<u>DECISIONS OF THE 28th MEETING OF THE MEDICAL DEVICE BOARD (MDB)</u> <u>HELD ON 28-02-2021</u>

1. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.</u>

S.No	Name of Establishment	Director/Proprieto r/ partners	Cold Chain (Yes/No	Decisioin
1.	M/s SAS National Company, Abbas Houe, Near District Court, Main Bazar Dir, District Dir Upper. Godown Address: Same as above.		No.	Approved for storage of non cold chain medical devices.
2.	M/s Eastern Medical Technology Services, 3-Aziz Avenue, Gulberg-V, Lahore. Godown Address: Same as above.	Ghulam Ali Shakir	No	Approved for storage of non cold chain medical deives.
3.	M/s Medonix Pakistan, Plot No. 4, Street No. 1, Umer Garden, Shah di Khoye, Lahore. Godown Address: Same as above.	Mr. Asif Iqbal	No	Approved for storage of non cold chain medical deives.
4.	M/s Highnoon Laboratories Limited, 17.5 KM, Multan Road, Lahore.	Mr. Tausif Ahmad Khan. Dr. Adeel Abbas Haideri. Mr. Ghulam	No.	Approved for storage of non cold chain medical deives.
	Godown Address: 19KM Multan Road	Hussain Khan.		

	(Din Muhammad Town, Chung), Lahore.	Mr. Romesh A. I Elapata. Ms. Nael Najam. Mr. Shazib Masud. Mr. Taufiq Ahmed Khan. Mrs. Zainub Abbas.		
5.	M/s Universal Medicine & Surgical Suppliers, Office No.A/50, First Floor Liberty Mall Plaza, Main Univerwsity Road, Tambwanu Mur, Peshawar. Godown Address: No.49, 1st Floor Liberty Mall University Road, Peshawar.	Mr. Mukhtiar Ali Mr. Amjad Ali	No	Approved for storage of non cold chain medical devices.
6.	M/s Roche Pakistan L B, Block-6, PECHS, I Addition of New Goo No.116, Sector 15, KI	Karachi. down: R-PI, Plot	No	Approved the addition of new godown at , Plot No.116, Sector 15, KIA, Karachi.

2. <u>CLEOCAP TM COVID-19 (SARS-CoV-2) RT PCR KIT DEVELOPED BY THE UNIVERSITY OF LAHORE AND REPORT OF NIH THEREOF.</u>

Decision: Based on the results of testing in National Institute of Health (NIH) wherein the CleoCap COVID-19 Kit showed very low sensitivity, MDB rejected the application of University of Lahore for consideration of their kit for analysis of COVID-19. The Board advised to upgrade their kit and reapply for assessment /evaluation by the Exprt Group for Assessment/Evaluation of Locally Manufactured Medical Devices (COVID-19) PCR Testing Kits.

3. <u>APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.</u>

3.1.

M/s Textile Testing International, 347-S, Quaid-e-Azam Industrial Estatem Kot Lakhpat, Lahore has requested for grant of permit to import medical device namely **3 Ply Surgical Masks** (**Qty: 200**) from M/s Banyan USA, LLC, 24 Central Drive, Farmingdale, NY 11745 for testing purpose only.

Decision: The Board approved/endorsed/ratified the issuance of Import Permit to import medical device, namely, 3 Ply Surgical Masks (Qty: 200) by M/s Textile Testing International, 347-S, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore.

3.2.

Dr. Muhammad Saqib Shahzad, Director of M/s Surgimed Laboratory and Research Center, Surgimed Hospital, 1-Zafar Ali Road, Gulberg-V, Lahore has requested for grant of permit to import following medical devices manufactured by Eryigits Endustriyel Makina VE Tibbi Chlazlar Malat-Ankara, Turkey for the **purpose of testing** of COVID-19 virus at **Surgimed Laboratory & Research Centre, Surgimed Hospital, 1-Zafar Ali Road, Gulberg-V, Lahore:-**

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

Decision: The Board discussed the matter and decided to defer the case for provision of studies performed on the kit by the manufacturer in the country of origin and clearly state the purpose of import and what type of data needs to be optimized in Pakistan

3.3.

M/s Schazoo SPL Consumer Healthcare, 71-B/C2, Gulberg-III, Lahore has requested for grant of permit to import following medical devices for evaluation of samples by NDMA:-

Sr	:No.	Name	of	Medical	Name of Manufacturer	Quantity
		Device.				

1.	labGun COVID-19	M/s LabGenomics Co., Ltd, #	20 Kits
	Rapid Antigen Kit	1204, 12F, 147, Gwanggyo-ro,	
		Yeongtong-gu,Suwon-Si,	
		Gyeonggi-do, 16229, Republic	
		of Korea.	
2.	PCL Covid 19 Ag	PCL, Inc., No,701, (Gasan-	20 Kits
	Rapid FIA Kit	Dong, Stravalley), 99, Digital-	
		ro 9-gil, Geumcheon-gu,	
		Seoul, South Korea.	
3.	PCL Covid 19 Ag	PCL, Inc., No,701, (Gasan-	20 Kits
	Gold Saliva Kit	Dong, Stravalley), 99, Digital-	
		ro 9-gil, Geumcheon-gu,	
		Seoul, South Korea.	
4.	Wondfo 19-nCOV	M/s Guangzhou Wondfo	20 Kits
	Antigen Test Kit	Biotech Co. Ltd,, No.8,	
		Lizhishan Road, Science City,	
		Luognang District Guangzhou	
		510663, PR China.	

They have further submitted that **these samples will be submitted to NDMA exclusively for source evaluation by NDMA.** These kits will be imported from Korea and will aid to diagnose COVID-19, detection of SARS-COV-2 (COVID-19).

Submitted for consideration of MDB please.

Decision: The Board discussed the matter and decided to defer the case for provision of NDMA order for the above mentioned kits to the importer.

4. SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.

4.1.

The case of the M/s Sy'ah Impex, Karachi for the below medical device was considered by the MDB in its 27^{th} meting held on 21-01-2021 and approved subject to provsion of documents:-

S.No.	Name and Address of Establishment	Manufacturer detail	Name of Medical Device.	Brief Description
	M/s SY'AH IMPEX,	Legal	SHIFA Auto	AD syringes
1.	1-6/15 Sector No. 5,	Manufacturer:	Disable	include a
	Korangi Industrial Area	M/s Jiangyin	Syringes	reuse

H	Karachi Pakistan	Nanquan		prevention
		Macromolecule	(Auto -	feature i.e.,
l I	ELI: 00440	Product Co.,	disable	feature that
		Ltd No, 618	syringes)	activates after
		Jingxian Road,		intended use
		Xiagang Street,	Class -B	to prevent
		Jiang Yin City,		subsequent
		Jiangsu,	Shelf Life: 5	reuse of
		Province,	years	syringes.
		China.		These
			Sizes:	syringes
		FSC: China	0.05cc,	provide an
		Valid till:	0.1 ml, 0.5 ml,	opportunity to
		2021.09.29	1ml, 2ml	prevent reuse
				of injection
				equipment.
				The products
				are sterilized
				with EO Gas.
				The products
				are sterile, no
				toxicity, no
				pyrogen

Decision: The Board approved the above mentioned medical devices on the basis of CE marked documents.

4.2.

The case of the M/s Zenith International, Karachi for the below medical device was considered by the MDB in its 11^{th} and 13^{th} metings held on 01-02-2019 and 05-08-2019 respectively and approved as mentioned againgt each:-

S.No.	Name and	Manufacturer	Name of	Brief	Decision of
	Address of	detail	Medical	Description	MDB
	Establishment		Device.		
	M/s Zenith	Manufacturer:	K&K Zenith	Disposable	Approved
1.	International,	M/s Evereast	Disposable	Trachea	subject to
	Room No. 104,	Medical Products	Endotracheal	Cannula	inspection of
	Tahir Plaza,	Group Co., Ltd.,	Tube, Sterile		manufacturer
	A/20, Block	No.1 Wangzhuang	With Cuff		abroad under
	7&8, KCHSU,	Village, Shejia			Rule 71 of
	Karachi	Town, Changyuan	Class B		MDR, 2017.
	(ELI-00090	County, Henan	Shelf Life: 5		
		453400, China	Years		
	(MDB-11)		1 cars		

		(FSC China Valid			
		Till 22-05-2023)	Codes as per		
		1111 22 05 2025)	Free Sale		
			Certificate		
	-do-	-do-	Perfect	Disposable	Approved
2.			Disposable	Latex Foley	subject to
	(MDB-11)		Urethral	Balloon	inspection of
			Catheter	Catheter, Sterile	manufacturer
			(Disposable	·	abroad under
			Foley		Rule 71 of
			Catheter)		MDR, 2017.
			Class B		
			Shelf Life: 5		
			Years		
			Sizes: (2way)		
			6fr, 8fr, 10fr,		
			12fr, 14fr,		
			16fr, 18fr,		
			20fr, 22fr, 24fr		
			(3way) 16fr,		
			18fr, 20fr, 22fr, 24fr		
	-do-	-do-	K&K Zenith	Disposable	Approved
3.	40	ų.	Disposable	Trachea	subject to
	(MDB-11)		Endotracheal	Cannula	inspection of
	(=====)		Tube, Sterile		manufacturer
			Wihtout Cuff		abroad under
					Rule 71 of
					MDR 2017.
			Class B		
			Shelf Life: 5 Years		
	-do-	Legal	Perfect	Disoposable I.V.	Approved
4.		Manufacturer:		Catheter, Sterile	subject to
	(MDB-13)	Suzhou Lingyan	Disposable		Inspection
		Medical Technology	I.V. Catheter,		abroad by the
		Co., Ltd	Sterile		panel of
		99 Maopeng RD,			inspectors.
		Xujiang Industrial	(Sizes: 18G,		The board
		Park, Wuzhong	20G, 22G,		also
		District Suzhou,	24G)		authorized the
		China.	CI D		secretary
		E00 1/ 1/ 1/11 00	Class B		MDB to issue
		FSC Valid till 08-	Shelf Life: 05		registration
		04-2022)	Years		certificate if

					recommended by the panel of inspectors.
_	-do-	Legal	PERFECT	Pregnancy Test	Approved
5.		Manufacturer:		is a rapid	subject to
	(MDB-13)		HCG	chromatographic	Inspection
		Nantong EGENS	Pregnancy	immunoassay	abroad by the
		BIOTECHNOLOGY	Test (Urine)	for the	panel of
		CO., LTD		qualitative	inspectors.
		Block A Fifteenth	Class B	detection of	The board
		Factory-Building No.	Shelf Life: 3	human chorionic	also
		1692 Xighu Avenue	Years	Gonadotropin	authorized the
		Nantong Economic		(HCG) in urine	secretary
		& Technological	Strip I Type:	sample to aid in	MDB to issue
		Development Zone,	50 Test	the early	registration
		China	Kit/Box, 100	detection of	certificate if
		/EGG II 1' 1 1 0 1 2	Test Kit /Box	pregnancy by	recommended
		(FSC Valid 19-12-	Cassette I	both	by the panel
		2019)	Type: 25 Test	professional and	of inspectors.
			Kit/Box,	home users.	
			40 Test		
			Kits/Box		
			Midstream I		
			Type: 1 Test		
			Kits/Box, 25		
			Test Kit/Box		

Decision: The Board approved the products mentioned at Serial No.1-4 on the basis of Free Sale Certificate of Medicine and Healthcare Products Regulatory Agency (MHPRA) UK and product at Serial No.5 on the basis of CE marked documents.

4.3.

