vitro QL detective of total antibodies (IgG & IgM) to hepatitis A virus in human pediatric and adult (ages 02- 21years) serum and plasma.	Approved.
42.	-do-	Legal & Actual Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. Codes & Sizes as per	COBAS Elecsys IgE-II (Allergy Panel). IVD-Cluster. Class:B It consists of i. COBAS Elecsys	COBAS Elecsys IgE-II Immunoassay for the in vitro quantitative determination of IgE in human	Approved.

		FSC of Germany.	<p>IgE-II. (100-Tests)</p> <p>ii. COBAS Elecsys IgE-II. (100-Tests)</p> <p>iii. COBAS Elecsys IgE CalSet. (4x 1.0ml).</p> <p>iv. COBAS Diluent Universal (45.2ml).</p> <p>Claimed Shelf Life: 21-months for Elecsys IgE-II while for CalSet 18-months.</p>	serum and plasma. Determination of total IgE is useful as an aid in the diagnosis of allergic disease. The electro-chemiluminescence immune-assay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.	
43.	-do-	<p>Legal Manufacturer/Manufacturing site: Roche Molecular Systems Inc., 1080 US Hwy 202, South Branchburg, NJ 08876 USA.</p> <p>(FSC Germany issued on 17-04-2020)</p>	<p>Cobas SARS-CoV-2 Kit</p> <p>Class C</p> <p>Cobas SARS-CoV-2 Code: 09175431190 Shelf life: 12 months (study ongoing)</p> <p>Cobas SARS CoV-2 Control Kit Code: 09175440190 Shelf life: 12 months (study ongoing)</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Cobas® SARS-CoV-2 for use on the Cobas® 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients with signs and symptoms suggestive of COVID-19 (e.g., fever and /or symptoms of acute respiratory illness). Results are for the detection of SARS-CoV-2 RNA that are detectable in nasopharyngeal and oropharyngeal swab samples during infection.</p>	<p>Approved</p> <p>The firm shall provide quarterly update on the product safety and performance in EU.</p>

				<p>Positive results are indicative of 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, and epidemiological information. Cobas® SARS-CoV-2 is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.</p>			
44.	<p>M/s. ASTO Life Sciences (Pvt) Ltd. Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore (ELI-00103)</p>	<p>Manufacturer: BECTON, DICKINSON & Co.,7 Loveton CIR Sparks, MD USA 21152</p> <p>FSC USFDA valid till 19-09-2020</p>	<p>BD BACTEC MGIT 960 SYSTEM</p> <p>Class C</p> <p>Ref No: 445870</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>An invitro diagnostic instrument designed and optimized for the rapid detection of mycobacteria from clinical specimen (except blood and urine)</p>	<p>Approved</p> <p>Before issuance of registration letter, the firm shall provide valid FSC.</p>		
45.	<p>M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)</p>	<p>Manufacturer: DePuy Orthopaedics, Inc. 700 Orthopaedic Dr. Warsaw, IN USA, 46582.</p> <p>(FSC US FDA valid till</p>	<p>Sigma Primary Knee</p> <p>Class D</p> <p>Codes:</p> <table border="1" data-bbox="846 1866 1073 1898"> <tr> <td>Product</td> <td>Sh</td> </tr> </table>	Product	Sh	<p>Total knee prosthesis</p>	<p>Approved .</p>
Product	Sh						

