DECISONS OF THE 25th MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 02-12-2020

1. 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 Nextek Healthcare, Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.	Quratul Ain Faisal Malik	Yes	**Approved.**
2.	M/s Med Elec Corporation, RR 20/3/1 Room No. 403, Marston Road P 8, Karachi. **Godown Address:** RR-20/3/1, Marston Road, Karachi.	Muhammad Arif Khalil	No.	**Approved.**
3.	M/s Reliable Medical Supply, Shop No. 26, 1st floor, Cantonment Plaza near Dr. Shirazi Jamal Clinic, Dabgari Garden, Peshawar. **Godown Address:** Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar.	Mr. Muhammad Haroon	No	**Approved.**
4.	M/s Advance Systems, 630 Shadman-1, Lahore.	Mr. Sabir Ali Hussain Mr. Mahboob Haider Mr. Ammar Alam. Mr. Waseem Mazhar Mirza Mst. Anbreen Zafar.	No	**Approved.**
5.	M/s Medoptics, Flat	Mr. Atif Imran	No	**Approved.**

	No. 3, 3rd Floor, Hafiz Plaza, M-Block, Model Town, Lahore.			

2. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

S.No	Name of Establishment & Directors	Address	Name of Production Incharge	Name of QC Incharge	Inspection panel & date of inspection
1.	M/s Pak Electron Beam Irradiation (Pvt) Limited.	Plot No.E-65, North Wewstern Industrial Zone, Port Qasim, Karachi.	Mr. Muhammad Azeem (Pharm-D)	Ms. Maheen Nafees Khan (Pharm-D)	Dr. Najam-us-Saqib, Additional Director, DRAP, Karachi. Mrs. Hira Buutto, Assistant Director, CDL, Karachi. 26-10-2020.

Decision: The Board deferred the case for clarification and asked to provide the capacity of sterilization unit with the names/classes of products (medical devices) to be sterilized.

3. POST LICENSE VARIATIONS.

M/s Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi has requested for addition of new godown at their Establishment License to import medical devices (ELI-00109) issued on 03-08-2018 at below mentioned address:-

"Plot No.36-A, Punjab Small Industries Corporation (PSIC),
Small Industrial Estate, Taxila".

Decision: The Board approved the inclusion of new Godown at "Plot No.36-A, Punjab Small Industries Corporation (PSIC), Small Industrial Estate, Taxila" of M/s Global Marketing Services, 111-B, Hali Road,Westridge-1, Rawalpindi.

4. SITE APPROVAL OF M/S PHARMATEC PAKISTAN (PRIVATE) LIMITED, KARACHI FOR ESTABLISHMENT OF MANUFACTRUING UNIT OF MEDICAL DEVICES.

Decision: The following facts were discussed:

(i) The QC Lab is present at 5th floor and is part of a pharmaceutical unit having valid Drug Manufacturing License.
(ii) Consideration for grant of approval of site for ground floor, 1st, 2nd, 3rd and 4th floor with subsequent grant of establishment license for manufacturing medical devices would result in issuance of two licenses to the same premises;
(iii) the Medical Devices Rules, 2017 are silent for issuance of establishment license for manufacturing medical devices in the same premises that also possess drug manufacturing license;
(iv) approving site of an independent building for manufacturing of medical devices would save cost of land and building;
(v) the QC Lab at 5th floor will be shifted in a period of three years;
(vi) there will be no cross contamination from QC Lab or manufacturing area at 1st floor;

In view of the above discussion, the Board decided to refer the matter to Authority for consideration with the recommendation that the site may be approved conditionally subject to assurance that there will be no cross contamination and the QC Lab at 5th floor will be moved after a period of three years.

5. APPROVAL OF ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES

M/s Uniferoz (Pvt) Limited, 32/8 & 33/2, Sector-15, Korangi Industrial Area, Karachi has requested for approval of additional sizes of their following already registered/Enlisted medical devices for local manufacture as per detail mentioned below:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDME-0000006	Dermapore(Non-Woven Fabric Surgical Tape)	2.5 cm x 10M 4 Rolls 5cm x 10M 2 Rolls 10cm x 10M 1 Roll 7.5cm x10M 2 Rolls	2.5 cm x 5M 5cm x 5M 10cm x 5M 7.5cm x 5M

			15cm x 10M 1 Rolls	15cm x 5M
2.	MDME-0000010	NichiporeSuurgical Tape	12mm x 4.5M (24 Roll) 25mm x 4.5M (12 Roll) 75mm x 4.5M (4 Rolls) 100mm x 4.5M (3 Rolls) 20mm x 4.5M (10 Rolls) 50mm x 4.5M (6 Rolls)	12mm x 9.14M 20mm x9.14M 25mm x9.14M 50mm x9.14M 75mm x9.14M 100mm x9.14M
3.	MDME-0000012	Dermapore Non-Woven Paper Surgical Tape.	12mm x 4.5M 24 Rolls 20mm x 4.5M 10 Rolls 25mm x 4.5M 12 Rolls 50mm x 4.5M 6 Rolls 75mm x 4.5M 4 Rolls 100mm x 4.5M 3 Rolls	12mm x9.14M 20mm x9.14M 25mm x9.14M 50mm x9.14M 75mm x9.14M 100mm x9.14M

Decision: The Board acceded to the request of the firm /company and approved the additional sizes/codes of above mentioned medical device as mentioned below:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	New Approved Additional Sizes.
1.	**MDME-0000006**	**Dermapore (Non-Woven Fabric Surgical Tape)**	**2.5 cm x 10M 4 Rolls 5cm x 10M 2 Rolls 10cm x 10M 1 Roll 7.5cm x10M 2 Rolls 15cm x 10M 1 Rolls**	**2.5 cm x 5M 5cm x 5M 10cm x 5M 7.5cm x 5M 15cm x 5M**
2.	**MDME-0000010**	**NichiporeSuurgical Tape**	**12mm x 4.5M (24 Roll) 25mm x 4.5M (12 Roll) 75mm x 4.5M (4 Rolls) 100mm x 4.5M (3 Rolls) 20mm x 4.5M (10 Rolls) 50mm x 4.5M (6 Rolls)**	**12mm x 9.14M 20mm x9.14M 25mm x9.14M 50mm x9.14M 75mm x9.14M 100mm x9.14M**
3.	**MDME-0000012**	**Dermapore Non-Woven Paper Surgical Tape.**	**12mm x 4.5M 24 Rolls 20mm x 4.5M 10 Rolls 25mm x 4.5M 12 Rolls 50mm x 4.5M 6 Rolls 75mm x 4.5M 4 Rolls 100mm x 4.5M 3 Rolls**	**12mm x9.14M 20mm x9.14M 25mm x9.14M 50mm x9.14M 75mm x9.14M 100mm x9.14M**