The case of the M/s Sultansons, Karachi for the below medical devices was considered by the MDB in its 13th meting held on 05-08-2019 and approved as mentioned againgt each:-

S.No.	Name and Address of	Manufacturer	Name of	Brief	Decision of
	Establishment	detail	Medical	Description	MDB
			Device.		
	M/s Sultansons, 133	Manufacturer:	ST Classic	Disposable	Approved
1.	Kutchi Gali #1,	M/s Shandong	Disposable	Insulin	subject to
	Marriott Road, Karachi	Wuzhou	Sterile Insulin	Syringe U-	foreign
		Medical	Syringe	100 Sterile	inspection of
	(ELI-00051)	Equipment Co.,			manufacturer
		Ltd., Dingtao	Class B		abroad. The
		(YanTai)			Board also

		Industrial Zone, China (FSC China Valid Till 05-02-2020)	Shelf Life: 5 Years U-100 (1ml, 0.5ml) Rs.25,000/-		authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
2.	-do-	-do-	ST Classic Disposable Sterile Infusion Set with Needle (100ml, 150ml) Class B Shelf Life: 5 Years Rs.25,000/-	Disposable Infusion Set with Needle Sterile	Approved subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
3.	-do-	-do-	ST Classic Intravenous Infusion Sets with Burette Class B Shelf Life: 5 Years 100ml, 150ml Rs.25,000/-	IV Infusion Set	Approved subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.

	-do-	-do-	ST Classic	Disposable	Approved
4.			Disposable	Syringes	subject to
			Sterile		foreign
			Syringes		inspection of
					manufacturer
			Class B		abroad. The
					Board also
			Shelf Life: 5		authorized the
			Years		Secretary
					MDB to issue
			1ml, 2ml,		registration of
			3ml, 5ml,		the product, if
			10ml, 20ml,		the panel of
			30ml, 50ml		experts
					approve the
			Rs.25,000/-		manufacturing
					plant.

Decision: The Board approved the above mentioned products at Serial No.1-4 on the basis of Free Sale Certificate of Medicine and Healthcare Products Regulatory Agency (MHPRA) UK, however for product at serial No. 4 only 1ml, 10ml, 20ml, 30ml, 50ml are approved.

5. POST REGISTRATION VARIATIONS.

5.1.

M/s Essity Pakistan Limited, A-69,SITE, Manghopir Road, Karachi has requested for approval of change of importer (company) name from M/s BSN Medical (Pvt) Limited to M/s Essity Pakistan Limited in their already registered/enlisted medical devices for import as per detail given below:-

S.#	Regn. No.	Name of Medical Device	Existing Name of importer on Registration/ Enlistment letters	Proposed Name of Importer on Registration/ Enlistment letters
1.	MDIE-0000011	Leukomed (Absorbent Wound Dressing	M/s BSN Medical (Pvt) Limted, A- 69,SITE, Manghopir Road, Karachi	M/s Essity Pakisrtan Limited, A-69,SITE, Manghopir Road, Karachi.
2.	MDIE-0000012	Fixomull Stretch (Adhesive Tape)	-do-	-do-

3.	MDIE-0000013	Leukomed T Plus (Transparent Absorbent Would Dressing)	-do-	-do-
4.	MDIE-0000029	Soffban Plus (Synthetic Orthopedic Padding)	-do-	-do-
5.	MDIR-0000348	Cutimed Gel	-do-	-do
6.	MDIR-0000349	Cutimed Cavity	-do-	-do
7.	MDIR-0000350	Cutimed Siltec	-do-	-do
8.	MDIR-0000715	Cutimed Sorbact Hydroactive	-do-	-do

Decision: The Board acceded to the request of the firm for change of importer (company) name from M/s BSN Medical (Pvt) Limted to M/s Essity Pakistan Limited on registration certificates of their above mentioned registered/enlisted medical devices for import.

5.2.
M/s Essity Pakistan Limited, A-69, S.I.T.E, Manghopir Road, Karachi has requested for approval of additional sizes of their following already enlisted medical device for import as

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDIE-0000012	Fixomull Stretch (Adhesive Tape)	02036-00 10 m x 5cm 24 Boxes per Shipper 02037-00 10 m x 10cm 24 Boxes per Shipper	10cm x 1cm

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:-

per detail mentioned below:-

Regn.No	Name of Product	Name of Manufacturer	Existing Approved Sizes	Demanded Additional Sizes.
MDIE- 0000012	Fixomull Stretch (Adhesive Tape)	M/s Essity Pakisrtan Limited, A- 69,SITE, Manghopir Road, Karachi. (M/s BSN Medical GmbH, Quickbornstrab e 24, 20253 Hanburg, Germany)	02036-00 10 m x 5cm 24 Boxes per Shipper 02037-00 10 m x 10cm 24 Boxes per Shipper	10cm x 1cm

5.3.

M/s N-ovative Health Technologies (NHT) Pvt. Ltd, National University of Science and Technology (NUST) Sector H-12, Islamabad, has requested for approval of additional sizes of their following already registered medical device for local manufacture as per detail mentioned below:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDMR-000081	VASOGLIDE Rapid Exchange PTCA Angioplasty Balloon Catheter (Sterile Single Use)	Sizes (mm): 2.0 x 12, 2.0 x 16, 2.0 x 20, 2.0 x 22, 2.0 x 26, 2.0 x 30, 2.0 x 34, 2.5 x 12, 2.5 x 16, 2.5 x 20, 2.5 x 22, 2.5 x 26, 2.5 x 30, 2.5 x 34, 3.0 x 12, 3.0 x 16, 3.0 x 20, 3.0 x 22, 3.0 x 26, 3.0 x 30, 3.0 x 34, 3.5 x 12, 3.5 x 16, 3.5 x 20, 3.5 x 22, 3.5 x 26, 3.5 x 30, 3.5 x 34, 4.0 x 12, 4.0 x 16, 4.0 x 20, 4.0 x 22, 4.0 x 26,	Sizes (mm): 2.0 x 10 2.5 x 10 2.0 x 15 2.5 x 15.

Ī		4.0 x 30 , 4.0 x 34	

Decision: The Board acceded to the request of the firm /company and approved the additional sizes/codes of above mentioned medical device for local manufacture as mentioned below. Firm may also be asked to submit stability data quarterly:-

Regn.No	Name of Product	Existing Approved Sizes	New Approved Additional Sizes.
MDMR- 000081	VASOGLIDE Rapid Exchange PTCA Angioplasty Balloon Catheter (Sterile Single Use)	Sizes (mm): 2.0 x 12, 2.0 x 16, 2.0 x 20, 2.0 x 22, 2.0 x 26, 2.0 x 30, 2.0 x 34, 2.5 x 12, 2.5 x 16, 2.5 x 20, 2.5 x 22, 2.5 x 26, 2.5 x 30, 2.5 x 34, 3.0 x 12, 3.0 x 16, 3.0 x 20, 3.0 x 22, 3.0 x 26, 3.0 x 30, 3.0 x 34, 3.5 x 12, 3.5 x 16, 3.5 x 20, 3.5 x 22, 3.5 x 26, 3.5 x 30, 3.5 x 34, 4.0 x 12, 4.0 x 16, 4.0 x 20, 4.0 x 22, 4.0 x 26, 4.0 x 30, 4.0 x 34	Sizes (mm): 2.0 x 10 2.0 x 15 2.5 x 10 2.5 x 15.

6. POST LICENSE VARIATIONS.

M/s OscarTech Pakistan, Opposite Union Council Kotla Arab Ali Khan, Tehsil Kharian, District Gujrat has requested for approval of change of qualified/technical person in their ELI-00318 issued on 25-02-2019 as per detail given below:-

Existing Technical Person	Proposed Technical Person	
Shahzada Zulfiqar Hyder, House No.C-55,	Mr. Abdul Jabbar Qaureshi, PO Khas, Guliana,	
Shahdman Colony, Gujrat.	Kharian, District Gujrat.	
	CNIC # 34202-5912261-1	
CNIC # 33201-0429490-9.		
	(B.Pharmacy)	

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

Previous Technical Person	New Approved Technical Person				
Shahzada Zulfiqar Hyder, House No.C-	Mr. Abdul Jabbar Qureshi, PO Khas,				
55, Shahdman Colony, Gujrat.	Guliana, Kharian, District Gujrat.				
	CNIC # 34202-5912261-1				

CNIC # 33201-0429490-9.	
	(B.Pharmacy)

7. <u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES).</u>

S.	Name and	Manufacture Details	Name of Medical	Brief	Decision
#	Addresses of	•	Device with sizes/	Description	
	Establishment		Class/ Shelf Life		
1.	AGP Limited, B-23-C, SITE, Karachi (ELI-00571)	Legal Manufacturer: M/s PT. Onject Indonesia Olympic Raya Kav. B9 Kawasan Industri Sentul Bogor 16810- Indonesia. FSC Indonesia valid till (15-06-2022)	Oneject Auto Disable Syringe 0.05ml. Class B Claimed Shelf Life: 05-years.	Polypropylene syringe with latex free rubber gasket and stainless needle with sharp injury prevention	Approved
2.	-do-	WHO prequalified. Legal Manufacturer: M/s PT. Onject Indonesia Olympic Raya Kav. B9 Kawasan Industri Sentul Bogor 16810- Indonesia. FSC Indonesia valid till (15-06-2022) WHO prequalified.	Oneject Auto Disable Syringe 0.5ml Class B Claimed Shelf Life: 05-years.	Polypropylene syringe with latex free rubber gasket and stainless needle with sharp injury prevention	Approved

8. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

	Name of Firm (s)	Name of	Name of Medical	Brief	Decision
S. #		Manufacturer	Devices.	Description	
1.	M/s Zedco,	Legal	Teruflex® CPDA-	Sterile plastic	Approved
	Office No. 203, Sky	Manufacturer:	1 Double Blood	collapsible	

	Mark Tower, Plot A-	Terumo BCT Ltd.,	Bag (with	containers for	The firm shall
	13, Block 7/8, K.C.H.S.U, Shahrah-e-	Old Belfast Road, Millbrook, Larne,	anticoagulant)	single use only, and used for	submit valid full QA certificate at
	Faisal, Karachi.	BT40 2SH, United	Class D	collection,	the time of
	,	Kingdom	Shelf Life: 36	processing,	issuance of
	(ELI-00347)		Months	storage and	registration letter
		Manufacturing site:		transfusion of	
		Terumo BCT	Codes:	whole blood or	
		Vietnam Co. Ltd.	2CD256E8	blood	
		Long Duc Industrial	2CD356E0	components.	
		Park, Long Duc	2CD356E8 2CD356S8		
		Commune, Long Thanh District, Dong	2CD336S8 2CD456E0		
		Nai Province,	2CD456E8		
		Vietnam.	2CD+30L0		
			Fee submitted: Rs.		
		(FSC Vietnam valid	50,000/		
		till 09-03-2020)			
		FSC UK MHRA valid			
		till 16-04-2019)			
2.	-do-	Legal	Teruflex® CPDA-	Sterile plastic	Approved
		Manufacturer:	1 Single Blood	collapsible	771 C' 1 11
		Terumo BCT Ltd.,	Bag (with	containers for	The firm shall
		Old Belfast Road, Millbrook, Larne,	anticoagulant)	single use only, and used for	submit valid full QA certificate at
		Millbrook, Larne, BT40 2SH, United	Class D	collection,	the time of
		Kingdom	Class D	processing,	issuance of
			Shelf Life: 36	storage and	registration letter
		Manufacturing site:	Months	transfusion of	
		Terumo BCT		whole blood or	
		Vietnam Co. Ltd.	Codes:	blood	
		Long Duc Industrial	1CD256E8	components.	
		Park, Long Duc	1CD256E0		
		Commune, Long	1CD356E8		
		Thanh District, Dong	1CD356E0		
		Nai Province,	1CD456E8		
		Vietnam.	1CD456E0		
		(FSC Vietnam valid	Fee submitted: Rs.		
		till 09-03-2020)	50,000/-		
		32 33 20,			
		FSC UK MHRA valid			
		till 16-04-2019)			
3.	-do-	Legal	Teruflex® CPDA-	Sterile plastic	Approved
		Manufacturer:	1 Quadruple	collapsible	
		Terumo BCT Ltd.,	Blood Bag (with	containers for	The firm shall
		Old Belfast Road, Millbrook, Larne,	anticoagulant)	single use only, and used for	submit valid full QA certificate at