		04-04-2021) (FSC US FDA valid till 21-05-2021)	<table border="1"> <thead> <tr> <th>Descriptio n</th> <th>elf- life</th> </tr> </thead> <tbody> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 2</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 3</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 4</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 5</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 1.5</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® Modular Ti Tibia Tray Non- Porous Cemented 2.5</td> <td>10 ye ars</td> </tr> <tr> <td>Sigma® CR Non- Porous Cemented FEM LT SZ 2</td> <td>5 ye ars</td> </tr> <tr> <td>Sigma® CR Non- Porous Cemented</td> <td>5 ye ars</td> </tr> </tbody> </table>	Descriptio n	elf- life	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 2	10 ye ars	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 3	10 ye ars	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 4	10 ye ars	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 5	10 ye ars	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 1.5	10 ye ars	Sigma® Modular Ti Tibia Tray Non- Porous Cemented 2.5	10 ye ars	Sigma® CR Non- Porous Cemented FEM LT SZ 2	5 ye ars	Sigma® CR Non- Porous Cemented	5 ye ars		
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			Sigma® CR Non- Porous Cemented FEM LT SZ1.5	5 ye ars		
			Sigma® CR Non- Porous Cemented FEM LTSZ2.5	5 ye ars		
			Sigma® CR Non- Porous Cemented FEM RT SZ 2	5 ye ars		
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			Sigma® AP PS Tibia 12.5 mm SZ4	5 ye ars		
			Sigma® AP PS Tibia 15 mm SZ4	5 ye ars		
			Sigma® Modular CoCr Tibia Tray Non- Porous Cemented 1.5	10 ye ars		
			Sigma® Modular CoCr Tibia Tray Non- Porous Cemented 2	10 ye ars		
			Sigma® STB GVF Tibia Insert SZ 1.5 8 mm	5 ye ars		
			Sigma® STB GVF Tibia Insert SZ 1.5 10 mm	5 ye ars		
			Sigma® STB GVF Tibia Insert SZ 1.5 12.5 mm	5 ye ars		
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			Sigma® STB GVF Tibia Insert SZ 4 17.5 mm	5 ye ars		
			Sigma® STB GVF Tibia Insert SZ 4 20 mm	5 ye ars		
			Sigma® Modular CoCr Tibia Tray Non- Porous Cemented 2.5	10 ye ars		
			Sigma® STB GVF Tibia Insert SZ 5 8 mm	5 ye ars		
			Sigma® STB GVF Tibia Insert SZ 5 10 mm	5 ye ars		
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			Sigma® STB GVF Tibia Insert SZ 5 15 mm	5 ye ars		
			Sigma® Modular CoCr Tibia Tray Non-	10 ye ars		

			Porous Cemented 3	
			Sigma® Modular CoCr Tibia Tray Non-Porous Cemented 4	10 years
			Sigma® Modular CoCr Tibia Tray Non-Porous Cemented 5	10 years
			Sigma® CR CVD GVF Tibia Insert SZ 1.5 8 mm	5 years
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			Sigma® CR CVD GVF Tibia Insert SZ 5 15 mm	5 ye ars		
			Sigma® Modular+ Ti Tibia Tray Non Porous Cemented 5	10 ye ars		
			Sigma® Modular+ Ti Tibia Tray Non Porous Cemented 1.5	10 ye ars		
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			Sigma® Modular+ Ti Tibia Tray Non Porous Cemented 2	10 ye ars		
			Sigma® Modular+ Ti Tibia Tray Non Porous Cemented 3	10 ye ars		
			Sigma® Modular+ Ti Tibia Tray Non Porous Cemented 4	10 ye ars		
			Fee submitted: Rs. 50,000/-			

46.	M/s. Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, COSTA Rica FSC Ireland Valid till 26-05-2021	Viking™Quadpolar Fixed Curve Diagnostic Catheter Class-D Codes: Quadpolar codes as per FSC Ireland No. CFS007824 dated 26-05-2016 Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.	Approved. The firm shall apply separately for other types of catheters.
47.	-do-	Legal Manufacturer M/s. Boston Scientific Corporation,300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland FSC USFDA Valid till 09-10-2021	Wallstent Colonic and Duodenal Endoprosthesis with Unistep Plus Delivery System Class: C Codes: as per FSC US FDA No. 298-10-2019 Shelf Life : 2 years Fee submitted: Rs. 50,000/-	Indicated for palliative treatment of colonic, duodenal or gastric outlet obstruction or strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.	Approved.
48.	-do-	Legal Manufacturer M/s. Boston Scientific Corporation,300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland FSC USFDA Valid till 09-10-2021	WallFlex Enteral Duodenal Stent with Anchor Lock Delivery System Class : C Codes: M00565010 M00565020 M00565030 Shelf Life : 2 years Fee submitted: Rs. 50,000/-	Indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms	Approved.