6. <u>ISSUANCE OF IMPORT PERMIT FOR TESTING OR ANALYSIS.</u>

M/s IBL Healthcare Limited, 2nd Floor, One IBL Centre, Plot # 1, Block-7&8, DehliMerchantile Muslim Cooperative Housing Society, Tipu Sultan Road, Off. Shahrah-e-Faisal, Karachi has requested for grant of permit to import following medical devices (Blood Collection Tubes and Needles) from M/s Shandong Weigao Group Medical Polymer Co., Ltd, China for the purpose of testing or analysis in **Fatimid Hospital, Husseini, PIMS, AFIT and Allied Hospital** (complete addresses of hospitals not provided):-

S.#	Name of Medical Device	Quantity
1.	EDTA K3 (Purple Cap) 2ml	1000 Pcs
2.	EDTA K2 (Purple Cap) 2ml	1000 Pcs
3.	Flouride Oxalate (Grey Cap) 3ml	1000 Pcs
4.	Sodium Citrate (Blue Cap) 1.8 ml	1000 Pcs
5.	Gel (Yellow Cap) 3ml	1000 Pcs
6.	Gel (Yellow Cap) 5ml	1000 Pcs
7.	Plain (Red Cap) 3ml	1000 Pcs
8.	Black Cap 2.4 ml	1000 Pcs
9.	Blood Collection Needle 21G	1000 Pcs
10.	Blood Collection Needle 22G	1000 Pcs

Decision: The Board discussed the matter at length and considering the fact that firm has applied import of above referred products (medical devices) for clinical trials decided to reject the application.

7. 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. Now the firm has submitted the documents: -

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description
1.	M/s Medtronic 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 55432 Manufacturing site: 1) Medtronic Singapore Operations Pte Ltd. 49 Changi South Avenue 2,	Attesta™ SR MRI Surescan™ (Model: ATSR01) (Single Chamber pacemaker, rate responsive, MR-conditional) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	Single chamber implantable pulse generator is a multiprogrammable cardiac device that monitors and regulates patient's heart rate by providing single chamber rate responsive

		Nasaco Tech Centre, Singapore, 486056 2) Medtronic Inc. 8200 Coral Sea St., Mounds View, MN 55112, USA (FSC US FDA Valid till 15-08-2021)		bradycardia pacing. Sterile, single-use
2.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 (FSC US FDA Valid till 27-02-2021)	Affinity Pixie™ Hollow fiber Oxygenator and Cardiotomy /venous Reservoir with Balance™Biosurface (BBP241) Class C Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	The oxygenator is intended to be used in an extracorporeal perfusion ciricuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. Cardiotomy/venous reservoir is intended to be used in extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures upto 6 hours in duration. Sterile, single-use
3.	M/s. RA Healthcare (SMC-PVT) Limited 2nd Floor, Building# 50, Mir Arcade,	**Legal Manufacturer:** Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ	**FIREFIGHTER ™**PTCA Balloon Catheter **Class: D. Codes and sizes as per FSC of Netherlands.**	Firefighter™ PTCA Balloon Catheter is a semi-compliant Percutaneous Transluminal Coronary

	Mini Commercial, Phase 7, BahriaTown, Islamabad. (ELI-00482)	High-Tech Park, Shanghai, P.R. China. **Manufacturer Site(s):** Shanghai MicroPort Medical (Group) Co, Ltd 501 Newton Road 201203; Shanghai, P.R. China. 1. Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road 201203; Shanghai, P.R. China. **Sterilization site:** Shanghai MicroPort Medical (Group)Co. Ltd. Building 4 No, 51 Hangfan Road 201316; Shanghai P.R. China.		Angioplasty (PTCA) Rapid Exchange System that consists of an integrated shaft and a balloon at the distal end if the catheter.
4.	**-do-**	**Legal Manufacturer:** Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ High-Tech Park, Shanghai, P.R. China. **Manufacturer Site(s):** Shanghai MicroPort Medical (Group) Co, Ltd 501 Newton Road 201203; Shanghai, P.R. China. 2. Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road 201203;	**FOXTORT™ PRO** PTCA Balloon Catheter. **Class: D. Codes and sizes as per FSC of Netherlands.**	FOXTROT™ PTCA (Percutaneous Transluminal Coronary Angioplasty) balloon catheter has an integrated shaft system balloon near the distal tip. The shaft has a combination of single lumen and dual lumens tubing. One lumen is used for inflation of the balloon with contrast medium, and the second lumen in the

		Shanghai, P.R. China. **Sterilization site:** Shanghai MicroPort Medical (Group)Co. Ltd. Building 4 No, 51 Hangfan Road 201316; Shanghai P.R. China.		distal shaft, permits the use of a guide-wire to facilitate advancement of the dilatation catheter to, and through the stenosis to be dilated. The dilatation catheter is coated with hydrophilic coating.

Decision:- The Board considered and approved the above deferred cases at serial No.1-4.

8. REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore (ELI: 00150)	Legal Manufacturer Drager Medical System Inc. 3135, Quarry Road Telford PA USA 18969. **Manufacturing site:** Drager Medical Systems Inc. 6 Tech Drive, Andover, MA USA 01810 FSC US FDA valid till 19.06.2021	Infinity Delta monitor (Physiological Monitoring System) Class C Ref: MS18597 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for mult-parameter monitoring of adult, pediatric and neonatal patients.	**Approved.** The firm shall apply separately for Model Delta XL and kappa.
2.	-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 Vapor 2000 (Vapour Delivery Device) Class C Ref: M35054 Shelf Life: N/A Fee submitted: Rs. 50,000/-	An unheated, calibrated anesthetic vaporizer for the enrichment of dry, fresh medical gas in anesthesia workstations with precisely controlled concentrations of vapor from liquid anesthetic	**Approved.** The firm shall apply separately for D-vapor.

				agents.	
3.	-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 Vapor 3000 (Anesthesia Unit Vaporizer) Class C Ref: M36500 Shelf Life: N/A Fee submitted: Rs. 50,000/-	An unheated, calibrated anesthetic vaporizer for the enrichment of dry, fresh medical gas in anesthesia workstations with precisely controlled concentrations of vapor from liquid anesthetic agents.	**Approved.**
4.	-do-	Legal Manufacturer Drager Medical System Inc. 3135, Quarry Road Telford PA USA 18969. Manufacturing site: Drager Medical Systems Inc. 6 Tech Drive, Andover, MA USA 01810 FSC US FDA valid till 19.06.2021	Infinity Acute Care System (IACS) Monitoring with C500 (Physiological Monitoring System) Class-C Ref: MS25510 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for multi-parameter patient monitoring of adult, pediatric and neonatal patients.	**Approved.** Other models to be applied separately
5.	-do-	Legal Manufacturer Dragerwerk AG &Co, KGaAMoislingerAllee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany. FSC: Germany Date of issue: 15-10-2019	Drager ClassicStar NIV Mask Class B Shelf Life: 5 years Codes & sizes: **w/AAV, S** **w/AAV, M** **w/AAV, L** **SE, S** **SE, M** **SE, L**	**Non-invasive ventilation** (NI V) is the use of breathing support administered through a face mask, nasal mask, or a helmet.	**Approved.**
6.	M/s. Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK)-Pakistan.	Legal Manufacturer: Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN USA 55441	PTFE Peelable Introducer Kit Class: B	Intended for use in the percutaneous insertion of pacing leads or	**Approved.**