		BT40 2SH, United Kingdom Manufacturing site: Terumo BCT Vietnam Co. Ltd. Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam. (FSC Vietnam valid till 09-03-2020) FSC UK MHRA valid till 16-04-2019)	Shelf Life: 36 Months Codes: 4CD456E0 4CD456E8 Fee submitted: Rs. 50,000/-	collection, processing, storage and transfusion of whole blood or blood components.	the time of issuance of registration letter
4.	M/s. Promed International, CB- 6349, Amarpak Plaza, Jhelum Road, Rawalpindi. ELI-00020	Legal Manufauter: Biosensors Europe SA, 29 rue de Lausanne, 1110 Morges, Switzerland. Manufacturing Site: Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, 619266, Singapore FSC Switzerland valid till 06.05.2022	RISE TM NC Non-Complaint PTCA Balloon Catheter Class: D Sizes and Codes as per FSC Switzerland dated 06.05.2019 Shelf Life: 24 months Fee submitted: Rs. 50,000/-	Indicated for Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and post-delivery expansion of balloon expandable coronary stents. Sterile, single-use	Approved The firm shall submit valid Agency agreement and MRP before issuance of registration letter
5.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	Legal Manufacturer: Ethicon Endo- Surgery, LLC 475 Calle C Guaynabo, PR USA 00969 Manufacturing site: M/s Ethicon Endo-	Contour® Curved Cutter Stapler Class C Shelf life: 5 Years Codes CS40B	Intende d for use in gastrointestinal surgical procedures for transection and resection of tissues. Sterile, single-use	Approved The firm shall submit valid FSC at the time of issuance of registration letter

		Surgery S.A. DE C.V. Avenida De Las Torres No. 7125 Colonia Salvarcar 118 Ciudad Juarez, Chihuahua 32580, Mexico (FSC US FDA valid till 12-02-2020)	CS40G Fee submitted: Rs.50,000/-		
6.	-do-	Legal Manufacturer: Ethicon Endo- Surgery, LLC 475 Calle C Guaynabo, PR USA 00969 Manufacturing site: M/s Ethicon Endo- Surgery S.A. DE C.V. Avenida De Las Torres No. 7125 Colonia Salvarcar 118 Ciudad Juarez, Chihuahua 32580, Mexico (FSC US FDA valid till 12-02-2020)	Proximate® Skin Stapler (Fixed Head) Class B Shelf life: 5 Years Codes: PXW35, PXR35 Fee submitted: Rs. 25,000/-	Sterile, single patient use instrument designed to deliver rectangle, stainless steel staples for routine wound closure.	Approved The firm shall submit valid FSC at the time of issuance of registration letter Other types of staplers to be applied separately
7.	-do-	Manufacturer: M/s M/s Johnson & Johnson International, c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE- 1831 Diegem, Belgium (FSC Belgium Issued on 02-07-2019)	Proceed TM Ventral Patch (Self-Expanding Partially Absorbable Mesh Device) Class D Shelf life: 2 Years Codes: PVPS PVPM Fee submitted: Rs. 50,000/-	Intended for the repair of hernias or other abdominal fascial defects that require addition of a reinforcing or bridging material to obtain the desired surgical result. Sterile, single-use	Approved subject to provision of original FSC and CE-documents

8.	-do-	Legal Manufacturer	VICRYL	VICRYL	Approved.
		Johnson & Johnson	(Polyglactin 910)	Sutures are	• •
		International c/o	Sterile Synthetic	intended for	
		European Logistics	Absorbable	use in general	
		Centre Leonardo Da	Surgical Suture	soft tissue	
		Vincilaan 15, BE-		approximation	
		1831, Diegem	Class D	and/or ligation,	
		Belgium.	Chalf I :fa. OF	including use	
			Shelf Life: 05 Years	in ophthalmic	
			Tears	surgery, peripheral	
		FSC Belgium	Rs.50,000/-	nerve	
		Issuance Date 02-07-	·	anastomosis	
		2019	Codes & Sizes as	and	
			per FSC	microsurgery	
				for vessels less	
				than 2mm	
				diameter.	
9.	M/s. Noor	Legal	HITEC CARE	Tracheobron	Deferred for
	international, 29-D,	Manufacturer:	Tracheobronchial	hial Tube.	provision of
	Block 6, PECHS,	M/s Hitec Medical	Tube.		following
	Karachi. ELI-00061.	Co., Ltd, No.703, Hengnan RD 1328,	Class-B.		documents:-
	ELI-0001.	Minhang District	Class-D.		• Original &
		201114, Shanghai,	claimed shelf life:		valid free sale
		China.	05-years.		certificate of
		FSC China Valid Till			country of
		(14-10-2021)	Codes & Sizes as		origin and SRA
			per FSC.		OR CE- Mark
					Certifications
					of Product
					Quality
					Assurance and
					Production
					Quality
					Assurance to
					the
					manufacturer.
					• The provided
					GMP
					certificate is
					concluded as
					non-
					conformance of
					directives
<u></u>		l			3110011.00

					93/42/EEC &
					ISO 13485,
					hence it is
					advised to
					submit the
					conformance/
					follow-up
					report.
10.	-do-	Legal Manufacturer:	HITEC CARE	Tracheostomy Tube.	Deferred for
		M/s Hitec Medical	Tracheostomy Tube.	Tube.	provision of
		Co., Ltd, No.703,	Class-B		following
		Hengnan RD 1328,	Class B		documents:-
		Minhang District	claimed shelf life:		
		201114, Shanghai,	05-years.		• Original &
		China.			valid free sale
		FSC China Valid Till	Codes & Sizes as		certificate of
		(14-10-2021)	per FSC.		country of
					origin and SRA
					OR CE- Mark
					Certifications
					of Product
					Quality
					Assurance and
					Production
					Quality
					Assurance to
					the
					manufacturer.
					• The provided
					GMP
					certificate is
					concluded as
					non-
					conformance of directives
					93/42/EEC &
					ISO 13485,
					hence it is
					advised to
					submit the
					conformance/
					follow-up
					report.

-do-	Legal	MEDCAPTAIN	Syringe pump	Deferred for
	Manufacturer:	(Syringe pump)	- J8- P *****P	provision of
	M/s Medcaptain	Class-C		following
	Medical Technology			documents:-
	Co., Ltd, 1w2th	Codes & Sizes as		documents
	Floor, Baiwang	*		0::1
	L			• Original &
				valid free sale
		05-years.		certificate of
	,			country of
	Guanguong, Cinna,			origin duly
	FSC China Valid Till			notarized by
				the embassy as
				per 4(xiv) of
	FSC Germany: Date			Form-7A.
	of Issuance: 05-01-			• Provide the
	2019.			original &
				valid agency
				agreement
				AND valid
				certificate of
				ISO-13485.
				150 15405.
-do-	Legal	MEDCAPTAIN	Infusion pump	Deferred for
	Manufacturer:	(Infusion pump)		provision of
	M/s Medcaptain			following
	0,	-		documents:-
				• Original &
		03-years.		valid free sale
				certificate of
	518055 Shenzhen,			country of
	Guangdong, China;			J
				origin duly
	FSC China Valid Till			notarized by
	(07-02-2020)			the embassy as
	Egg C			per 4(xiv) of
				Form-7A.
				• Provide the
	2019.			original &
	201).			_
	2017.			valid agency
	2017.			valid agency agreement
	2017.			valid agency
	-do-	Manufacturer: M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China; . FSC China Valid Till (07-02-2020) FSC Germany: Date of Issuance: 05-01- 2019. Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China; . FSC China Valid Till (07-02-2020) FSC Germany: Date of Issuance: 05-01-	Manufacturer: M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China; Codes & Sizes as per FSC. Class-B. Claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. Claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. Claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. Claimed shelf life: 05-years. Class-B. Claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. Claimed shelf life: 05-years.	Manufacturer: M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China; FSC China Valid Till (07-02-2020) FSC Germany: Date of Issuance: 05-01- 2019. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. claimed shelf life: 05-years. MEDCAPTAIN (Infusion pump) Codes & Sizes as per FSC. Class-B. claimed shelf life: 05-years.

12	M/s. Sind Medical	Logal	MUREX Anti-	In vitro	Annaged
13.	Stores, 13-B, Block 6,	Legal Manufacturer:	MUREX Anti- HCV (Version	diagnostic kit	Approved subject to
	PECHS, Karachi.	M/s DiaSorin S.p.A.	4.0) IVD Kit.	diagnostic kit	provision of
	ELI-00010.	UK Branch Central	Class-D.		valid certificate
	LL1-00010.	Road, Dartford, DA1	claimed shelf life:		of ISO-13485 or
		5LR, UK	12 Months.		valid GMP
		JLK, UK	Codes & Sizes as		Report of
		FSC UK Issuance	per FSC.		manufacturer.
		Date (28-02-19)	per rsc.		manuracturer.
14.	-do-	Legal	MUREX HBsAg	In vitro	Approved
17.	-40-	Manufacturer:	(Version 3)	diagnostic kit	subject to
		M/s DiaSorin S.p.A.	IVD Kit.	diagnostic kit	provision of
		UK Branch Central	Class-D.		valid certificate
		Road, Dartford, DA1	claimed shelf life:		of ISO-13485 or
		5LR, UK	12 Months.		valid GMP
		JLK, UK	Codes & Sizes as		Report of
		FSC UK Issuance	per FSC.		manufacturer.
			per rsc.		manuracturer.
15.	-do-	Date (11-01-19) Legal	ICE* Syphilis	In vitro	Approved
13.	-40-	Manufacturer:	IVD Kit.	diagnostic kit	subject to
		M/s DiaSorin S.p.A.	Class-D.	diagnostic Kit	provision of
		UK Branch Central	claimed shelf life:		valid certificate
		Road, Dartford, DA1	12 Months.		of ISO-13485 or
		5LR, UK	Codes & Sizes as		valid GMP
		JLK, UK			
		FSC UK Issuance	per FSC.		Report of manufacturer.
		Date (11-01-019)			manuracturer.
16.	M/s. Sultan Sons. 133,	Legal	CLASSIC	Blood Lancets,	Deferred for
10.	Kutchi Gali no.01,	Manufacturer:	(Blood Lancets,	Sterile	
	Marriot road, Karachi.	M/s Huaian Helen	Sterile)	Sterric	provision of
	Warnot road, Taraom.	Medical Instruments	Class-B.		original & valid
		Co., Ltd., Group 3,	claimed shelf life:		free sale
		Dentai village matou	05-years.		certificate of
		town, Huaiyin	os years.		country of origin
		district, huaian city,			and SRA duly
		Jiangsu, china			notarized by the
					embassy.
		FSC China.			embassy.
17.	M/s OscarTech	Legal	Nhancer RX	It's a dual	Approved.
	Pakistan, Opposite	Manufacturer:		lumen micro	rr
	Union Council, Kotla	M/s IMDS Operation	NRX 1413518	catheter,	
	Arab Ali Khan, Dist	B.V., Ceintuurbaan		indicated for	
	Gujrat, Teh Kharian	Noord 150, 9301 NZ	Class D	bifurcation	
	(ELI-00318)	Roden, The		complex	
		Netherlands	Shelf life: 02	angioplasty	
			Years.	procedure.	
		FSC Netherlands		r	
			Rs.50,000/-		
		Valid Till 21-05-2022			

18.	M/s Usmanco International, 220, Block: 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121)	Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020) Legal	Codes & Sizes as per FSC Thoracic Catheter Thoracic Catheter without Trocar Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 18012011 18016011 18024011 18028011 18032011, 18036011,18040011 B-Leuko	Thoracic catheter is a sterile single use medical device designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest.	Deferred for provision of Free Sale Certificate of any reference country OR CE mark documents.
19.	-do-	Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020)	B-Leuko B-Leuko (Leukocyte Depletion filter) Class C Shelf Life: 2 Years Sizes & Codes as Per FSC 15700131	Bicakcilar bed- side leukocyte filtration system is intended to reduce the level of leukocyte and microaggregate s from 1-2 units of red blood cells or whole blood during blood transfusion.	provision of Free Sale Certificate of any reference country OR CE mark documents.
20.	-do-	Legal Manufacturer: Chilecom Medical Devices Co., Ltd. 106 Boyi Road, Boluo County, Guangdong. (FSC China Valid Till 11-05-2022)	Endosoft E.T Tube with cuff Class B Shelf Life: 3 Years Sizes & Codes as Per FSC	Disposable Endotracheal tube is used to establish and maintain an airway in seconds in emergency situations.	Approved.