49.	-do-	<p>Legal Manufacturer: M/s. Boston Scientific Corporation 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA</p> <p>Manufacturing Site: M/s Boston Scientific Limited, Cashel Road, Clonmel Co. Tipperary, Ireland.</p> <p>FSC Ireland Valid till 14-01-2021</p>	<p>Products Name: INGEVITY MRI Implantable Lead (Defibrillator/pace maker Lead)</p> <p>Codes: Models: 7731,7732, 7735, 7736, 7740, 7741, 7742</p> <p>Class: D</p> <p>Shelf Life: 2 years</p>	<p>Indications for use are identical for MRI and non-MRI models within each fixation type. INGEVITY passive fixation leads are indicated for use as follows:</p> <ul style="list-style-type: none"> • Intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator. INGEVITY active fixation leads are indicated for use as follows: • Intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator. 	Approved.
50.	-do-	<p>Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA</p> <p>Manufacturing Site: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112</p> <p>FSC, US, FDA: Date of issue: 29-08-</p>	<p>Acuity X4 Lead, defibrillator/pacemaker, implantable)</p> <p>Class: D</p> <p>Codes & Models: 4671, 4672, 4674, 4675, 4677, 4678</p> <p>Shelf Life: 2 years</p>	<p>Intended for chronic, left-ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator.</p>	Approved Before issuance of registration letter, the firm shall provide valid FSC.

		2018 Valid till: 28-08-2020			
51.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070	Legal Manufacturer FIAB SpA Via Paolo Costoli 4, 50039 VICCHIO- Florence, Italy Manufacturing Site Via Bruno Passerini 2, 4, 6/Via della Resistenza 18, 50039 VICCHIO, Florence-Italy FSC: Italy Date of issue 12.04.2018	(MYOPACE) (Sterile single use Epicardial Electrodes) Class: D Self-Life: 4 years Codes & sizes: 50060TZ 50060TzM Rs, 50000/-	Sterile single use Epicardial Electrodes	Approved.
52.	M/s. Mubarak Vision 32-A Usman Center, Shah ALam Market, Lahore. (ELI-00045)	Legal Manufacturer: Al.CHI.MI.A.Sr.I.viale Austra 14, (35020 Ponte San Nicolo (PD) Italy FCS Italy Date of issue 06.03.2017	Eye DRO 2ml (Viscoelastic Fluids in Ophthalmology use) Eye DRO, 2ml Class B Shelf Life: 36 months Code: EDO 001	Eye DRO is a sterile solution for temporary and topic use, intended to hydrate and protect the corneal surface, maintain the optical transparency, and allow the use of diagnostic glasses, during Ophthalmology use.	Approved.
53.	-do-	Legal Manufacturer: M/s Sterimedix Ltd Madely Road, North Moons Moat, Redditch, Worcestershire, B98 9NB, UK FSC UK Valid till 06.02.2021	Scleral Markers – M7500 Class A Shelf Life: 05 years Codes & sizes: M7500	Sterile invasive device used to mark the point for any pars plana incision or injection point. They are intended for transient use.	Approved. The firm shall apply separately for Irrigating Luer Handle-M1000.

54.	-do-	<p>Legal Manufacturer:</p> <p>Al.CHI.MI.A.Sr.I.viale Austra 14, (35020 Ponte San Nicolo (PD) Italy</p> <p>FCS Italy</p> <p>Date of issue 06.03.2017</p>	<p>GOT Multi SF6 75 ml</p> <p>(Retinal Tamponade Medium, Postoperative)</p> <p>Class C</p> <p>Shelf Life: 24 months</p> <p>Code & sizes: GOT 007-00</p>	<p>Intended for long-term intraocular tamponade vitreoretinal surgery.</p>	<p>Approved</p> <p>The firm shall apply separately for GOT Multi C2F6 75 ml and GOT Multi C3F8 75 ml</p>
55.	<p>M/s DKT Pakistan Pvt. Ltd, 37-C RJ Building, 2nd Stadium Lane, Phase V, Defence Housing Authority, 75500 Karachi Pakistan.</p> <p>(ELI-</p>	<p>Legal Manufacturer:</p> <p>Thai Nippon Rubber Industry Public Company Limited.</p> <p>49, 49/ 1 LaemChabang Industrial Estate, Moo 5 , Sukhumvit Road, ThungSukhlaSubdistrict, Si Racha District, Chon Buri Province 20230.</p>	<p>Condom Prudence Condom</p> <p>Condom Prudence Condom</p> <p>Class C</p> <p>Shelf Life: 5 Years</p>	<p>Buttercup condoms 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 other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.</p>	<p>Deferred for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore.</p>
56.	-do-	<p>Legal Manufacturer:</p> <p>Thai Nippon Rubber Industry Public Company Limited.</p> <p>LaemChabang Industrial Estate 49-49/ 1 Moo 5 , Sukhumvit Road, ThungSukhlaSubdistrict, Si Racha District, Chon Buri Province 20230.</p>	<p>Condom Buttercup</p> <p>Condom Buttercup</p> <p>Class C</p> <p>Shelf Life: 5 Years</p>	<p>Buttercup condoms 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 other sexually transmitted diseases,</p>	<p>Deferred for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore.</p>