	ELI-00120	Manufacturing Site: Greatbatch Medical, S. de R.L. de C.V. Boulevard Hector Teran Teran #20120 Ciudad Industrial, Tijuana, Baja California, MEXICO 22444 FSC US FDA valid till 07-03-2021	Codes: 7089 7090 7091 7093 7095 7096 7097 7099 7127 7129, 7131, 7133 Shelf Life: 2 years Fee submitted: Rs. 25,000/-	catheters in the venous system	
7.	M/s Ferozsons Laboratories Ltd P.O Fersozsons, Amangarh, Nowshera (KPP) Pakistan ELI-00120	**Legal Manufacturer** Boston scientific Corporation 300, Boston scientific way Marlborough, MA **Manufactuign Sites:** Boston Scientific Corporation wo Scimed Place Maple Grove FSC: U.S. FDA Valid till: 03.05.2020	**Guidezilla ™ II Guide Extension Catheter** Vascular Guide catheter, single-use Class-B Shelf Life: 24 months Codes & Sizes: H7493933515060 Guide Extension Catheter, 6F,150cm H7493933515070 Guide Extension Catheter, 7F,150cm H7493933515080 Guide Extension Catheter, 8F,150cm	The Guidezilla ™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and /or peripheral vasculature, and to facilitate placement of interventional devices. Guidezilla is not intended for use in the cerebral vasculature. The device ae provided non-pyrogenic, sterile, and intended for one procedure only.	**Approved.** Before issuance of registration certificate, the firm shall provide valid FSC.
8.	-do-	**Legal Manufacturer:** M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA	**ESSENTIO MRI Model: L110** Single Chamber Pacemakers (rate responsive)	ESSENTIO MRI L110 is clinically indicated for the treatment of the following conditions: • Symptomatic paroxysmal or	**Approved.**

		01752 USA **Manufacturing Site:** Boston Scientific Clonmel Ltd Cashel Road Clonmel Co. Tippery, Ireland. FSC **US, FDA:** Date of issue: 30-04-2019 Valid till…29-04-2021	Class: D Shelf Life: 2 years	permanent second- or third-degree AV block; • Symptomatic bilateral bundle branch block; • Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block); • Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; • Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.	

				Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following: • Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; • VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm; • Low cardiac output or congestive heart failure secondary to bradycardia.	
9.	-do-	**Legal Manufacturer:** M/s. Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Clonmel Ltd Cashel Road Clonmel Co. Tippery, Ireland. FSC **US, FDA:** Date of issue: 30-04-2019	**ESSENTIO MRI Model: L111** Dual chamber Pacemakers (rate responsive) Class: D Shelf Life: 2 years	ESSENTIO MRI L111 is clinically indicated for the treatment of the following conditions: • Symptomatic paroxysmal or permanent second- or third-degree AV block; • Symptomatic bilateral bundle branch block; • Symptomatic	**Approved.** Firm shall apply separately for mode L131.

		Valid till…29-04-2021		paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block); • Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; • Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from	

				maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following: • Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; • VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm; • Low cardiac output or congestive heart failure secondary to bradycardia.	
10.	-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 Ireland Valid till…12-04-2023	**PROMUS Element™ Plus MONORAIL™ Everolimus-Eluting Coronary Stent System** (Drug-eluting coronary artery stent, non-bioabsorbable – polymer-coated) Codes: H7493918408220 PROMUS Element Plus MR/ 8 mm x 2.25 mm H7493918412220 P ROMUS Element Plus MR / 12 mm x 2.25 mm	Indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease. This includes patients with acute myocardial infarction and patients with concomitant diabetes mellitus due to discrete de novo native coronary artery lesions. Also indicated to include treatment of the following patient and	**Approved** the renewal of the product as medical device.

			H7493918416220 PROMUS Element Plus MR / 16 mm x 2.25 mm H7493918420220 PROMUS Element Plus MR / 20 mm x 2.25 mm H7493918424220 PROMUS Element Plus MR / 24 mm x 2.25 mm H7493918428220 PROMUS Element Plus MR / 28 mm x 2.25 mm H7493918432220 PROMUS Element Plus MR / 32 mm x 2.25 mm H7493918408250 PROMUS Element Plus MR / 8 mm x 2.50 mm H7493918412250 PROMUS Element Plus MR / 12 mm x 2.50 mm H7493918416250 PROMUS Element Plus MR / 16 mm x 2.50 mm H7493918420250 PROMUS Element Plus MR / 20 mm x 2.50 mm H7493918424250 PROMUS Element Plus MR / 24 mm x 2.50 mm H7493918428250 PROMUS Element Plus MR / 28 mm x	lesion subsets: coronary artery ostial lesions; unprotected left main coronary artery lesions; coronary artery total occlusion lesions; in-stent restenosis in coronary artery lesions; coronary bifurcation lesions. The treated lesion length should be less than the nominal stent length (8mm, 12mm, 16mm, 20mm, 24mm, 28mm, 32mm and 38mm) with a reference vessel diameter of 2.25 mm - 4.0 mm.	

			2.50 mm H7493918432250 PROMUS Element Plus MR / 32 mm x 2.50 mm H7493918438250 PROMUS Element Plus MR / 38 mm x 2.50 mm H7493918408270 PROMUS Element Plus MR / 8 mm x 2.75 mm H7493918412270 PROMUS Element Plus MR / 12 mm x 2.75 mm H7493918416270 PROMUS Element Plus MR / 16 mm x 2.75 mm H7493918420270 PROMUS Element Plus MR / 20 mm x 2.75 mm H7493918424270 PROMUS Element Plus MR / 24 mm x 2.75 mm H7493918428270 PROMUS Element Plus MR / 28 mm x 2.75 mm H7493918432270 PROMUS Element Plus MR / 32 mm x 2.75 mm H7493918438270 PROMUS Element Plus MR / 38 mm x 2.75 mm H7493918408300		

			PROMUS Element Plus MR / 8 mm x 3.00 mm H7493918412300 PROMUS Element Plus MR / 12 mm x 3.00 mm H7493918416300 PROMUS Element Plus MR / 16 mm x 3.00 mm H7493918420300 PROMUS Element Plus MR / 20 mm x 3.00 mm H7493918424300 PROMUS Element Plus MR / 24 mm x 3.00 mm H7493918428300 PROMUS Element Plus MR / 28 mm x 3.00 mm H7493918432300 PROMUS Element Plus MR / 32 mm x 3.00 mm H7493918438300 PROMUS Element Plus MR / 38 mm x 3.00 mm H7493918408350 PROMUS Element Plus MR / 8 mm x 3.50 mm H7493918412350 PROMUS Element Plus MR / 12 mm x 3.50 mm H7493918416350 PROMUS Element Plus MR / 16 mm x		