		FSC US FDA valid			
21.	-do-	till 03-11-2021	ET Tube cuffed 101302, 101303, 101304, 101305, 101306, 101307, 101308, 101309, 101310, 101311, 101312, 101313. 101314. Feeding Catheter/	Feeding tubes	Deferred for
		Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020)	tube Feeding Catheter Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 19704201 19705201 19706201 19708201 19710201 19712201	are placed into the stomach or the duodenum for diagnostic and/ or therapeutic purposes.	provision of Free Sale Certificate of any reference country OR CE mark documents.
22.	-do-	Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020)	Yankauer Suction Connecting set Suction connecting tube with cut-to-fit connector. Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 16801801 16802101 16802501 16803501	Yankauer is a suction set purposive for the removal of blood and fluids during surgery. Yankauer suction set is used for general suction purposes. It has a rigid transparent suction handle available with bulb tip. It is obtainable with and without control vents.	•
23.	-do-	Legal	Nelaton Catheter	Nelaton	Deferred for

Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ 52020) 19550011 19550011 195100			Manufacturer:		catheter is a	provision of Free
Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Class B Shelf Life: 5 years urine drainage system, in order to plsowoll provide drainage and/ of the bladder.			ivialiulacial Cl.	Nelaton Catheter-		1
Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020) 2020) Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Porter Manufacturer Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Porter SC Vears Sterile single use medical use medical dof of draining air and/ or fluishing of the bladder. Porter d for provision of Free Sale Certificate of any reference country OR CE mark documents. Deferred for provision of Free Sale Certificate of any reference country OR CE mark documents. Deferred for provision of Free Sale Certificate of any reference country OR CE mark documents. Deferred for provision of Free Sale Certificate of any reference country OR CE mark documents.			Bicakcilar Tibbi cih			
Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 24.				Zine 10 cm		•
Comangazi Mah. Gazi Cad. No: 21/Esenyurt/ Istanbul/ Turkiye. Gas B Shelf Life: 5 Years Gas B Connector to a wine drainage system, in order to provide drainage and/ or flushing of provide provide drainage and/ or flushing and/ or flus				Nelaton Cathetor-	· ·	•
Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020) 24do- Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 M/s Dragerwerk AG & CO, KGAA Moislinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Class B Shelf Life: 5 Years Thoracic Catheter with Trocar with Trocar catheter is a sterile single device designed for draining air and/ or fluids from the pleural and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Deferred for provision of Free designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Deferred for provision of Free designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Drager O2Star Non-rebreather Oxygen Mask oxyg					_	man documents.
Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05-2020) 24do- Legal Manufacturer: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05-2020) 25. M/s Vertex Medical ELI: 00150 Moslinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: Manufacturin				Line 10 cm	· · · · · · · · · · · · · · · · · · ·	
Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05-2020) 2020) 1				Class B		
Years Sizes & Codes as System, in order to 19506011 19512011 19512011 19522011 1852			_			
(FSC Turkey Valid 36 Month from date of issuance 20-05- 2020) 24do- Legal			Turkiy C.			
24. -do-			(FSC Turkey Valid		_	
of issuance 20-05- 2020) 19506011 19508011 19510011 19512011 19512011 19512011 19516011 19516011 19522011 18212011 18212011 18212011 18212011 18212011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18223011 18222011 18223011 18222011 18223011 18223011 19522						
2020) 1950011 19510011 19510011 19510011 19510011 19510011 19510011 19510011 19510011 19520011 195						
24do- Legal Manufacturer: with Trocar with Trocar catheter with Trocar with Trocar catheter sterile single use medical process of the bladder. Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 pleural and/ or mediastinal spaces in the of issuance 20-05-2020) 18228011 process in the of sisuance 20-05-2020) 18228011 process in the of sisuance 20-05-255 23542 Lubeck Germany Manufacturing Site: Manufacturing					-	
24do- Legal Manufacturer: with Trocar with Trocar catheter with Trocar with Trocar sterile single use medical of any reference country OR CE mark documents. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 18223011 2020) Drager O2Star Non-rebreather Oxygen Mask Oxygen			2020)		_	
24do- Legal					_	
24.					the stadaet.	
24do- Legal Thoracic Catheter with Trocar Catheter is a sterile single use medical device Country OR CE Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Sizes & Codes as Esenyurt/ Istanbul/ Turkiye. 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore Molislinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: 19522011 19522011 19522011 19522011 Thoracic Catheter is a sterile single use medical device designed for draining air and/ or fluids and/ or fluids from the pleural and/ or mediastinal spaces in the chest. 26. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore Molislinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: 19522011 Thoracic Catheter is a sterile single use medical device designed for draining air and/ or fluids and/ or mediastinal spaces in the chest. 18212011 18222011 18228011 18228011 18232011 Approved. Approved. Approved. Approved. O2 concentration. years Oily to be used on						
24do- Legal Manufacturer: with Trocar catheter is a sterile single use medical device of any reference country OR CE mark documents. Class B Self Life: 5 Years designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the of issuance 20-05- 18232011 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore Class B Shelf Life: 3 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturer: With Trocar catheter is a sterile single use medical device designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Drager O2Star Non-rebreather Oxygen Mask Non-rebreather Oxygen Mask Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Deferred for provision of Free Sale Certificate of any reference country OR CE mark documents. Drager O2Star Non-rebreather Oxygen Mask Shelf Life: 3 years Only to be used on				19520011		
Legal Manufacturer: Thoracic Catheter with Trocar Catheter is a sterile single use medical device designed for draining air and/ or fluids from the pleural and/ or mediastinal (FSC Turkey Valid 36 Month from date of issuance 20-05-2020) Seal Manufacturer Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: Manufacturing Site: Manufacturing Site: Thoracic catheter is a sterile single use medical device designed for draining air and/ or fluids from the pleural and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Sizes & Codes as Per FSC from the pleural and/ or mediastinal spaces in the chest. Sizes & Codes as Per FSC from the pleural and/ or mediastinal spaces in the chest. Sizes & Codes as Per FSC from the pleural and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Sizes & Codes as Per FSC from the pleural and/ or mediastinal spaces in the chest. Sizes & Codes as Per FSC from mark documents. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as Per FSC from mark documents. Sizes & Codes as Per FSC from mark documents. Sizes & Codes as Per FSC from mark documents. Sizes & Codes as Per FSC from mediastinal spaces in the chest. Sizes & Codes as part from mediastinal spaces in the chest. Sizes & Codes as per FSC from mediastinal spaces in the chest. Sizes & Codes as per FSC from mediastinal spaces in the chest. Sizes & Codes as part from mediastinal spaces in the chest. Sizes & Codes as per FSC from mark documents. Sizes from mark documents from mediastinal spaces in the chest. Sizes from mark documents from mark docume						
Manufacturer: Manufacturer: with Trocar sterile single use medical device designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest.	24	1.	Lacal		The aug - : -	Doforma J.f.
Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 18222011 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Class B Shelf Life: 5 Years Sizes & Codes as Pre FSC 18212011 18222011 18222011 18222011 18223011 Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. For inhalation and insufflation of breathing gas with increased O2 Concentration. Years Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. For inhalation and insufflation of breathing gas with increased O2 Concentration. Years Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference device mark documents. Sale Certificate of any reference device mark documents. Sale Certificate of any reference country OR CE mark documents. Sale Certificate of any reference country OR CE mark documents.	24.	-do-				
Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Turkiye. Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Turkiye. Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Turkiye. Bizes & Codes as Esenyurt/ Istanbul/ Turkiye. Bizes & Codes as Per FSC 18212011 Pver Insulation 18220011 1822011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18222011 18232011 Drager O2Star Non-rebreather Oxygen Mask Class B Shelf Life: 5 Years Use medical device designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. For inhalation and insufflation of breathing gas with increased O2 O2 O2 Shelf Life: 3 years Only to be used on			Manufacturer:	with Trocar		*
Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 18220011 18220011 18228011 2020) 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 18220011 18220011 18228011 18228011 18228011 18232011 Porager O2Star Non-rebreather Oxygen Mask Class-B With increased O2 concentration. Shelf Life: 5 Years device designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Approved. Approved. Approved. Shelf Life: 3 years Only to be used on			Disalzailan Tibbi aib	Class D	C	
Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. 18212011 18220011 18224011 36 Month from date of issuance 20-05- 2020) 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 Moslinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Years designed for draining air and/ or fluids from the pleural and/ or mediastinal spaces in the chest. Por inhalation and insufflation of breathing gas with increased O2 concentration. years Only to be used on						•
(Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. (FSC Turkey Valid 36 Month from date of issuance 20-05- 2020) M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 (CSmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Sizes & Codes as Per FSC 18212011 pleural and/ or mediastinal spaces in the chest. Drager O2Star Non-rebreather Non-rebreather Oxygen Mask M/s Dragerwerk AG & Class-B ELI: 00150 (CSmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/			_			
Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye. Per FSC 18212011 18226011 18220011 36 Month from date of issuance 20-05- 2020) 1823 2011 Prager O2Star Non-rebreather Oxygen Mask ELI: 00150 M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Sizes & Codes as from the pleural and/ or mediastinal spaces in the chest. Prager O2Star Non-rebreather and insufflation of breathing gas with increased O2 Class-B with increased O2 Concentration. Only to be used on				rears	•	mark documents.
Esenyurt/ Istanbul/ Turkiye. Beenyurt/ Istanbul/ Turkiye. 18212011 18216011 18216011 18220011 18224011 18224011 18228011 18232011 Por FSC				Sizes & Codes es	•	
Turkiye. Turkiye. 18212011 18216011 18220011 36 Month from date of issuance 20-05- 2020) 18228011 18232011 Legal Manufacturer Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: 18212011 pleural and/ or mediastinal spaces in the chest. For inhalation and insufflation of breathing gas with increased O2 concentration. Only to be used on						
25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 Most Vertex Medical Put Ltd, 70-B-1, Gulberg III, Lahore Most Dragerwerk AG & CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany Manufacturing Site: 18216011			1			
(FSC Turkey Valid 36 Month from date of issuance 20-05- 18228011 18232011 25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 ELI: 00150 (FSC Turkey Valid 18220011 18224011 chest. Drager O2Star Non-rebreather Oxygen Mask insufflation of breathing gas with increased O2 concentration. Only to be used on			Turkiye.		-	
25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI: 00150 M/s Dragerwerk AG ECO, KGaA Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: M/s Vertex Medical Regal Manufacturer Drager O2Star Non-rebreather Oxygen Mask insufflation of breathing gas with increased O2 concentration. Only to be used on			(ESC Turkey Valid			
of issuance 20-05- 2020) 18228011 18232011 Legal Manufacturer Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Drager O2Star Non-rebreather Oxygen Mask insufflation of breathing gas with increased O2 concentration. Only to be used on					_	
25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany Shelf Life: 3 years Moise Manufacturing Site: Drager O2Star Non-rebreather Oxygen Mask insufflation of breathing gas with increased O2 concentration. Only to be used on					CHOSt.	
25. M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Drager O2Star Non-rebreather Oxygen Mask Class-B with increased O2 concentration. Only to be used on						
Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Non-rebreather Oxygen Mask Class-B with increased O2 concentration. Only to be used on			2020)	10232011		
Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Non-rebreather Oxygen Mask Class-B with increased O2 concentration. Only to be used on						
Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Non-rebreather Oxygen Mask Class-B with increased O2 concentration. Only to be used on						
Pvt Ltd, 70-B-1, Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Manufacturing Site: Non-rebreather Oxygen Mask Class-B with increased O2 concentration. Only to be used on	25.	M/s Vertex Medical	Legal Manufacturer	Drager O2Star	For inhalation	Approved.
Gulberg III, Lahore M/s Dragerwerk AG &CO, KGaA ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Shelf Life: 3 years Oxygen Mask insufflation of breathing gas with increased O2 concentration. Only to be used on		Pvt Ltd, 70-B-1,			and	
ELI: 00150 &CO, KGaA Moislinger Allee 53- 55 23542 Lubeck Germany Shelf Life: 3 years Only to be used on			M/s Dragerwerk AG	Oxygen Mask	insufflation of	
ELI: 00150 Moislinger Allee 53- 55 23542 Lubeck Germany Shelf Life: 3 years Only to be used on			_		breathing gas	
Shelf Life: 3 concentration. Manufacturing Site: O2 concentration. Only to be used on		ELI: 00150	1	Class-B	0 0	
Manufacturing Site: years Only to be used on					O2	
Manufacturing Site: used on			Germany	Shelf Life: 3	concentration.	
Manufacturing Site: used on				years	Only to be	
Dragoryyork AC&Co Sizzas nationts with			Manufacturing Site:		used on	
Diagetwerk Adaco. Sizes: patients with			Dragerwerk AG&Co.	Sizes:	patients with	