				including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.	
57.	-do-	<p>Legal Manufacturer:</p> <p>Thai Nippon Rubber Industry Public Company Limited.</p> <p>LaemChabang Industrial Estate 49-49/1 Moo 5 , Sukhumvit Road, ThungSukhlaSubdistrict, Si Racha District, Chon Buri Province 20230.</p>	<p>Condom UniquePull</p> <p>Condom UniquePull</p> <p>Class C</p> <p>Shelf Life: 5 Years</p>	<p>Buttercup condoms 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 other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.</p>	<p>Deferred for clarification of Sole Agency Agreement from M/s Nwill Healthcare, Lahore</p>
58.	M/s Vertex Medical Pvt LTd, 70-B-1, Gulberg - II Lahore ELI: 00150	<p>Legal Manufacturer Dragerwerk AG &Co, KGaA Moislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaA Revalstrabe 1 23560 Lubeck, Germany.</p> <p>FSC: Germany Date of issue: 15-10-2019</p>	<p>Drager</p> <p>Ventstar Breathing Circuits</p> <p>Class B</p> <p>Shelf Life: 3 years</p>	<p>The VentStar Breathing Circuits are single-use, disposable, accessory devices that are used with a ventilator or anesthesia machine to provide mechanical ventilation and critical breathing support to both children and adults.</p>	<p>Approved.</p>

59.	-do-	<p>Legal Manufacturer Dragerwerk AG &Co, KGaA Moislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaA Revalstrabe 1 23560 Lubeck, Germany.</p> <p>FSC: Germany Date of issue: 15-10-2019</p>	<p>Humidstar HME Breathing filters Class-B Codes & Sizes: Humidstar 55 Humidstar 25 Humidstar 10A Humidstar 2 Humidstar Trach</p> <p>Shelf life: 5 years</p>	<p>Heat and moisture exchanger for humidifying respired gases for the patient.</p>	Approved.
60.	-do-	<p>Legal Manufacturer Dragerwerk AG &Co, KGaA Moislinger Allee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaA Revalstrabe 1 23560 Lubeck, Germany.</p> <p>FSC: Germany Date of issue: 15-10-2019</p>	<p>Dragersorb Soda Lime</p> <p>Class B</p> <p>Shelf Life: 4 years</p> <p>Codes & sizes: Dragersorb 800 plus (5L) Dragersorb Free (5L)</p>	<p>Medical soda lime in pellet form with color indicator, used to absorb CO2 from breathing system of anesthesia workstations.</p>	Approved.
61.	-do-	<p>Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53- 55, 23542 Lubeck, Germany</p> <p>Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany</p> <p>FSC Germany Date of issue: 15-10-2019</p>	<p>Atlan A300 (Anesthesia Workstation)</p> <p>Class C</p> <p>Ref: 8621300</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Intended for use in anesthetizing adults, pediatric patients and neonates. Can be used for mechanical ventilation, manual ventilation, pressure- supported spontaneous breathing and spontaneous breathing</p>	Approved. The firm shall apply other models separately