			3.50 mm H7493918420350 PROMUS Element Plus MR / 20 mm x 3.50 mm H7493918424350 PROMUS Element Plus MR / 24 mm x 3.50 mm H7493918428350 PROMUS Element Plus MR / 28 mm x 3.50 mm H7493918432350 PROMUS Element Plus MR / 32 mm x 3.50 mm H7493918438350 PROMUS Element Plus MR / 38 mm x 3.50 mm H7493918408400 PROMUS Element Plus MR / 8 mm x 4.00 mm H7493918412400 PROMUS Element Plus MR / 12 mm x 4.00 mm H7493918416400 PROMUS Element Plus MR / 16 mm x 4.00 mm H7493918420400 PROMUS Element Plus MR / 20 mm x 4.00 mm H7493918424400 PROMUS Element Plus MR / 24 mm x 4.00 mm H7493918428400		

			PROMUS Element Plus MR / 28 mm x 4.00 mm H7493918432400 PROMUS Element Plus MR / 32 mm x 4.00 mm H7493918438400 PROMUS Element Plus MR / 38 mm x 4.00 mm Class: D Shelf Life: 2 years		
11.	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 28-01-2016)	Vysis 1p36/1q25 and 19q 13/19p 13 FISH Probe Kit Class C Code: 04N60-020 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Fluorescence in situ hybridization (FISH) probe is intended to detect deletion of 1p36 and 19q13 chromosome regions	**Approved.**
12.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	UroVysion Bladder Cancer Kit Class C Code: 02J27-020 Shelf Life: 12 Months Fee submitted: Rs. 50,000/-	Designed to detect aneuploidy for chromosomes 3, 7, 17 and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer.	**Approved.**
13.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL	Vysis Prader-Willi/Angelman Region SNRPN/CEP	Intended to detect the large common deletion	**Approved.** Firm shall apply separately for

		60018, USA (FSC GERMANY issued on 28-01-2016)	15/PML FISH Probe Kit Class C Code: 06N27-010 Shelf Life: 24 Months Fee submitted: Rs. 50,000/- (Challan: 0580495)	involving the SNRPN gene region on the chromosome region 15q11-q13 using the fluorescence in situ hybridization (FISH) technique	Vysis SRY/CEP X FISH Probe.
14.	-do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT EG7+ Cartridge (Kit) Class C i) i-STAT EG7+ Cartridge Code: 03P76-25 Shelf Life: 242 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of carbon dioxide partial pressure, pH, oxygen partial pressure sodium, potassium, ionized calcium, and red blood cell volume fraction in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
15.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019) (FSC USFDA Valid Till 12-09-2019)	i-STAT EC8+ Cartridge (Kit) Class C i) i-STAT TriControls Control Level 1 Code: 05P71-01 Shelf Life: 547 Days ii) i-STAT TriControls Control Level 2 Code: 05P72-01 Shelf Life: 547 Days iii) i-STAT TriControls Control Level 3 Code: 05P73-01 Shelf Life: 547	Intended for use in the invitro quantification of carbon dioxide partial pressure, pH, sodium, potassium, chloride, glucose, BUN/Urea, Hct in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.

			Days iv) i-STAT TriControls Calibration Verification Set Levels 1-5 Code: 05P70-01 Shelf Life: 547 Days v) i-STAT EC8+ Cartridge Code: 03P79-25 Shelf Life: 213 Days Fee submitted: Rs. 50,000/-		
16.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT CHEM8+ Cartridge (Kit) Class C i) i-Stat CHEM8+ Cartridge Code: 09P31-25 Shelf Life: 180 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, BUN/Urea, creatinine and red blood cell volume fraction in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
17.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019) (FSC USFDA Valid Till 12-09-2019)	i-STAT BhCG Cartridge (Kit) Class B i) i-STAT Total b-hCG Control Level 1 Code: 02R29-01 Shelf Life: 730 Days ii)) i-STAT Total b-hCG Control Level 2 Code: 02R29-02 Shelf Life: 730 Days	An invitro diagnostic test for the quantitative and qualitative determination beta human chorionic gonadotropin in whole blood or plasma samples.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.

			iii) i-STAT Total b-hCG Control Level 3 Code: 02R29-03 Shelf Life: 730 Days iv) i-STAT Total b-hCG Control Calibration Verification Kit Code: 05P59-04 Shelf Life: 730 Days v) i-STAT Total b-hCG Cartridge Code: 05P58-25 Shelf Life: 167 Days Fee submitted: Rs. 50,000/-		
18.	-do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT CG8+ Cartridge (Kit) Class C i) i-STAT CG8+ Cartridge Code: 03P88-25 Shelf Life: 242 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of carbon dioxide partial pressure, oxygen partial pressure, pH, sodium, potassium, glucose, ionized calcium and red blood cell volume fraction in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
19.	-do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT G3+ Cartridge (Kit) Class C i) i-STAT G3+ Cartridge Code: 03P78-25 Shelf Life: 242 Days ii) i-STAT Control Level 1 Code: 06F12-01	Intended for use in the invitro quantification of carbon dioxide partial pressure, oxygen partial pressure and pH in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.

			Shelf Life: 547 Days iii) i-STAT Control Level 2 Code: 06F13-01 Shelf Life: 547 Days iv) i-STAT Control Level 3 Code: 06F14-01 Shelf Life: 547 Days v) i-STAT Calibration Verification Set Levels 1-5 Code: 06F15-01 Shelf Life: 547 Days Fee submitted: Rs. 50,000/-		
20.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT EC4+ Cartridge (Kit) Class C i) i-STAT EC4+ Cartridge Code: 03P81-25 Shelf Life: 270 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of sodium, potassium, glucose and packed red blood cell volume fraction in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
21.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019) (FSC USFDA Valid Till 12-09-2019)	i-STAT Creatinine Cartridge Class B Code: 03P84-25 Shelf Life: 180 Days Fee submitted: Rs. 50,000/-	Quantitative determination of creatinine in whole blood	**Approved.** Before issuance of registration letter, firm shall provide valid FSC**.**
22.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road,	i-STAT CG4+ Cartridge (Kit) Class C	Intended for use in the invitro quantification of carbon dioxide	**Approved.** Before issuance of registration

		Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i) i-STAT CG4+ Cartridge Code: 03P85-25 Shelf Life: 242 Days Fee submitted: Rs. 50,000/-	partial pressure, oxygen partial pressure, pH and lactate in arterial, venous or capillary whole blood.	letter, firm shall provide valid FSC.
23.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT 6+ Cartridge (Kit) Class C i) i-STAT 6+ Cartridge Code: 03P80-25 Shelf Life: 270 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of sodium, potassium, chloride, glucose, BUN/Urea, Hct in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
24.	do-	Manufacturer: M/s Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL, USA 60064 (FSC USFDA Valid Till 13-09-2019)	i-STAT G Cartridge (Kit) Class C i) i-STAT G Cartridge Code: 03P83-25 Shelf Life: 270 Days Fee submitted: Rs. 50,000/-	Intended for use in the invitro quantification of glucose in arterial, venous or capillary whole blood.	**Approved.** Before issuance of registration letter, firm shall provide valid FSC.
25.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	Vysis MDM2/CEP 12 FISH Probe Kit Class C Code: 01N15-010 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Intended to detect the copy number of the LSI MDM2 probe target located at chromosome 12q15 using the using the fluorescence in situ hybridization (FISH) technique	**Approved.** Firm shall submit separate application for Vysis EWSR1 Break Apart Fish Probe Kit, Vysis FOXO1 Break Apart Fish Probe Kit, Vysis SS18 Break Apart Fish Probe Kit.