	I	VCa A DarrelateDa 1	Mask nonreb	an antan	
		KGaA RevalstrBe 1	O2Star w tube S/	spontaneous breathing in	
		23560, Lubeck,		\mathcal{C}	
		Germany.	M/ L	medical	
		Edd d		environment.	
		FSC: Germany			
		Date of issue:			
		15.10.19			
26.	M/s Johnson Mathew	Legal	KardiaMobile	The	Deferred for
	Pakistan (Pvt) Ltd.,	Manufacturer:	System	Kardiamobile	provision of
	Unit C-304, Falak	AliveCor 444 Castro		System is a	following
	Tower, Frere Town	Street, Suite 600	Class-B	trans-	documents
	Karachi 75530,	Mountain View, CA		telephonic	alongwith
	Pakistan.	USA 94041.	Shelf Life: 2	(Transmission	application on
		Contract	years	by telephone)	Form 7A as
		Manufacturer:	(life time limiting	ECG event	device falls in
		China Turnkey	factor is the	recorder that	Class-B:-
		Solutions logistics	battery used in	records, stores,	
		(Shenzen) Co, Ltd.	the KardiaMobile	and transfers	
		9F. Building A, ZTY	hardware, non-	and analyzes	• Original and
		Logistic Centre	rechargeable	single channel	embassy
		Futian Free Trade	commonly used	or two channel	attested
		Zone Shenzen,	in wrist watches	ECG rhythm	documents as
		Guangdong, Chna	and other	recordings.	the provided
		518045.	electronic	The device	documents are
			equipment.	utilizes the	without
		FSC US FDA valid	Battery is	computing	attestation and
		till 23-09-2021.	replaceable.	power of	notarization.
				Apple, Inc.,	• FQA
			Model:	iOS or Google	certificate.
			KardiaMobile 1L	LLC, Android-	Manufacturing
			(single lead)	based	and QC
				smartphones to	processes
				obtain and	documents.
				analyze single-	
				channel ECG.	
27.	-do-	Legal	KardiaMobile	The	Deferred for
		Manufacturer:	System	Kardiamobile	provision of
		AliveCor 444 Castro		System is a	following
		Street, Suite 600	Class-B	trans-	documents
		Mountain View, CA		telephonic	alongwith
		USA 94041.	Shelf Life: 2	(Transmission	application on
		Contract	years	by telephone)	Form 7A as
		Manufacturer:	(life time limiting	ECG event	device falls in
		China Turnkey	factor is the	recorder that	Class-B:-
		Solutions logistics	battery used in	records, stores,	
		(Shenzen) Co, Ltd.	the KardiaMobile	and transfers	
		9F. Building A, ZTY	hardware, non-	and analyzes	• Original and
		71. Dunuing A, Z1 I	naidwaie, non-	and anaryzes	- Original and

	Ī	La sistia Cautus		ain ala -1 1	-
		Logistic Centre	rechargeable	single channel	embassy
		Futian Free Trade	commonly used	or two channel	attested
		Zone Shenzen,	in wrist watches	ECG rhythm	documents as
		Guangdong, Chna	and other	recordings.	the provided
		518045.	electronic	The device	documents are
			equipment.	utilizes the	without
		FSC US FDA valid	Battery is	computing	attestation and
		till 23-09-2021.	replaceable.	power of	notarization.
				Apple, Inc.,	• FQA
			Model:	iOS or Google	certificate.
			KardiaMobile 6L	LLC, Android-	 Manufacturing
			(Six Leads)	based	and QC
			,	smartphones to	processes
				obtain and	documents.
				analyze single-	documents.
				channel ECG.	
28.	M/s Abbott	Legal	Alinity c HBDH,	The Alinity c	Approved.
	Laboratories	Manufacturer:	Clinical	HBDH assay is	-FF-2.444
	(Pakistan) Ltd,		Chemistry	used for the	
	Opposite Radio	M/s Sentinel CH.		kinetic	
	Pakistan Transmission	SpA Robert Koch, 2-	Class B	determination	
	Center, Hyderabad	20152 Milano Italy.	C14.55 2	of a-	
	Road, Landhi, Karachi	20102 Milano Raij.	Shelf Life: 15	hydroxybutyrat	
	(ELI-00019)	(FSC Italy issuance	Months	e	
	(EEI 0001))	12-10-2018)	TVIOITIIS	dehydrogenase	
		12 10 2010)	Sizes & Codes as	(HBDH)	
			Per FSC	according to	
				the Deutsche	
			Alinity c HBDH	Gesellschaft	
			Reagent Kit	fur Klinische	
			01R0122	Chemie	
				(DGKC) 1	
			Alinity c Clinical	recommedation	
			Chemistry	s in serum or	
			Calibrator Kit	plasma on the	
			08P6503	Alinity c	
			001 0303	analyzer.	
			Alinity c Clinical	anaryzer.	
			Chemistry		
			Control 1 Kit		
			08P6515		
			Alinity c Clinical		
			Chemistry		
			Control 2 Kit		
			08P6516		
20	M/s. Remington	Logol		Sodium	Annuariad
29.		Legal	HYLO GEL		Approved.
	Pharmaceutical	Manufacturer:	Sodium	Hyaluronate 2	
	Industries (Pvt) Ltd	URSAPHARM	Hyaluronate 2	md/ml,eye	

	ELI-00395	Arzneimittel GmbH IndustriestraBe 35 66129 Saarbrucken Germany. FSC Germany Date of issue 17.01.2019 (original)	md/ml, eye drops (44237 Lubricant, eye) Class B Shelf Life: 3 years.	drops	
30.	M/s Elite Traders Office 342-B 1 st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	Legal Manufactuer: IMPLANTCAST GmbH :imenirger Schanze 26D-21614 Buxtehude Germany FSC: Germany (Original) Date of issue 07.03.2019	HIP IMPLANTS (Hip Arthroplasty System/total Hipreplacement System) Class-D Shelf Life: 5 years Codes/ models as per FSC	In a total hip replacement (also called total hip arthroplasty), the damaged bone and cartilage is removed and replaced with prosthetic components. The prosthesis is designed to replicate the movement of a normal, healthy joint.	Approved.
31.	M/s Meher Traders, Office No. A-21-22 First Floor Zeenat Medecine Market North Nappier Road, Karachi. (ELI-00128)	Manufacturer: Hunan Luzhou Huikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China. FSC China valid till 13-10-2021	Wellmed Infusion Set Class-B Shelf Life: 5 Years Sizes & Codes as per FSC HB6-2, HB6-3, HB6-4, HB6-5, HB6-7, HB6-8.	Sterile infusion set for single use: hypodermic needle intended for the aspiration of fluids or for the injection of fluids immediately after filling.	Deferred for provision of Free Sale Certificate of any Reference Country or CE mark documents.
32.	-do-	Legal Manufacturer: Nanchang Kaimed	WellMed Endotracheal Tube	Tracheal tubes may also be used as a route for	Deferred for provision of Free Sale Certificate of any Reference

		Medical Apprautus Co., Ltd. Jinxian Medical Device Industrial Area, Nanchang City, Jiangxi Province, 331700 China. (FSC valid till 01-06- 2021)	Class-B Shelf Life: 5 Years Sizes & Codes as per FSC Endotracheal Tube Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 9.5mm, 9.0mm, 9.5mm, 10.0mm	administration of certain medications such as salbutamol, atropine, epinephrine, ipratropium, and lidocaine. Tracheal Tubes are commonly used for airway management in the settings of general anesthesia, critical care, mechanical ventilation, and	Country or CE mark documents
22	do	Manufacturan	Wallmad	emergency medicine.	Defound for
33.	-do-	Manufacturer: Hunan Luzhou Huikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China. FSC China valid till 13-10-2021	Disposable Syringe (with Needle) 1ml, 3ml, 5ml, 10ml Class B Shelf Life: 5 Years Sizes & Codes as per FSC 1ml. 3ml, 5ml, 10ml	The Sterile syringe with hypodermic needle intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe will be rendered unusable after use.	Deferred for provision of Free Sale Certificate of any Reference Country or CE mark documents.
34.	M/s. Raffay Associate Office No 04, 2 nd Floor Ahmed Plaza range, Road Rawalpindi.	Legal Manufacturer: Sewoon Medical Co., Ltd 60 Dorim- gil,IPjang Myeon Seobuk-Gu Korea	BONASTENT BonashimStent Biliary stent (Self-Expandable	BONASTENT are indicated for the palliative treatment of	Approved.
	ELI 00021	FSC – Korea Date of issue	Metallic Stent Class-C	strictures caused by malignant and	

35.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi. ELI-00020	16.05.2016 FSC UK issuance 17- 05-2018 Legal Manufacturer M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	Shelf Life: 3 years Sizes & Codes as per FSC Adult Mapleson C Bagging System with 2L Bag, 1.8M (Mapleson Breathing System) Class B Shelf Life: 03 years Code: 2108000	/or benign tumors. It is use to deliver and remove respiratory gases from a patient via a system of tubing and connectors.	Approved.
36.	-do-	Legal Manufacturer M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	Gas Monitoring Line Gas Monitoring Line Code: 2734000 Class B Shelf Life: 05 years	It is use to convey gases or monitor pressure between a breathing system and a monitoring machine.	Approved.
37.	-do-	Legal Manufacturer M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	Intersurgical T-Piece Connectors Class: B Shelf Life: 5 years Code: 1980000 1986000	It is used to make secure, gas tight connections to other respiratory taper connectors.	Approved.

9. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief	Decision
1.	M/s. Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi ELI-00240.	Legal Manufacturer: M/s Hefei Jingcheng Plastic Products Co. Ltd, 700 Meters east of Hong Tu Avenue and Dian Zhong Road Junction, Cuo Zhen Circular Economy Industrial Park, Hefei, China FSC UK Issuance Date 24-06-2019.	Careplus (Adult Diaper) Codes & Sizes as per FSC Class-A. claimed shelf life: N/A.	Adult Diaper	Approved subject to provision of technical details of the product.
2.	M/s Meher Traders, Office No. A-21-22 First Floor Zeenat Medecine Market North Nappier Road, Karachi. (ELI-00128)	Manufacturer: M/s Shanghai Yuechen Medical Supply Co., Ltd., 8 th Building, No. 776 Huhang Road, Fengxian District, Shanghai City, China. FSC China Valid (02-12-2022)	Wellmed Disposable ECG Electrodes Class A Shelf Life: 5 Years Sizes & Codes as per FSC HS01, HS02, HS03, HS4, HS5, HS6, HS07, HS08, HS09, HS10, HS11, HS12, HS13, HW01, HW02, HW03, HW04, HW05, HW06, HW07, HW08, HW07, HW08, HW09, HW10, HW11, HW12, HW13, HW14, HA01, HA02, HA03, HA04, HA05, HA06, HA07, HA08,	Disposable ECG Electrodes	Approved subject to provision of Full QA Certificate.