62.	-do-	<p>Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany</p> <p>Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany</p> <p>FSC Germany Date of issue: 15-10-2019</p>	<p>Primus (Anesthesia System)</p> <p>Class C</p> <p>Ref: 8603800</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Anesthesia workstation for adults, children and neonates with automatic and manual ventilation as well as spontaneous breathing with or without pressure support.</p>	<p>Approved.</p>
63.	-do-	<p>Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany</p> <p>Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany</p> <p>FSC Germany Date of issue: 15-10-2019.</p>	<p>Fabius Plus (Anesthesia Workstation)</p> <p>Class C</p> <p>Ref: 8606800</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions</p>	<p>Approved.</p> <p>The firm shall submit separate application for Fabius Plus XL</p>
64.	-do-	<p>Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany</p> <p>Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany</p> <p>FSC Germany Date of issue: 15-10-2019</p>	<p>Perseus A500 (Anesthesia System)</p> <p>Class C</p> <p>Ref: MK06000</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Anesthesia workstation intended for use in anesthetizing adults, children and neonates and can be used for automatic and manual ventilation, pressure-supported spontaneous breathing and spontaneous breathing</p>	<p>Approved.</p>

65.	-do-	<p>Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany</p> <p>Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany</p> <p>FSC Germany Date of issue: 15-10-2019</p>	<p>Fabius GS Premium (Anesthesia Workstation)</p> <p>Class C</p> <p>Ref: 8607000</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions</p>	<p>Approved.</p> <p>The firm shall submit separate application for Fabius MRI</p>
66.	<p>M/s Universal Enterprises, 29-Block-3, Overseas Co-Operative Housing Society, Stadium Road, Karachi. (ELI-00079)</p>	<p>Legal Manufacturer:</p> <p>Contract sterilization services Pte Ltd, 2 Tukang Innovation Grove, #08-03-05 JTC Medtech Hub, Singapore 618305</p> <p>FSC Singapore valid till 24-10-2020</p>	<p>Terumo</p> <p>Custom Tubing Pack</p> <p>Class B</p> <p>Shelf Life: 36 Months</p> <p>(Sizes & Codes as Per FSC) 35-001155-00 35-001163-00 35-001219-00 35-001267-00</p>	<p>The set intended for use during surgery requiring cardiopulmonary or other surgical techniques.</p>	<p>Deferred for provision of valid FSC of reference country or CE marked documents.</p> <p>FSC expired but it was valid at the time of submission.</p>
67.	<p>M/S Optimus Entrepôt 194-F/1 Block Johar, Town, Lahore ELI-00125</p>	<p>Legal Manufacturer: M/S LENSTEC (BARBADOS) INC Located at Airport Commercial Centre. Pilgrim Road. Christ Church, Barbados BB17092, Telephone: (246)420-6795.</p> <p>FSC: (Barbados, West Indies): Date of Issue: May 22, 2018</p> <p>FSC (FDA, USA): Date of Issue: Feb 14, 2109 Valid till: Feb 13, 2021</p>	<p>Softec –HD (Posterior chamber intraocular lens)</p> <p>Class: C</p> <p>Shelf Life: 5 Years</p>	<p>The Softec HD Posterior Chamber Intraocular Lens (PCIOL) is a single-piece intraocular lens with “modified C loop” haptics designed for insertion in the posterior chamber of the eye for visual correction of aphakia. The Softec I (PCIOL) can be inserted through a small clear</p>	<p>Approved.</p>

				corneal incision and is manufactured completely from medical grade Hydroxyethylmethacrylate (HEMA, 26% water content) a polymerizable UV blocker that are proven biocompatible. Lenstec produces its own HEMA acrylic buttons to make intraocular lenses.	
68.	M/s Krestacorp, 76-C, 3rd Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 7, Karachi (ELI-00258)	Legal Manufacturer/ Manufacturing Site: M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia (FSC Malaysia Valid Till13-02-2021) MHRA, UK FSC issuance30-01-2019	Feel Studded condoms Natural rubber latex Male Condoms Class C Shelf Life: 5 Years Sizes & Codes as Per FSC P53D	Natural Rubber Latex Condoms is a non-Sterile, Single use device made of natural rubber latex, lubricated with silicone oil. It is used for contraception and prevention of sexually transmitted disease.	Approved.
69.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia (FSC Malaysia Valid Till13-02-2021) MHRA, UK FSC issuance17-07-2019	Feel Max Condoms Natural Rubber Latex Male Condoms Class C Shelf Life: 5 Years Sizes & Codes as Per FSC P53S	Medicated Natural Rubber latex condoms is a non-sterile, single use device made of natural rubber latex, lubricated with silicone oil. It is used for contraception and prevention of sexually transmitted disease.	Approved.

8. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Remarks
1.	M/s Usmanco International 220, D.M.C.H.S., Block-3 S. Abdul Tawwab Road, Karachi-Pakistan.	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR Extension lines with 250PSI Small bore 250PSI & T connector Class-A Model: 12011201, 12011451, 12011501, 01271501, 01271001	Extension line is used for extension of infusion lines.	Approved.
2.	-do-	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR B Flow (Flow regulator) Class-A Model: 10600031	It is designed to administer a specified volume of a solution in a specific time frame.	Approved.
3.	-do-	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR b-Safe Extension line, Dou, trio, with T connector Class-A Model: 13200111	b-Safe Extension line, Dou, trio, with T connector used in infusion sets for the administration or withdrawal of liquids without the use of a needle.	Approved.
4.	-do-	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR 3-way Stopcock plain & Extension line with 3-way stopcock 72 PSI & 1200 PSI Class-A Model: 3-way Stopcock plain 76030311 Extension line with	3-way Stopcock plain is used for channeling fluids to different lines during I.V therapy.	Approved.

			3-way stopcock 12310101, 12310301, 12311201, 12310251, 12311451, 12311001, 12310501		
5.	-do-	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR Pressure lines 800PSI, M/F, 150CM & 1200PSI Class-A Model: 13530251, 13540501, 13530501, 13531501, 13540251, 13541001, 13831451, 13531001, 13530751, 13540751, 13520501, 13830901, 13531231, 13521251, 13831201, 13520251, 13830301, 13830601, 13830751, 13831501, 13520751	Pressure lines are used for extension of Angiographic pressure infusion lines infusion lines.	Approved.
6.	-do-	Legal Manufacturer: BicakcilarTibbiChazlar sanayiveTicaret A.S OsmangaziMahallesi Gazi Cad No. 21 Esenyurt 34522 Istanbul Turkiye. FSC Turkey validity 11-08-2020	BICAKCILAR Urimeter 500 plus Class-A Model: 22710221, 22710091	Its intended to monitor the urine flow and collect urine.	Approved.
7.	M/s Essity Pakistan Limited., A/69, S.I.T.E., Manghopir Road, Karachi (ELI-00011)	Legal Manufacturer: BSN Medical INC. 5825 Carnegie Blvd., Charlotte, NC USA 28209 Manufacturing Site:	Delta-Net® Stockinette Class A Shelf life: N/A	Soft 100% polyester knitted stockinette for use under casts or for bandage retention. Non-	Approved.

		Paceline, Inc. 10737 Independence Pointe Pkwy Matthews, NC, USA 28105 (FSC USA Valid 09-07-2021)	Sizes: 2" x 25 YDS WHITE 2.5CM x 22.8 M WHITE 5 CM X 22.8 M WHITE 7.5 CM X 22.8 M WHITE 10 CM X 22.8 M WHITE 15 CM X 22.8 M WHITE Fee submitted: Rs. 5,000/-	sterile	
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9. CASES WHICH WERE APPROVED IN PREVIOUS MDB MEETINGS SUBJECT TO PROVISION OF DOCUMENTS.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Legal Manufacturer: Abon Biopharm (Hangzhou) Co., Ltd. # 198 2th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China. FSC Germany Issuance 21-03-2019 FSC China Validity 24.02.2020 FSC China Validity 04.06.2019	ABON™ hCG One Step Pregnancy Test Strip (Urine) FHC-101 hCG One Step Pregnancy Test Device (Urine) FHC-102 hCG One Step Pregnancy Test Strip (Urine/Serum) FHC-201 hCG One step Pregnancy Test Device (Urine/Serum) FHC-202 Early Detection One Step Pregnancy Test	The hCG One step pregnancy test Strip(Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin for early detection of pregnancy.	Approved