26.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	Vysis IGH/MYC/CEP 8 Tri-Color DF FISH Probe kit Class C Code: 04N10-020 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	The fluorescence in situ hybridization (FISH) probes intended to detect the t(8;14) (q24;q32) reciprocal translocation involving the IGH and MYC gene regions.	**Approved.** Firm shall submit separate applications for other two probes.
27.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe Class C Code: 08L57-020 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	The fluorescence in situ hybridization (FISH) probe is intended for the detection of translocations involving the MLL gene	**Approved.** Firm shall submit separate application for Vysis LSI ETV6 (TEL)/RUNX1 (AML1) ES Dual Color Translocation Probe Set
28.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC GERMANY issued on 28-01-2016)	Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Set Class C Code: 01N36-020 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	The fluorescence in situ hybridization (FISH) probe set is intended to detect the t(15;17) (q22;q12-21) that results in the PML/RARA gene fusion	**Approved.** Firm shall submit separate applications for other probes.
29.	**-do-**	**Legal Manufacturer:** M/s Abbott GmbH & Co KG Max-Planck-Ring 2 65205 Wiesbaden, Germany.	**AlinitycAspartate Aminotransferase** Reagent Kit **AlinitycActivated Aspartate Aminotransferase**	**The subject kits of Alinity**is used for the determination of the AST, ALT and	**Approved** subject to provision of; ISO-13485/ GMP certificate of Mfg. site:

		Manufacturing site: Thermo Fisher Scientific Inc. 8365, Valley Pike Middletown, VA 22645, USA.	Reagent Kit **Alinity c** Activated **Alanine Aminotransferase** Reagent Kit **AlinitycAlkaline Phosphatase** Reagent Kit. FSC Germany Issuance Date (19-07-018 & 19-04-2017.)	AlklinePhosphatase in human serum and plasma on the Alinity-i analyzer. • Claimed Shelf-life: 13-months. • **Class-B**	Thermo Fisher Inc. USA.
30.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. FSC USFDA Valid Till (03-03-2021)	• ICT Serum Calibrator. Codes & Sizes as per FSC. • Claimed Shelf-life: 15-months. **Class-B**	**The subject kits of** ICT Serum Calibrator. is used for serum calibration in human serum. Firm applied for; a. ICT Serum Calibrator; **&** b. ICT Urine Calibrator. in the subject application as a **cluster**, but these are two different medical devices because of having different manufacturing site, methodology and intended use. So, does not fall in the Cluster Category, Accordingly, the **ICT Serum Calibrator** could be considered here only. 2. Firm does not submit MRP, DOC, Labels approved from country of origin and EPSP.	**Deferred;** Firm shall be asked to submit the separate application for ICT Urine Calibrator. 2. Firm also submit MRP, DOC, Labels approved from country of origin and EPSP.

31.	**-do-**	**Legal Manufacturer**: M/s Abbott Diabetes Care Ltd. Range Road, Witney, Oxon OX29 0YL, UK. **Manufacturing site:** Bionostics Inc. 7-jackson Road, Devens, MA, 01434, USA.	MediSense Glucose and Ketone Control Solution. **Class-C.** • Claimed Shelf-life: 23-months. FSC UK Issuance Date (10-04-2018). Codes & Sizes as per FSC	MediSense Glucose and Ketone Control Solution.is used for determination of glucose and Ketone in human serum and plasma.	**Approved** subject to provision of ISO-13485/ GMP certificate of Bionostics Inc. USA.
32.	**-do-**	**Legal Manufacturer:** M/s Abbott GmbH & Co KG Max-Planck-Ring 2 65205 Wiesbaden, Germany. **Manufacturing site:** Sekisui Diagnostic P.E.I. Inc. 70 watts Ave. Charettetown, Prince Edward Island, CIE2B9, Canada. FSC Germany Issuance Date (19-07-2018)	**Alinity c Gamma-Glutamyl Transferase** Reagent Kit **Alinity c Amylase** Reagent Kit **Alinity c Lactate Dehydrogenase** Reagent Kit. **Class-B (Cluster).** **Claimed shelflife**for Alinity c **Gamma-GT** is 13-Months, **For Amylase** is 30-Months and **forLDH**is 12-Months.	**The subject kits of Alinity**is used for determination of gamma GT, Amylase and LDH in human serum and plasma. Codes & Sizes as per FSC.	**Approved;** Firm shall submit the Application form with MRP , all manufacturing sites and all coded particulars before the issuance of registration certificate.
33.	**-do-**	**Legal Manufacturer**: M/s Abbott Laboratories 1921 Hurd Dr Irving, TX 75038, USA **Manufacturing sites:** Thermo Fisher Scientific Inc. 8365, Valley Pike Middletown, VA 22645, USA. M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Rd Abbott Park, IL 60064, USA. FSC of USA Valid Till (03-03-2021)	Total Protein Reagent Kit Albumin BCG Reagent Kit Albumin BCP Reagent Kit Prealbumin Reagent & Calibrator Kit. **Claimed shelf life** for Total Protein is 18-Months, **For** Albumin BCG Reagent is 24-Months and **for** Prealbumin Reagent &Calibratoris 12-13 Months respectively. **Class-B (Cluster)**	**The subject kits are** used for determination of Total Protein, Albumin BCG, Albumin BCP and Prealbumin in human serum and plasma. Firm asked for; 1. Total Protein; 2. Albumin BCG, 3. Albumin BCP; & 4. Prealbumin Reagent & Calibrator in the subject application as a **cluster**, but on fee challan form	**Approved** subject to provision of ISO-13485/ GMP certificate of Mfg. site: Thermo Fisher Inc. USA. • The products approved are same as it is mentioned on fee deposit slip; i.e., 1. Total Protein;& 2. Albumin Reagent Kit.