	HA09, HA10,	
	HA11, HA12,	
	HA13	

10. CASES APPROVED IN DIFFERENT OF MDB SUBJECT TO PROVISION OF DOCUMENTS.

Following applications for registration of Medical Devices for import were placed before the MDB in its different meetings and approved subject to provision of document. Now firm submitted the shortcomings

S. #	Name of Firm	Name of	Name of Medical	Brief	Decision
	(s)/Importer	Manufacturer	Device	Desciption	
1.	M/s. RA Healthcare (SMC-PVT) Limited 2 nd Floor, Building# 50, Mir Arcade, Mini Commercial, Phase 7, BahriaTown, Islamabad. (ELI-00482)	Legal Manufacture r: Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ High-Tech Park, Shanghai, P.R. China. Manufacture r Site(s): Shanghai MicroPort Medical (Group) Co, Ltd 501 Newton Road 201203; Shanghai, P.R. China. 1.Shanghai MicroPort Medical (Group) Co, Ltd 501 Newton Road 201203; Shanghai, P.R. China. 1.Shanghai MicroPort Medical (Group) Co., Ltd. 1601 ZhangdongR oad 201203; Shanghai.	FOXTORT™ NCPTCA Balloon Catheter. Codes & Sizes as per FSC of SRA. Class: D.	FOXTROTTM NC PTCA (Percutaneous Transluminal Coronary Angioplastry) balloon catheter has an integrated shaft system and a non- compliance 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 distal shaft, permits the use of a guide-wire to facilitate advancement of the	Approved.

	dilatation	
	catheter to,	
	and through	
	the stenosis	.0
	be dilated.	

11. <u>DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

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

S.#	Name of Firm	Name of	Name of Medical	Brief
	(s)/Importer	Manufacturer	Device	Desciption
1.	M/s. Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi. (ELI-00034)	Legal Manufacturer: M/s Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium. Manufacturing Site: M/s Terumo Corporation Ashitaka Factory, 150 Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418- 0015, Japan M/s Terumo Vietnam Co., Ltd. Lot 44a44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi City, Vietnam FSC Belgium Issuance Date	Radifocus Guide Wire M Class D Claimed Shelf Life: 24-Months Rs. 50,000/- Codes & Sizes as per FSC	Catheter Guide Wire. Radifocus Guidewire M Stiff type is a stiff Nitinol hydrophilic guidew ire covered with polyurethane containing tungsten and a hydrophilic polymer coating (M Coat) for good torque control and shape memory as well as high stiffness and resistance.

		(20-06-19)		
		(1 1 1 1)		
2.	-do-	Legal Manufacturer: M/s Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium. Manufacturing Site: M/s	RADIFOCUS OPTITORQUE Catheter. Class D Claimed Shelf Life: 36 Months Rs. 50,000/- Codes & Sizes as per FSC	Catheter for Angiography. An angiographic or diagnostic catheter is intended for use in angiographic procedures. It
		Terumo Corporation Ashitaka Factory, 150 Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418- 0015, Japan M/s Terumo Vietnam Co., Ltd. Lot 44a44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi		delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guidewire or a catheter into the target site.
		City, Vietnam FSC Belgium Issuance Date (20-06-19)		

Decision: The Board discussed and decided to approve the above mentioned products.

12. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr.	Name & Address of	Name of Medical	Brief Description	Decision
No.	Establishment	Devices With Size		

	Karim Industries,	Ortho Cot	Non-Absorbent	Approved.
	135-C, Nawab		Cotton Wool	
	Town, Thokar Niaz	Class A		
	Baig, Lahore			
1.	(ELM-0014)	Shelf Life: 05		
		Years		
		Rs.5000/-		

13. RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014)	Medi Band Open wove bandage BPC- 1973 Class A Shelf Life: 05 Years Rs.5000/- Renewal Sizes as existing registration	A cotton bandage is used to protect dressing and hold them in a place and to give support and, if necessary.	Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly basis.
2.	-do-	Medi Band Open wove Bandage BP II (1988) Class A Shelf Life: 05 Years Rs.5000/- Renewal Sizes as existing registration	A cotton bandage is used to protect dressing and hold them in a place and to give support and, if necessary.	Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly basis.
3.	-do-	Absorbent Cotton Wool BPC-1973 (Medi Cot)	Absorbent cotton wool comply with requirements in this monograph	Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly

Shelf Life: 05 Years Rs.5000/-	for staple length and neps is suitable for cleaning	basis.
Renewal Sizes as existing registration		

14. <u>APPLICATION FOR RENEWAL/CONVERSION OF DML INTO ESTABLISHMENT</u> LICENSE TO MANUFACTURE MEDICAL DEVICES.

The below mentioned firm has applied for renewal and conversion of DML into Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel was constituted for inspection of renewal of DML for the period from **27-09-2016** to **26-09-2021**.

S.No	Name of Establishmen t	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Jassh Pharma,	20 KM Ferozpur	Mr. Jamil Asghar Rana	Ms. Rehana Tabbasum
	,	Road, Lahore.	(Production Incharger) (B.Pharmacy	QC Incharge (B.Pharmacy)

Decision: The Board discussed and approved the conversion of DML into Establishment License and renewal of Establishment License for the period from 27-09-2016 to 26-09-2021 of M/s Jassh Pharma, 20 KM Ferozpur Road, Lahore.

15. APPROVED/DEFERRED CASES RELATING TO IVD CLUSTER.

Following applications for registration of IVD Clusters of different firms were placed before the MDB in its different meeting and were approved/deferred for clarification of grouping and differential fee:-

1.	M/s. Future	Legal Manufacturer	5HIAA ELISA, Dopamine,	Enzyme
	Scientific,	& Manufacturing	Metanephrine Plasma	Immunoassay for
	FS House,	Site:	ELISA,	the quantitative
	Opposite		Metaephrine Urine ELISA,	determination.
	Street No. 4,	Demeditec Diagnostic	Normetanephrine Plasma	

	Main Daad	CmbII Lica Maitra	ELICA	
	Main Road	GmbH Lise-Meitner	ELISA,	
	Shaheen	Strasse 2, D-24145	Normetanephrine Urine	
	Town,	Kiel Germany.	ELISA	
	Gangal			
	West, Post	FSC Germany	Class B	
	Office,	Issuance 13-03-2019		
	Fazaia		DEE1900 5HIAA ELISA	
	Colony,	MDB-14	Shelf Life: 30 Months	
	Rawalpindi.			
	rawaipinai.		DEE6300 Dopamine	
	ELI-00209		Shelf Life: 19 Months	
	ELI-00209		Shell Life. 19 Monuis	
			DEE0100M / 1 '	
			DEE8100Metanephrine	
			Plasma ELISA	
			Shelf Life: 24 Months	
			DEE8400 Metanephrine	
			Urine ELISA	
			Shelf Life: 36 Months	
			DEE8200 Normetanephrine	
			Plasma ELISA	
			Shelf Life: 24 Months	
			DEE8500 Normetanephrine	
			Urine ELISA.	
			Shelf Life: 36 Months	
			Rs.25,000/-	
2.	M/s Muslim	Legal Manufacturer:	Uryxxon® Relax	For Strips and
_,	Trading	g		controls N/A
	Agencies,	Macherey-Nagel	Medi Test Urine analysis	Controls 14/11
	_	GmbH & Co. KG	Wicai Test Office aliarysis	
	3 Syed Moj		Mod: Tost Classes	
	Darya Road,	Neumann-Neander str.	Medi-Test Glucose	
	Lahore.	6-8, 52355 Düren,	93001, 93024	
		Germany	Shelf Life: 2.5 years	
	(ELI-00359)			
			Medi-Test Combi 3A	
		FSC Germany	93007, 93030	
		Issued 22-06-2018	Shelf Life: 2.5 years	
		MDB-14	Medi-Test Combi 10 SGL	
		III III	93067, 93077	
			<i>,</i>	
			Shelf Life: 2 years	
			Made That II. Got I	
			Medi-Test Uryxxon Stick	
			10	
			93068, 930872	

			CI ICT'C O	
			Shelf Life: 2 years	
			Class B	
			Class D	
			Rs.25,000/-	
3.	M/s	Manufacturer:	AESKUSLIDES	Indirect immuno
	Hospicare	M/s AESKU.	1. AESKUSLIDES ANA -	fluorescence assays
	Systems,	Diagnostics GmbH &	HEp-2	to detect
	Mezzanine	Co. KG Mikroforum	Kit 120 tests	autoantibodies in
Ì	Floor,	Ring 2, D-55234,	Ref: 51.100	human serum
	Rabbiya Garden, Plot	Wendelsheim, Germany	Shelf life: 2 years	
	No. 3,	,	2. AESKUSLIDES ANA-	
	MCHS	(FSC Germany Issue	HEp-2	
Ì	Society,	Date	Kit 600 tests	
	Shaheed-e-	27-04-2018)	Ref: 51.100.Bulk5	
	Millat Road,	,	Shelf life: 2 years	
	Karachi	MDB-15	·	
	(ELI-00274)		3. AESKUSLIDES ANA-	
			HEp-2	
			Kit 120 tests	
			Ref: 51.101	
			Shelf life: 2 years	
			4. AESKUSLIDES ANA-	
			HEp-2	
			Kit 600 tests	
			Ref: 51.101. Bulk5	
			Shelf life: 2 years	
			5. AESKUSLIDES EMA	
			IgA	
			Kit 50 tests	
			Ref: 512.050	
			Shelf life: 18 months	
			6. AESKUSLIDES EMA	
			IgG	
			Kit 50 tests	
			Ref: 512.060	
			Shelf life: 18 months	
			7. AESKUSLIDES EMA	
			IgA	
			Kit 100 tests	
			Ref: 512.100	
			Shelf life: 18 months	

8. AESKUSLIDES EMA

IgG

Kit 100 tests Ref: 512.101

Shelf life: 18 months

9. AESKUSLIDES rLKS

(wrapped) Kit 50 tests Ref: 517.050

Shelf life: 18 months

10. AESKUSLIDES rLKS

(separated) Kit 50 tests Ref: 517.051

Shelf life: 18 months

11.AESKUSLIDES rLKS

(separated) Kit 100 tests Ref: 517.100

Shelf life: 18 months

12. AESKUSLIDES rLKS

(wrapped) Kit 100 tests Ref: 517.101

Shelf life: 18 months

13. AESKUSLIDES nDNA

(Crithluc) Kit 100 tests Ref: 53.100

Shelf life: 24 months

14. AESKUSLIDES

ANCA Ethanol (Crithluc)

Kit 60 tests Ref: 54.050

Shelf Life: 24 months

15. AESKUSLIDES

ANCA Formalin

Kit 60 tests Ref: 54.051

Shelf life: 18 months

4.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. (ELI-00209)	Legal Manufacturer: DemedtitecDiagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance 13-03-2019) MDB-15	16. AESKUSLIDES ANCA Ethanol Kit 120 tests Ref: 54.100 Shelf Life: 24 months 17. AESKUSLIDES ANCA Formalin Kit 120 tests Ref: 54.101 Shelf life: 18 months Class B Fee submitted: Rs. 25,000/- DEMEDITEC Androstenedione ELISA KIT DEMEDITEC Dihydrotestosterone ELISA KIT DEMEDITEC Testosterone free Androstenedione ELISA Dihydrotestosterone ELISA Testosterone free Class B Shelf Life: 9 Months Codes As per FSC Rs.25,000/- DE3265 Androstenedione ELISA DE2330 Dihydrotestosterone ELISA DE2924 Testosterone free	The DEMEDITEC Androstenedione ELISA is an enzyme immunoassay for the quantitative in vitro diganostic measurement of Androsternedione is serum and EDTA plasma.
5.	-do-	Legal Manufacturer: Demedtitec Diagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany.	DEMEDITECAndrostene dione ELISA Dihydrotestosterone ELISA Testosterone free Androstenedione ELISA	The DEMEDITEC Androstenedione ELISA is an enzyme immunoassay for the quantitative in
		(FSC Issuance13-03-2019) MDB-15	Dihydrotestosterone ELISA Testosterone free Class B Shelf Life: 9 Months Codes: DE3265	vitro diganostic measurement of Androsternedione is serum and EDTA plasma.