			Urine) FHC-103 Class B Shelf Life:24 Months		
2.	-do-	<p>Legal Manufacturer:</p> <p>Abon Biopharm (Hangzhou) Co., Ltd. # 198 2th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.</p> <p>FSC Germany Issuance 21-03-2019</p> <p>FSC China Validity 24.02.2020</p> <p>Certificate of Export China Validity 08.01.2020</p> <p>FSC China Validity 17.10.2019</p>	<p>ABON™ Multi-Drug One Step Screen Test Panel (Urine)</p> <p>DOA-124 DOA-134 DOA-144 DOA-154 DOA-164 DOA-174 DOA-184 DOA-194 DOA-1104 DOA-1114 DOA-1124</p> <p>Class B Shelf Life: 24 Months</p>	<p>Multiple Drugs of Abuse/Toxicology Rapid Test</p> <p>DOA-124 Cocaine, Marijuana</p> <p>DOA-134 Cocaine, Amphetamine, Marijuana</p> <p>DOA-144 Cocaine, Amphetamine, Marijuana, Benzodiazepines</p> <p>DOA-154 Methamphetamine, Marijuana, Opiate, Benzodiazepines, Buprenorphine</p> <p>DOA-164 Cocaine, Amphetamine, Methamphetamine, Marijuana, Opiate, Benzodiazepines</p> <p>DOA-174 Cocaine, Amphetamine, Marijuana, Morphine, Tramadol, Barbiturates, Benzodiazepines</p>	Approved

				<p>es</p> <p>DOA-184 Cocaine, Amphetamine, Methamphetamine, Marijuana, Opiate, Tramadol, Benzodiazepines, K2 (synthetic cannabinoids)</p> <p>DOA-194 Cocaine, Amphetamine, Methamphetamine, Marijuana, Methadone, Morphine, Phencyclidine, Barbiturates, Benzodiazepines</p> <p>DOA-1104 Cocaine, Amphetamine, Methamphetamine, Marijuana, Methadone, Morphine, Phencyclidine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants</p> <p>DOA-1114 Cocaine, Amphetamine, Methamphetamine, Marijuana, Methadone, Ecstasy, Morphine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants K2 (synthetic</p>	
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				cannabinoids) DOA-1124 Cocaine, Amphetamine, Methamphetamine, Marijuana, Methadone, Ecstasy, Morphine, Opiate, Phencyclidine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants	
3.	-do-	<p>Legal Manufacturer:</p> <p>Abon Biopharm (Hangzhou) Co., Ltd. # 198 2th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.</p> <p>FSC Germany Issuance 21-03-2019</p> <p>Certificate of Export China Validity 08.01.2020</p>	<p>ABON™ Multi-Drug One Step Multi-Line Screen Test Device (Urine) DOA-125, DOA-135, DOA-145, DOA-155, DOA-165, DOA-175, DOA-185, DOA-195, DOA-1105, DOA-1115, DOA-1125</p> <p>Class B</p> <p>Shelf Life: 24 Months</p>	<p>Multiple Drugs of Abuse/Toxicology Rapid Test</p> <p>DOA-125 Morphine, Marijuana DOA-135 Amphetamine, Morphine, Marijuana DOA-145 Amphetamine, Morphine, Methamphetamine, Marijuana DOA-155 Amphetamine, Cocaine, Morphine, Marijuana, Benzodiazepine DOA-165 Methamphetamine, Amphetamine, Cocaine, Morphine, Marijuana, Benzodiazepine</p>	Approved