			Codes & Sizes as per FSC.	and receipt of endorsed by B&A section only following two products are mentioned: - 1. Total Protein; & 2. Albumin Reagent Kit. So, the case is placed before MDB to consider above mentioned two products or all four products for registration. 3. MRP and mfg. site not mentioned on application form. 4. ISO-13485/ GMP certificate of **Mfg. site:** Thermo Fisher Inc. USA. Not provided.	
34.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories Diagnostics Division, 100 Abbott Park Road, Abbott Park, IL 60064 USA. **Manufacturing sites:** Thermo Fisher Scientific Inc. 8365, Valley Pike Middletown, VA 22645, USA.	Aspartate Aminotransferase Activated Aspartate Aminotransferase Alanine Aminotransferase Activated Alanine Aminotransferase Alkaline Phosphatase Codes & Sizes as per FSC. **Class-B.** FSC USFDA valid till (03-03-2021). **Claimed shelf life** for AST is 12-Months, **For** Activated AST is 12-Months, **shelf life** for ALT is 18-Months, **For** Activated ALT	**The subject kits are** used for the determination of the AST, ALT and Alkline Phosphatase in human serum and plasma.	**Approved** subject to provision of ISO-13485/ GMP certificate of Mfg. site: Thermo Fisher Inc. USA.

			is 12-Months and **for** and **for** Alkaline Phosphatase is 13-Months.		
35.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories Diagnostics Division, 100 Abbott Park Road, Abbott Park, IL 60064 USA. **Manufacturing sites:** Thermo Fisher Scientific Inc. 8365, Valley Pike Middletown, VA 22645, USA.	**Creatine Kinase.** Claimed Shelf Life: 09-Months. **Class-C.** Codes & Sizes as per FSC.	**The subject kit** is used for determination of **Creatine Kinase** in human serum and plasma.	**Approved** subject to provision of; ISO-13485/ GMP certificate of Mfg. site: Thermo Fisher Inc. USA.
36.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. FSC USFDA Valid Till (03-07-2021)	Gamma-Glutamyl Transferase Amylase Lipase Lactate Dehydrogenase Lipase Calibrator Acid Phosphatase. **Claimed shelf life** for Gamma GT is 13-Months, **For** Amylase is 30-Months, **For** LDH is 12-Months, for Lipase Reagent with Calibrator is 24-Months and **for** Acid Phosphatase is 26-Months. Codes & Sizes as per FSC	**The subject kits are** used for determination of gamma GT, Amylase and LDH in human serum and plasma. **Remarks:** Firm asked for; 1. Gamma-Glutamyl Transferase; 2. Amylase; 3. Lactate Dehydrogenase; 4. Lipase Calibrator; & 5. Acid Phosphatase; in the subject application as a **cluster**, but on fee challan form and receipt of endorsed by B&A section only following two products are mentioned: a. Gamma-	**Approved**; the products mentioned on deposit fee slip; i.e., **1.** Gamma GT 2. L.D.H. 3. Amylase Approved; Firm shall submit the Application form with MRP , credentials of manufacturing sites and all coded particulars before the issuance of registration certificate.

				Glutamyl Transferase; b. Amylase; c. Lactate Dehydrogenase; So, the case is placed before MDB to consider above mentioned three products or all five products for registration. MRP and credentials not provided.	
37.	**-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 Codes & Sizes as per FSC. Claimed Shelf Life: 18-months. Class-B	**The subject kit** is used for determination of **C-Reactive Proteins** in human serum and plasma.	**Approved** subject to provision of; valid ISO-13485/ GMP certificate.
38.	**-do-**	**Legal Manufacturer:** M/s Abbott GmbH & Co KG Max-Planck-Ring 2 65205 Wiesbaden, Germany. FSC Germany Issuance Date (19-07-2018)	Architect Intact PTH Reagent Kit Calibrator & Controls. Claimed Shelf Life: 18-months of reagent while 09-months Calibrator & Controls. **Class-B** Codes & Sizes as per FSC.	**The subject kit** is used for determination of PTH in human serum and plasma.	**Approved;** Application form with MRP , credentials of manufacturing sites and all coded particulars before the issuance of registration certificate.
39.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. **Manufacturing sites:**BIT Analytical Instruments Am Kronberger Hang-3,65824, Scwalbach,	Cell-Dyn Emerald 22 Instrument Codes & Sizes as per FSC **Class-A.** FSC USFDA Valid Till (08-02-2020)	**The subject Cell-Dyn Analyzer** is used for determination of bio-chemical in human serum and plasma.	**Deferred;** • firm shall be asked for Valid free sale certificate. • Valid ISO-13485 certificate. • justification of Claimed service life: 15-years. • Apply on Form-

		Germany. free sale certificate of USA (expired on 08-02-2020).			7A alongwith differential fee, as the product fall in class-B.
40.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. **Manufacturing sites:** Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malven, Pennsylvania 19355, USA.	Alinity I Methotrexate Reagent Kit Alinity I Methotrexate Calibrators Alinity I Methotrexate Controls Alinity I Methotrexate Extended Range Control Class: Codes & Sizes as per FSC	**The subject kit** is used for determination of Methotrexate in human serum and plasma.	**Approved.**
41.	**-do-**	**Legal Manufacturer &**manufacturing **site:** M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland.	Alinity-i CMV IgG Reagent Kit Alinity-i CMV IgG Controls. **Class-C.** • Codes & Sizes as per FSC of Ireland. • Claimed Shelf-life: 12months.	Alinity-i CMV IgG Reagent Kit is used for the determination of the avidity of IgG antibodies to Cytomegalovirus in human serum and plasma on the Alinity-i analyzer.	**Deferred;** • firm shall be asked to provide the original and valid agency agreement. • fresh Application form with all coded particulars. • The product codes mentioned on FSC of Ireland are different as of DOC submitted and application form, clarification with reference is required.
42.	**-do-**	M/s Abbott Diabetes Care Ltd. Range Road, Witney, Oxon OX29 0YL, UK FSC UK Issuance Date (10-04-018)	FreeStyle**Optium H B-Ketone Test** Strips. **Class-B** Codes & Sizes as per FSC provided. • Claimed Shelf-life: 18months.	• To measure the ketone bodies from human serum or plasma.	**Deferred;** firm shall be asked to provide DOC, manufacturing & QC details and Stability study data for claimed

					shelf-life not submitted.
43.	M/s Mubarak Vision, 32-A Usman Centre, Shah ALam Market, Lahore **ELI-00045.**	**Legal Manufacturer:** Albomed GmbH Hildebrandstrasse 11 D-90592 Schwarzenbruck, Germany. **Mfg. Site/ Subcontractor:** Sothema BP1, Industrial Zone Bouskoura, Casablanca Morocco. **Packaging:** Albomed GmbH, Tronjestrasse 14, 44319 Dortmund, Germany. FSC Germany Date of Issue 01-04-2019.	***Pe-Ha-Luron F 3.0%.** (Hymaluronic Acid (Ophth. Intraocular Devices) **Class –B.** Claimed Shelf Life: 42 months. Rs. 25,000/-	**Pe-Ha-Luron 3.0%** Hymaluronic Acid **in HPMC;** used as viscoelastic solutionsfor intraocular use containing cannula for injection. • MRP not mentioned and grouping should be clear. • Firm applied multiple devices (different injectable strengths) in the same application, So, herein the **Pe-Ha-Luron F 3.0%** has been considered. • Rest of the products applied shoud be asked with separate application, fee and particulars as per MDR,2017 requirements. • The valid ISO-13485 certificate of manufacturing site, i.e., Sothema, Morroco.	**Approved** subject to provision of; valid ISO-13485/ GMP certificate of manufacturing site, i.e., Sothema, Morroco. • Remaining strenghts shall be applied separately.
44.	**-do-**	**Legal Manufacturer** Albomed GmbH Hildebrandstrasse 11 D-90592	**Pe-Ha-Visco Plus 2.4 %** (Hydroxypropyl Methylcellulose	Hydroxypropyl Methylcellulose (Ophthalmic Device.	**Approved** subject to provision of; valid ISO-13485/