	<u> </u>	T	A 1 / 1' TIT TO A	
			Androstenedione ELISA	
			DE2330	
			Dihydrotestosterone ELISA DE2924	
			Testosterone free	
			Rs.25,000/-	
-	M/a Clabal	Lacal Manufactures	VITEK® 2 AST Cards	Cross Nagative
6.	M/s. Global	Legal Manufacturer: BioMerieux, Inc. 100	VIIEK® 2 ASI Cards	Gram Negative
	Marketing Services.	· ·	Class B	Susceptibility Card intended to
		Rodolphe Street, Durham, North	Class B	determine the
	111, Hali Road	Carolina, 27712, USA	Codes:	susceptibility of
	Westridge1,	Caronna, 27712, USA	Vitek 2 AST-XN05	clinically significant
	Rawalpindi	Manufacturing site:	Ref No: 413230	aerobic gram-
	ELI-00109	BioMerieux, Inc. 595	Shelf Life: 548 days	negative bacilli to
	ELI-00109	Anglum Road,	Contents: SAM, ATM,	antimicrobial agents
		Hazelwood, Missouri	FEP, CFM, CRO, CXM, C,	antimicrobial agents
		63042	CS, ESB, LEV, MEM,	Gram Negative
		03042	MNO, MXF, PIP, TE,	Susceptibility Card
		FSC France issued on	TCC, TGC, TMP	intended to
		25-07-2018	No. of Cards: 20 Cards	determine the
		23 07 2010	Vitek 2 AST-GN81	susceptibility of
		MDB-15	Ref No: 413438	clinically significant
			Shelf Life: 548 days	aerobic gram-
			Contents: AN, AMC, AM,	negative bacilli to
			CZ, FEP, FOX, CAZ,	antimicrobial agents
			CRO, CIP, ETP, GM, LEV,	watering of the degrees
			MEM, FT, TZP, TE, TM,	Gram Negative
			SXT	Susceptibility Card
			No. of Cards: 20 Cards	intended to
				determine the
			Vitek 2 AST-GN84	susceptibility of
			Ref No: 413410	clinically significant
			Shelf Life: 548 days	aerobic gram-
			Contents: AMC, AM,	negative bacilli to
			ATM, CZ, FEP, CRO, CIP,	antimicrobial agents
			ETP, ESB, GM, IPM, LEV,	
			MEM, FT, TZP, TE, SXT	Gram Positive
			No. of Cards: 20 Cards	Susceptibility Card
				intended to
			Vitek 2 AST-GP67	determine the
			Ref No: 22226	susceptibility of
			Shelf Life: 548 days	Staphylococcus
			Contents: AM, P, OXSF,	spp., Enterococcus
			CIP, CM, E, GM, HLG,	spp., and S.
			ICR, LEV, LNZ, MXF. FT,	agalactiae to
			OX1, QDA, RA, HLS, TE,	antimicrobial agents
			TGC, SXT, VA	
			No. of Cards: 20 Cards	Gram Positive
		-		

Vitek 2 AST-GP74

Ref No: 414971 Shelf Life: 548 days Contents: AMX, P, CTX, CRO, C, ETP, E, LEV, LNZ, MEM, OFL, TEL, TE, SXT, VA

No. of Cards: 20 Cards

Vitek 2 AST-N204

Ref No: 412865 Shelf Life: 548 days Contents: AN, AMC, AM, FEP, CTX, CAZ, CIP, ETP, ESB, FOS, GM, IPM, MEM, FT, NOR, TZP No. of Cards: 20 Cards

Vitek 2 AST-N222

Ref No: 413083 Shelf Life: 548 days Contents: AN, ATM, FEP, CAZ, CIP, CS, GM, IPM, MEM, MNO, PEF, PIP, TZP, RA, TIC, TCC, TM, SXT

No. of Cards: 20 Cards

Vitek 2 AST-N235

Ref No: 413170 Shelf Life: 548 days Contents: AN, AMC, AM, CF, CFM, FOX, CAZ, CRO, CIP, ETP, FOS, GM, NA, FT, NOR, OFL, TZP, TIC, SXT

No. of Cards: 20 Cards

Vitek 2 AST-N374

Ref No: 423008 Shelf Life: 548 days Contents: AN, AMC, AM, FEP, CTX, CAZ, CXM, CIP, ETP, ESB, GM, IPM, MEM, TZP, SXT No. of Cards: 20 Cards Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents

Gram Negative
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant
aerobic gramnegative bacilli to
antimicrobial agents

Gram Negative
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant
aerobic gramnegative bacilli to
antimicrobial agents

Gram Negative
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant
aerobic gramnegative bacilli to
antimicrobial agents

Gram Negative
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant

Vitek 2 AST-P580

Ref No: 22233 Shelf Life: 548 days Contents: P, OXSF, CM, E, FOS, FA, GM, ICR, LEV, LNZ, MXF, MUP, FT, OX1, RA, TEC, TE, TGC, TM, SXT, VA

No. of Cards: 20 Cards

Vitek 2 AST-P592

Ref No: 22287 Shelf Life: 548 days Contents: AM, P, OXSF, CIP, CM, E, FOS, FA, GM, HLG, IPM, ICR, LNZ, MXF, OX1, RA, HLS, TEC, TE, TGC, SXT, VA No. of Cards: 20 Cards

Vitek 2 AST-YS05

Ref No: 411945 Shelf Life: 548 days Contents: CAS, FLU, VRC No. of Cards: 20 Cards

Vitek 2 AST-YS07

Ref No: 414967 Shelf Life: 548 days Contents: AB, CAS, FLU, FCT, MCF, VRC No. of Cards: 20 Cards

Vitek 2 AST-YS08

Ref No: 420739 Shelf Life: 548 days Contents: AB, CAS, FLU, FCT, MCF, VRC No. of Cards: 20 Cards

Vitek 2 AST-ST01

Ref No: 410028 Shelf Life: 548 days Contents AM, P, CTX, CRO, CM, E, ICR, LEV, LNZ, TE, SXT, VA aerobic gramnegative bacilli to antimicrobial agents.

Gram Positive
Susceptibility Card
intended to
determine the
susceptibility of
Staphylococcus
spp., Enterococcus
spp., and S.
agalactiae to
antimicrobial
agents.

Gram Positive
Susceptibility Card
intended to
determine the
susceptibility of
Staphylococcus
spp., Enterococcus
spp., and S.
agalactiae to
antimicrobial
agents.

Fungal
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant
yeasts to antifungal
agents

Fungal
Susceptibility Card
intended to
determine the
susceptibility of
clinically significant
yeasts to antifungal
agents

			No of Couder 20 C 1	Eng col
			No. of Cards: 20 Cards	Fungal
				Susceptibility Card
			Vitek 2 AST-ST03	intended to
			Ref No: 421040	determine the
			Shelf Life: 548 days	susceptibility of
			Contents: AM, P, CTX,	clinically significant
			CRO, C, CM, E, GM, ICR,	yeasts to antifungal
			LEV, LNZ, MXF, RA,	agents
			TEC, TE, TGC, SXT, VA	
			No. of Cards: 20 Cards	Streptococcus
				Susceptibility Card
			Fee submitted: Rs. 25,000/-	intended to
				determine the
				susceptibility of S.
				pneumoniae, beta-
				1
				hemolytic
				Streptococcus, and
				Viridans
				Streptococcus to
				antimicrobial agents
				G
				Streptococcus
				Susceptibility Card
				intended to
				determine the
				susceptibility of S.
				pneumoniae, beta-
				hemolytic
				Streptococcus, and
				Viridans
				Streptococcus to
				antimicrobial agents
7.	M/s Roche	Manufacturer:	Cobas ® Thyroid Cluster	1. Immunoassay for
	Pakistan	Roche Diagnostics		the in vitro
	Limited,	GmbH,	Class B	quantitative
	1st floor,	Sandhofer Str.116,	1. cobasElecsys T3	determination of
	37-B,	68305 Mannheim,	Size: 200 Tests	total
	Block-6,	Germany	Code: 11731360122	triiodothyronine in
	,	Comany	Shelf life: 18 months	human serum and
	P.E.C.H.S,	(ECC Common 1		
	Karachi.	(FSC Germany issued	2. cobasElecsys T3	plasma.
	(on 15-03-2017)	Size: 300 Tests	2. Immunoassay for
	(ELI-00009)	(FSC Germany issued	Code: 07027869190	the in vitro
		on 22-02-2018)	Shelf life: 18 months	quantitative
			3. cobasElecsys T3 Calset	determination of
		MDB-16	Code: 11731548122	total
			Shelf life: 24 months	triiodothyronine in
			4. cobasElecsys T4	human serum and
			Size: 200 Tests	plasma
			Size . Zoo Tests	prasma

C 1 12017700122	2 T2 C 1C 1: 1
Code: 12017709122	3. T3 CalSet is used
Shelf life: 18 months	for calibrating the
5. cobasElecsys T4	quantitative Elecsys
Size:300 Tests	T3 assay on the
Code: 07027885190	Elecsys and cobas e
Shelf life: 18 months	immunoassay
6. cobasElecsys T4 Calset	analyzers
Code:12017717122	4. Immunoassay for
Shelf life: 18 months	the in vitro
7. cobasElecsys FT3 III	quantitative
Size: 200 Tests	determination of
Code: 06437206190	thyroxine in human
Shelf life: 18 months	serum and plasma.
8. cobasElecsys FT3 III	5. Immunoassay for
Size: 300 Tests	the in vitro
Code: 07027362190	quantitative
Shelf life: 18 months	determination of
9. Roche cobasElecsys FT3	thyroxine in human
III Calset	serum and plasma.
Code: 06437222190	6. T4 CalSet is used
Shelf life: 18 months	for calibrating the
	_
10. cobasElecsys FT4 II Size:300 Tests	quantitative Elecsys
	T4 assay on the
Code:07027397190	Elecsys and cobas e
Shelf life: 18 months	immunoassay
11. cobasElecsys FT4 II	analyzers
Calset	7. Immunoassay for
Code: 06437290190	the in vitro
Shelf life: 18 months	quantitative
12. cobasElecsys FT4 III	determination of
Size:200 Tests	free
Code:07976836190	triiodothyronine in
Shelf life: 15 months	human serum and
13. cobasElecsys FT4 III	plasma.
Calset	8. Immunoassay for
Code:07976879190	the in vitro
Shelf life: 18 months	quantitative
	determination of
14. cobasElecsys TSH	free
Size:400 Tests	triiodothyronine in
Code:11731459122	human serum and
Shelf life: 18 months	plasma.
	9. FT3 III CalSet is
15. cobasElecsys TSH	used for calibrating
Size:300 Tests	the quantitative
Code:07028091190	Elecsys FT3 III
Shelf life: 18 months	assay on the Elecsys
Shell life. 10 monuis	and cobas e
1	and coods c