				DOA-175 DOA-185, DOA-195, DOA-1105 Methamphetamine, Amphetamine, Cocaine, Morphine, Marijuana, Benzodiazepine, Tricyclic Antidepressants, Barbiturates, Ecstasy, Methadone DOA-1115, DOA-1125 Methamphetamine, Amphetamine, Cocaine, Morphine, Marijuana, Benzodiazepine, Tricyclic Antidepressants, Barbiturates, Ecstasy, Methadone, Opiate, Phencyclidine DOA-1135	
4.	M/s S. Ejazuddin & Co. PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078)	Manufacturer: EKF-diagnostic GmbH Ebendorfer Chaussee 3 39179 Barleben, Germany. (FSC Germany ISSUED ON 07-08- 2018)	Pocket Chem A1C System A1C test system. Class B Shelf Life: Pocket Chem A1C Test kit: 12 months at 2 °C to 8 °C Pocket Chem A1C Test kit: 12 months at 2 °C to 8 °C Sizes As per FSC: Pocket Chem™ A1C Analyzer system	The Test System is intended for the invitro quantitative determination of glycated hemoglobin obtained from a finger prick or venous whole blood sample collection.	Approved.

			Model: 0114-0000 Catalogue No. 3108-0011_VS Pocket Chem™ A1C Test Kit Model 0130 Catalogue No: 3108-3011_VS Pocket Chem™ A1C Control Kit. Model 0135 Catalogue No. 3108-6011_VS Rs.25,000/-		
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Decision: The Board considered the submissions of the firms and decided to approve the above products at serial 1-4 as mentioned against each.

10. 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	M/s Renacon Pharma ltd. Lahore.	Renapuly hemodialysis concentrate Hemodialysis Concentrate Shelf Life 2 years. Class C Fee Submitted Rs 20,000	Used In Hemodialysis Of Kidney Failure Patients	Approved with following composition: Part-A (As per BP/EP): Sodium : 80-110mmol/l Potassium : 0-3.0 mmol/l Calcium : 0-2.0 mmol/l Magnesium: 0-1.2 mmol/l

				<p>Chloride : 90-120 mmol/l</p> <p>Glucose 0-12.0 mmol/l</p> <p>Part-B (As per BP/EP):</p> <p>Sodium : Not more than 45 mmol/l</p> <p>Bicarbonate: Not more than 45 mmol/l</p> <p>Part-C (Acetum):</p> <p>Acetic Acid: 2.5-10 mmol/l</p>
2	-do-	<p>Renapulv-N Hemodialysis concentrate</p> <p>Hemodialysis Concentrate Shelf Life: 2 years</p> <p>Class: C Fee Submitted Rs 20,000</p>	Used In Hemodialysis Of Kidney Failure Patients	<p>Deferred. As the composition of the product is not according to BP/EP. The claims that the product is according to BP/EP</p>

11. 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.	Usman Enterprises, Plot No. A116, Phase I, SITE, Super Highway, Karachi (ELM-0013)	MINIPLAST PLUS First Aid Bandage Class A Shelf Life: 02 Years Rs.5000/- Sizes as per form	Adhesive PVC Tape with Non Adherent Protective Pad	Approved.
2.	-do-	EZEEPLAST First Aid Bandage Class A Shelf Life: 02 Years Rs.5000/- Sizes as per form	Adhesive Polythylene Tape with Non-Adherent Protective Pad	Approved.
3.	Essity Pakistan Limited, A/69, SITE Manghopir Road, P O Box 3659, Karahi (ELM-00008)	Paragon (Zinc Oxide Adhesive Plaster) Class A Shelf Life: 05 Years Rs.5000/- Sizes As Applied On Form 6	Zinc Oxide Adhesive Plaster Used as a Fixation of dressing on normal skin.	Approved.

12. RENEWAL OF 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 The National Absorbent Cotton Mills Co. A-37, S.I.T.E Manghophir Road, Karachi.	Absorbent Cotton Wool Shelf Life: 03 years Rolls: 25, 50, 100, 200, 400grams Fee Rs.5000/-	Absorbent Cotton Wool	Approved.

13. APPLICATIONS FOR REGISTRATION OF MEDICAL DEVICES FOR EXPORT.

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1	M/s Faisal Pharmaceutical Industries, Faisalabad.	Steri Tulle (FarmycetinGuaze Dressing BP 1% Class: C Shelf Life: 3 Years	It is used in treatment of minor burns, scalds and sunburn.	Deferred for followings: i. Verification of manufacturing and testing facility of the product. ii. Submission of fee for subject product as specified in scedule-C of MDR-2017.

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