		Schwarzenbruck, Germany. **Mfg. Site/ Subcontractor:** GalenicaSeneseSrl, Via Cassia Nord,388, 53014 Monteroni d' Arbia SI, Italy. **Packaging:**Albomed GmbH, Tronjestrasse 14, 44319 Dortmund, Germany. FSC Germany Date of Issue 01.04.2019.	(Ophth. Device) **Class-B** Shelf Life: 60 months Rs.25,000/-	Firm applied multiple devices (different injectable strengths) in the same application, So, herein the **Pe-Ha-Visco Plus 2.4 %** has been considered. • Rest of the products applied shoud be asked with separate application, fee and particulars as per MDR,2017 requirements. • The valid ISO-13485 certificate of manufacturing site, i.e., GalenicaSenes eSrl. SI, Italy. • MRP not mentioned and grouping should be clear.	GMP certificate of manufacturing site, i.e., GalenicaSeneseSr l. SI, Italy. • Remaining strenghts shall be applied separately.
45.	**-do-**	Legal Manufacturer M/s IRIDEX Corporation 1212 Terrra Bella Avenue, Mountain View, CA 94043-1824 U.S.A. FSC USFDA Valid till 21-05-2021.	**Ophthalmic Endo-Lasers** Probes **Class-B**. Shelf Life: 12 months Rs.25,000/-	Ophthalmic Endo Lasers Hand piece/Probes.	**Deferred;** • Firm shall be asked for MRP and Full QA certificate. • 19-types of medical devices asked in the subject application, firm shall be asked for separate application for each type of medical device.

46.	**-do-**	Legal Manufacturer Katalyst Surgical 754 Goddard Ave.Chesterfiled,MO 63005 U.S.A. FSC USFDA Valid till 08-03-2022.	**DEX TIPS Canoe Forceps** Part# CVF-4000. (Ga:20-23-25-27) Ophthalmic Micro Forceps. **Class: - B**. Shelf Life: 03 years Rs.25,000/-	Ophthalmic Instruments & Micro Forceps Micro Scissors	**Deferred;** • Firm shall be asked for MRP and Full QA certificate. • Herein 50-types of medical devices asked in the subject application, firm shall be asked for separate application for each type of medical device.
47.	**-do-**	Legal Manufacturer Katalyst Surgical 754 Goddard Ave. Chesterfield, MO 63005 U.S.A FSC USFDA Valid till 08-03-2022.	Katalyst Fiber Optic & Laser Probes. **Class-B** **Rs.25,000/-**	Katalyst Fiber Optic & Laser Probes	**Deferred;** • Firm shall be asked for MRP and Full QA certificate. • Herein 50-types of medical devices asked in the subject application, firm shall be asked for separate application for each type of medical device. •
48.	**-do-**	Legal Manufacturer: France Chirurgie Instrumentation SAS 20/22 Rue Louis Arman (75015) Paris, France Manufacturer Site France Ghirurgie Instrumentation SAS, (FCI S.A.S 2 RUE CARL ZEISS 25000 BESANCON FCS Paris, France	BIKA Intubation Set Class –C Shelf Life: 05 Years Codes & sizes: S1.1000 S1.1010	Nasal intubation is indicated for treatments of epiphora in infants or adults, particularly in case of: Canalicular pathologies Dacryocystorhinostomy Imperforation of the nasolacrimal duct in the infant	**Approved** subject to provision of MRP and valid ISO.13485. Firm shall apply separately for each type of medical devices mentioned in the application.

		Date of issue 28.01.2019			
49.	**-do-**	**Legal Manufacturer:** M/s Sterimedix Ltd, Madeley Road, North Moons Moat, Redditch, Worcestershire, B98 9NB, UK. **FCS UK** **Valid till 06.02.2021**	Anaesthetic Needles Class-B Shelf Life: Five years Codes & sizes: M0275, M0637 M0638, M0641A M0642, M0643 M0641, M0642A	Surgically invasive device for injecting anesthesia into either the muscle cone, or around the globe, or into the sub-tenon space and intended for transient use.	**Approved** subject to provision of MRP. Firm shall apply separately for each type of medical devices mentioned in the application.
50.	**-do-**	**Legal Manufacturer:** **M/s AKtive S.R.L** **Via Giacomo Delitala, 106-00173 Rome Italy** **FSC-Italy** **Date of issue 04.05.2016**	Anterior/Posterior Vitrectomy Cutter Class-B Shelf Life: Five years Codes & sizes as per FSC	Single use sterile medical device for Ophthalmic surgery.	**Approved** subject to provision of MRP. Firm shall apply separately for each type of medical devices mentioned in the application.
51.	M/s S.Ejazuddin& Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi **(ELI-00078)**	**Legal Manufacturer:** Ansell Lank (Pvt) Ltd., Biyagma Export Processing Zone Biyagama- Srilanka (FSC of Sri-Lanka 10-10-2016)	Gammex Latex Powdered Gloves. Surgical Glove **Class B** Shelf Life: 3 Years (FSC of Sri-Lanka 10-10-2016) Rs.25,000/- FSC of Belgium and WHO-prequalification copy is provided.	The surgical glove is made of natural rubber latex intended as a protective barrier when worn on the hands of healthcare providers at the surgical site. The device is used mainly as a two-way barrier to protect both the patient and the staff against contamination from microorganisms. This is a single-use device, supplied sterile.	**Approved** subject to provision of valid Letter of Authorization (expired on 31-12-2019) before the of issuance of registration certificate. • Non-powdered gloves shall be applied separately.
52.	M/s Mana &Co.,, Office No. 401, 4th Floor,	Legal Manufacturing:	Medicare Plus Sterile Latex	Medicare Plus serileSurgicalLa	**Approved.**