16. cobaseled	esys TSH immunoassay
Calset	analyzers.
Code: 047385	551190 10. Immunoassay
Shelf life: 18	months for the in vitro
	quantitative
17.	determination of
cobasPreciCo	ontrolThyro free thyroxine in
Sensitive	human serum and
Code:064459	18190 plasma.
Shelf life: 36	*
	used for calibrating
18. cobasElec	esysTg the quantitative
Size:100 Test	• •
Code:064458	96190 assay on the Elecsys
Shelf life: 15	months and cobas e
	immunoassay
19. cobasElec	
Code:064459	• •
Shelf life: 18	months for the in vitro
	quantitative
20. cobasElec	csys T-Uptake determination of
Size:100 Test	free thyroxine in
Code:070281	05190 human serum and
Shelf life: 18	1
	13. CalSet FT4 III is
21. cobasElec	csys T-Uptake used for calibrating
Size:200 Test	ts the quantitative
Code:117313	94122 ElecsysFT4 III
Shelf life: 18	
	and cobas e
	csys T-Uptake immunoassay
Calset	analyzers.
Code:065283	
Shelf life: 24	
	quantitative
	determination of
	thyrotropin in
	human serum and
	plasma.
	15. Immunoassay
	for the in vitro
	quantitative
	determination of
	thyrotropin in
	human serum and
	plasma.
	16. TSH CalSet is
	used for calibrating

	the quantitative
	Elecsys TSH assay
	on the Elecsys and
	cobas e
	immunoassay
	analyzers.
	17.
	PreciControlThyro
	Sensitive is used for
	quality control of
	the Elecsys TSH
	and ElecsysTg II
	immunoassays on
	the Elecsys and
	cobas e
	immunoassay
	analyzers
	18. Immunoassay
	for the in vitro
	quantitative
	determination of
	thyroglobulin in
	human serum and
	plasma.
	Determination of Tg
	is used as an aid in
	monitoring after
	thyroid ablation.
	19.
	Tg II CalSet is used
	for calibrating the
	quantitative
	ElecsysTg II assay
	on the Elecsys and
	cobas e
	immunoassay
	analyzers.
	20. Immunoassay
	for the in vitro
	quantitative
	determination of
	thyroxine-binding
	capacity (TBC or T-
	uptake) in human
	serum and plasma.
	21. Immunoassay
	for the in vitro
	quantitative
·	

				determination of
				thyroxine-binding
				capacity (TBC or
				T4-uptake) in
				human serum and
				plasma.
				22. T-Uptake CalSet
				is used for
				calibrating the
				quantitative Elecsys
				T-Uptake assay on
				the Elecsys and
				cobas e
				immunoassay
				analyzers
8.	-do-	Manufacturer:	Cobas® Elecsys Thyroid	1. Immunoassay for
		Roche Diagnostics	antibodies and Anti-CCP	the in vitro
		GmbH, Sandhofer Str.	Cluster	quantitative
		116, 68305 Mannheim,		determination of
		Germany.	Class B	autoantibodies to
				TSH receptor in
		Manufacturing Site:	1. Anti-TSHR	human serum using
		Roche Diagnostics	Shelf Life: 18 Months	a human thyroid
		GmbH, Sandhofer Str.	Size 100 Tests	stimulating
		116, 68305 Mannheim,	Code: 04388780	monoclonal
		Germany.		antibody. The
			2. Anti-TSHR	anti-TSH receptor
		(FSC Germany issued	Shelf Life: 18 Months	determination is
		on 15-3-2017)	Sizes: 300 Test	used as an aid in the
		(FSC Germany issued	Code: 07026951190	differential
		on 22-02-2018)		diagnosis of Graves'
			3. Anti-TPO	disease.
		MDB-16	Shelf Life: 15 months	
			Sizes 100 Test	2- Immunoassay
			Code: 06368590	for the in vitro
			4 4 1 5550	quantitative
			4. Anti-TPO	determination of
			Shelf Life: 15 months	autoantibodies to
			Sizes 300 Test	TSH receptor in
			Code: 07026935190	human serum using
			5 A .: MDG G :	a human thyroid
			5. Anti-TPO Calset	stimulating
			Shelf Life: 18 Months	monoclonal
			Code: 06472931	antibody. The
				anti-TSH receptor
			6. Anti-TG	determination is
			Shelf Life: 15 Months	used in the
			Size: 100 Tests	assessment of

Code: 06368697 patients with suspect Graves' 7. Anti-TG disease Shelf Life: 15 Months (autoimmune Sizes: 300 Tests hyperthyroidism). Code" 07026919190 3- Immunoassay for 8. Anti-TG CalSet the in vitro Shelf Life: 15 Months quantitative determination of Code: 06368603 antibodies to 9. PreciControlThyro AB thyroid peroxidase Shelf Life: 15 Months in human serum and plasma. The Size: 100 Tests anti-TPO Code: 05042666 determination is 10.Anti-CCP used as an aid in the Shelf Life: 7 Months diagnosis of autoimmune thyroid Size: 100 Tests Code: 05031656 diseases. 11.Anti-CCP 4- Immunoassay for Shelf Life: 7 Months the in vitro Size: 100 Tests quantitative determination of Code: 07251670190 antibodies to thyroid peroxidase 12. PreciControl Anti-CCP Shelf Life: 36 Months in human serum and Code: 05031664 plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases 5- Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and cobas e immunoassay analyzers. 6- Immunoassay for the in vitro

quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. 7- Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. 8- Anti-TgCalSet is used for calibrating the quantitative Elecsys Anti-Tg assay on the Elecsys and cobas e immunoassay analyzers. 9-PreciControlThyro AB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsysand cobas e immunoassay analyzers.

		10- Immunoassay
		for the in vitro semi-
		quantitative determination of
		human IgG
		autoantibodies to
		cyclic citrullinated
		peptides in human
		serum and plasma.
		The results of the
		assay are intended
		to be used as an aid
		in the diagnosis of
		rheumatoid arthritis
		in combination with
		other clinical and
		laboratory findings.
		11- Immunoassay
		for the in vitro semi-
		quantitative
		determination of
		human IgG
		autoantibodies to
		cyclic citrullinated
		peptides in human
		serum and plasma.
		The results of the
		assay are intended
		to be used as an aid
		in the diagnosis of
		rheumatoid arthritis
		in combination with
		other clinical and
		laboratory findings.
		12 Dwg of Company
		12- PreciControl
		Anti-CCP is used
		for quality control
		of the Elecsys Anti-CCP
		immunoassay on the
		Elecsys and cobas e
		immunoassay
		analyzers.
<u> </u>	<u> </u>	unui y 2013.

9.	M/s Roche	Manufacturer:	Diabetes Assay CPS	1-Immunoassay for
	Pakistan	Roche Diagnostics	(Centralized and Point of	the in vitro
	Limited,	GmbH, Sandhofer Str.	Care Testing Solutions)	quantitative
	1st floor,	116, 68305 Mannheim,	Cluster	determination of
	37-В,	Germany.		C-peptide in human
	Block-6,		Class B	serum, plasma and
	P.E.C.H.S,	(FSC Germany issued		urine. The assay is
	Karachi.	on 15-03-2017)	1. Elecsys C-Peptide	intended for use as
		(FSC Germany issued	Shelf life: 19 months	an aid in the
	(ELI-00009)	on 22-08-2018)	Size:100 Tests	diagnosis and
		(FSC Germany issued	Code: 03184897	treatment of patients
		on 19-09-2016)		with abnormal
		(FSC Germany issued	2. Elecsys C-Peptide	insulin secretion
		on 09-01-2019)	Shelf life: 19 months	2-Immunoassay for
		(FSC Germany issued	Size:100 Tests	the in vitro
		on 09-07-2019-Not	Code: 07027168190	quantitative
		Embassy attested)		determination of
			3. C-Peptide CalSet	C-peptide in human
		MDB-17	Shelf life: 18 months	serum, plasma and
			Code:03184919	urine. The assay is
				intended for use as
			4. Elecsys Insulin	an aid in the
			Shelf life: 19 months	diagnosis and
			Size: 100 Tests	treatment of patients
			Code: 12017547	with abnormal
				insulin secretion.
			5. Elecsys Insulin	3- C-Peptide CalSet
			Shelf life: 19 months	is used for
			Size:100 Tests	calibrating the
			Code: 07027559190	quantitative Elecsys
				C-Peptide assay on
			6. Insulin CalSet	the Elecsys and
			Shelf life: 18 months	cobas e
			Code:12017504	immunoassay
				analyzers.
			7. cobas HbA1c	4-Immunoassay for
			(Hemoglobin A1c) Test	the in vitro
			Shelf life: 22 months	quantitative
			Size:10 Tests	determination of
			Code:06378676	human insulin in
				human serum and
			8. A1C-3 Tina-quant	plasma. The
			Hemoglobin A1c Gen.3	determination of
			Shelf life: 22 months	insulin is utilized in
			Size: 150 Tests.	the diagnosis and
			Code: 05336163190	therapy of various
				disorders of
			9. A1C-3 cobas c111 Tina-	carbohydrate

quant Hemoglobin A1c metabolism, Gen.3 including diabetes Shelf life: 18 months mellitus and Size: 2 x 100 Tests. hypoglycemia. 5-Immunoassay for Code: 05336180190 the in vitro quantitative 10. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3. determination of Shelf life: 18 months human insulin in Size: 200 Tests human serum and Code:08445699190 plasma. The determination of insulin is utilized in 11. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3 the diagnosis and Shelf life: 18 months therapy of various Size: 500 Tests disorders of Code: 08056668190 carbohydrate metabolism. including diabetes 12. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3 mellitus and Shelf life: 18 months hypoglycemia Size: 500 Tests 6-Insulin CalSet is Code: 07559674190 used for calibrating quantitative the 13. cobas HbA1c Control. Insulin Elecsys assay on the Elecsys Shelf life: 18 months Code: 06380204 and cobas e immunoassay 14. A1CD2 cobas c111 analyzers. Hemolyzing Reagent Gen.2 7- The cobas b 101 Shelf life: 18 months is an in vitro Code:05007232 diagnostic test system designed to quantitatively 15. A1CD2 Hemolyzing Reagent Gen.2 determine the Shelf life: 18 months % hemoglobin A1c Size:51 mL. (DCCT/NGSP) and Code: 04528182 mmol/mol hemoglo bin A1c (IFCC) in human capillary and 16. A1CD Hemolyzing Reagent venous whole blood Shelf life: 18 months by photometric Size: 50 mL transmission Code: 08463107190 measurement. An estimated average glucose level (eAG) 17. A1CD Hemolyzing Reagent is calculated by the Shelf life: 18 months cobas b 101 system.

Size:98 mL. The system is Code:07224648190 intended for 18. C.f.a.s. HbA1c professional use in a Shelf life: 24 months clinical laboratory Code: 04528417190 setting, or point of care (PoC) locations 19. PreciControl HbA1c 8-In vitro test for the quantitative norm Shelf life: 19 months determination of Code: 05479207190 mmol/mol hemoglobin A1c 20. PreciControl HbA1c (IFCC) and % hemoglobin A1c path (DCCT/NGSP) in Shelf life: 19 months Code: 05912504190 whole blood or in hemolysate on 21. Hemolyzing Reagent Roche/Hitachi Roce/Hitchi cobas c systems. Shelf life: 18 months 9-In vitro test for Size: 1000 mL. the quantitative Code: 11488457122 determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood and hemolysates prepared from whole blood on the cobas c 111 system. HbA1c determinations are useful for monitoring of longterm blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes 10-In vitro test for

		the quantitative
		determination of
		mmol/mol
		hemoglobin A1c
		(IFCC) and
		% hemoglobin A1c
		(DCCT/NGSP) in
		whole blood or
		hemolysate on Roche/Hitachi
		cobas c systems.
		HbA1c
		determinations are
		useful for
		monitoring of long-
		term blood glucose
		control in
		individuals with
		diabetes mellitus.
		Moreover, this test
		is to be used as an
		aid in diagnosis of
		diabetes and
		identifying patients
		who may be at risk
		for developing
		diabetes.
		11-In vitro test for
		the quantitative
		determination of
		mmol/mol
		hemoglobin A1c
		(IFCC) and
		% hemoglobin A1c
		(DCCT/NGSP) in
		whole blood or
		hemolysate on
		Roche/Hitachi
		cobas c systems.
		HbA1c
		determinations are
		useful for
		monitoring of long-
		term blood glucose
		control in
		individuals with
		diabetes mellitus.
		Moreover, this test
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	Tina-quant Hemoglobin A1c assays on the cobas c 111 system.
	15 -The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on
	cobas c systems. 16-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on cobas c systems.
	17-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1cDx Gen.3 assay on the cobas c 513 system.
	18-C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry
	analyzers as specified in the enclosed value sheets. 19-Preci Control
	HbA1c norm is for use in quality control by monitoring accuracy and precision for the quantitative methods as

	specified in the
	value sheets.
	20-Preci Control
	HbA1c path is for
	use in quality
	control by
	monitoring accuracy
	and precision for the
	quantitative
	methods as
	specified in the
	value sheets.
	21-In vitro test for
	the quantitative
	determination of
	mmol/mol
	hemoglobin A1c
	(IFCC) and
	% hemoglobin A1c
	(DCCT/NGSP) in
	whole blood or in
	hemolysate on
	Roche/Hitachi
	cobas c systems.

Decision: The MDB approved the products at Sr. No.1-9 in current fee structure of clusters as applicable of today.