	Masood Chamber, Shahrah-e-Liaqat, Kaachi. ELI:-00098	M/s Shandong Yuyuan Latex Gloves Co.Ltd, Industrial Zone, Linqing City 242600 Shandong Province, China FSC: China; Date of validity: 26.04.2020.	Surgical Gloves Sterile Surgical Gloves Codes & Sizes as per FSC. **Class-B** Shelf Life 05-years Rs.25,000/-	tex Gloves are disposable gloves used during medical examinations and procedures to help prevent cross-contamination between caregivers and patients.	
53.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	**Manufacturer:** M/s Medin Medical Innovations GmbH Adam-Geisler-Str. 1 82140 OlchingDeutschland/ Germany (FSC Germany Issuance Date 13-09-2017)	MedinSINDI Class C Shelf Life: 8 Years Code: 1080	The MedinSINDI® universal gas supply unit with pressure monitor is an electronic unit with microprocessor-controlled monitoring and use for enriching the breathing gas mixture with oxygen for premature and newborn infants as well as in connection with the nCPAP generator Medijet to support respiration with continuous positive airway pressure with monitoring and alarm parameters.	**Deferred** for provision of valid CE certificate, Shelf life studies data, Manufacturing & QC processes details.
54.	M/s Universal Enterprises, 29-Block-3, Overseas Co-Operative Housing Society, Stadium Road, Karachi. (ELI-00079)	**Legal Manufacturer: Terumo Cardiovascular System Corporation, 125 Blue Ball Road, Elkton, MD 21921, USA.** **FSC Belgium Issuance 28-04-2017**	Capiox Oxygenator Class D Shelf Life: 36 Months Codes: 3CX*RX15RW30 3CX*RX15RE30 3CX*RX15RW40	The set intended for use during surgery requiring cardiopulmonary or other surgical techniques.	**Approved** subject to submission of differential fee of Rupees 25,000 as the device falls in Class-D.

			3CX*RX15RE40		
55.	M/s Medica, House No. 188-1-B (First Floor) near Nursery area, Block 2, PECHS Karachi. (ELI-00237)	Legal Manufacturer: SaSanSaglikMazemeler I uretimvePazarlamaa.s. (DagyakaMah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye. (FSC issuance 09-03-2017)	Sasan Medical Disposable products. S.A. Tubing Set Adult Class B Shelf Life: 3 Years. (Sizes & Codes as Per FSC) Tubing Set SD9000CM/Z SD921001/A SD921301/A SD921301/B	Extracorporeal tubing set is a medical device that is used with Cardiopulmonary pump and oxygenator for oxygenation of blood in open heart surgeries and allows the blood to be sent to the oxygenator and then to the patient.	**Approved** subject to inspection of manufacturer abroad.
56.	-do-	Legal Manufacturer: SaSanSaglikMazemeler I uretimvePazarlamaa.s. (DagyakaMah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye.(FSC issuance 09-03-2017)	Sasan Medical Disposable products. S.A.Arterial Filter Loop Pediatric Class B Shelf Life: 3 Years. (Sizes & Codes as Per FSC) Arterial Filter Loop Pediatric Ref: SD9203CM/A	Extracorporeal tubing set is a medical device that is used with Cardiopulmonary pump and oxygenator for oxygenation of blood in open heart surgeries and allows the blood to be sent to the oxygenator and then to the patient.	**Approved** subject to inspection of manufacturer abroad.

9. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. FSC USFDA Valid Till (08-02-2020)	Cell-Dyn Emerald Instrument **Class-A.** Codes & Sizes as per FSC	**Approved;** Firm shall submit Service life studies before the issuance of registration certificate. • Form-7A alongwith differential fee, as the product fall in class-B.
2.	**-do-**	**Legal Manufacturer:** M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA. FSC USFDA Valid Till (08-02-2020)	m-Pima Analyzer. **Class-A.** Codes & Sizes as per FSC	**Approved;** Firm shall submit Service life studies & Application form with all coded particulars before the issuance of registration certificate. • Form-7A alongwith differential fee, as the product fall in class-B.
3.	**-do-**	Legal Manufacturer Standard Diagnostic INc, 65 Borahagal-Co. Giheung-gu, Yongin-si Gyeonggi-do, Republic of Korea FSC: Korea Date of issue: 11.08.2017.	Urometer. (UM0120-UM0720) **Class –A.** Codes & Sizes as per FSC	**Approved;** Firm shall submit Service life studies & Application form with all coded particulars before the issuance of registration certificate.
4.	**-do-**	**Legal Manufacturer:** M/s Abbott Point of Care Inc. 400 College Road East Princeton, NJ 08540 USA. **Manufacturing Site:** M/s Flextronics	i-STAT 1 Analyzer (Model No 300-G) **Class-A.** Codes & Sizes as per FSC. FSC USFDA Valid	**Approved;** Firm shall submit Service life studies before the issuance of registration certificate. • Form-7A

		Manufacturing (Singapore) Pte Ltd. 1 Kallang Place Singapore, South East, 339211, Singapore.	Till 24-02-2021.	alongwith differential fee, as the product fall in class-B.
5.	-do-	Legal Manufacturer: France Chirurgie Instrumentation SAS 20/22 Rue Louis Arman (75015) Paris, France Manufacturer Site France Ghirurgie Instrumentation SAS, (FCI S.A.S 2 RUE CARL ZEISS 25000 BESANCON FCS Paris, France Date of issue 28.01.2019	J.A Bernard Lacrimal Probe Class A Shelf Life: Five years Codes & sizes: A8.4060 SI.4025 S1.4030	**Approved** subject to provision of MRP and valid ISO-13485 certificate. Firm shall apply separately for Herein multiple-types of medical devices asked in the subject application.

10. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE (Form 7).

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Paktex Industries, 2.5 K.M. Tatlay Road, Sroyaabad, Kamoke Gujranwala (DML-000376)	Pro Pak Alcohol Guaze/Swab Class -C Shelf Life: 5 years Fee submitted Rs.20,000/- Size as per Form-7	Alcohol Guaze/Swabs	**Approved.**
2	-do-	Pop Bandages Size as per Form-7 Class -C Shelf Life: 5 years Fee submitted Rs.20,000/-	Plaster of Paris Bandage	**Approved.**

3.	-do-	Pak Optice Eye Pad Size as per Form-7 Class -C Shelf Life: 5 years Fee submitted Rs.20,000/-	Cotton Eye Pad	**Approved.**
4.	-do-	Pak Band Gauze / Swab Size as per Form-7 Class -C Shelf Life: 5 years Fee submitted Rs.20,000/-	Absorbent Gauze / Swabs USP Type IV	**Approved.**

11. 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 Usman Enterprises, Plot No. A116, Phase I, SITE, Super Highway, Karachi (ELM-0013)	Niplast Adhesive Plaster Class A Shelf Life: 02 Years Rs.5000/- RenewalSizes as existing registration.	Fabric backing with Zinc oxide Adhesive base Used for the firm support to fixation of tubing, catheter, cannula etc.	**Approved.**
2.	-do-	TRANSPLAS Plastic Surgical Tape Class A Shelf Life: 02 Years Rs.5000/- RenewalSizes as existing registration	Polyolefin (Polyehthylene) Backing with Acrylic adhesive	**Approved.**
3.	-do-	Kino White (Polyester Non Woven Backing with Acrylic Adhesive) Class A Shelf Life: 03 Years Rs.5000/-	Polyester Non Woven Backing with Acrylic Adhesive	**Approved.**

		Renewal Sizes as existing registration		