

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

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

<b>S.No</b>	<b>Name of Establishment</b>	<b>Director/Proprietor/ partners</b>	<b>Cold Chain (Yes/No)</b>	<b>Decision</b>
1.	M/s SAS National Company, Abbas Houe, Near District Court, Main Bazar Dir, District Dir Upper.  <b>Godown Address:</b> Same as above.	Mr. Sadaqat Ali  Mr. Shakir Ahmad  Mr. Abid Ali	No.	<b>Approved</b> for storage of non cold chain medical devices.
2.	M/s Eastern Medical Technology Services, 3-Aziz Avenue, Gulberg-V, Lahore.  <b>Godown Address:</b> Same as above.	Ghulam Ali Shakir	No	<b>Approved</b> 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.  <b>Godown Address:</b> Same as above.	Mr. Asif Iqbal	No	<b>Approved</b> for storage of non cold chain medical deives.
4.	M/s Highnoon Laboratories Limited, 17.5 KM, Multan Road, Lahore.  <b>Godown Address:</b> 19KM Multan Road	Mr. Tausif Ahmad Khan.  Dr. Adeel Abbas Haideri.  Mr. Ghulam Hussain Khan.	No.	<b>Approved</b> for storage of non cold chain medical deives.

	(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.  <b>Godown Address:</b> No.49, 1 <sup>st</sup> Floor Liberty Mall University Road, Peshawar.	Mr. Mukhtiar Ali Mr. Amjad Ali	No	<b>Approved</b> for storage of non cold chain medical devices.
6.	M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.  <b>Addition of New Godown:</b> R-PI, Plot No.116, Sector 15, KIA, Karachi.		No	<b>Approved</b> the addition of new godown at , Plot No.116, Sector 15, KIA, Karachi.

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

**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. APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.**

**3.1.**

M/s Textile Testing International, 347-S, Quaid-e-Azam Industrial Estate 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 Device.	Name of Manufacturer	Quantity
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1.	labGun COVID-19 Rapid Antigen Kit	M/s LabGenomics Co., Ltd, # 1204, 12F, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-Si, Gyeonggi-do, 16229, Republic of Korea.	20 Kits
2.	PCL Covid 19 Ag Rapid FIA Kit	PCL, Inc., No,701, (Gasandong, Stravalley), 99, Digital-ro 9-gil, Geumcheon-gu, Seoul, South Korea.	20 Kits
3.	PCL Covid 19 Ag Gold Saliva Kit	PCL, Inc., No,701, (Gasandong, Stravalley), 99, Digital-ro 9-gil, Geumcheon-gu, Seoul, South Korea.	20 Kits
4.	Wondfo 19-nCOV Antigen Test Kit	M/s Guangzhou Wondfo Biotech Co. Ltd., No.8, Lizhishan Road, Science City, Luognang District Guangzhou 510663, PR China.	20 Kits

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<sup>th</sup> meeting held on 21-01-2021 and approved subject to provision of documents:-

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

	Karachi Pakistan  ELI: 00440	Nanquan Macromolecule Product Co., Ltd No, 618 Jingxian Road, Xiagang Street, Jiang Yin City, Jiangsu, Province, China.  <b>FSC: China</b> <b>Valid till:</b> <b>2021.09.29</b>	(Auto - disable syringes)  Class -B  Shelf Life: 5 years  Sizes: 0.05cc, 0.1ml, 0.5ml, 1ml, 2ml	prevention feature i.e., feature that activates after intended use to prevent subsequent reuse of syringes. These syringes provide an opportunity to prevent reuse of injection equipment. The products are sterilized with EO Gas. The products are sterile, no toxicity, no pyrogen
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**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<sup>th</sup> and 13<sup>th</sup> meetings held on 01-02-2019 and 05-08-2019 respectively and approved as mentioned against each:-

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

		(FSC China Valid Till 22-05-2023)	Codes as per Free Sale Certificate		
2.	-do- <b>(MDB-11)</b>	-do-	Perfect Disposable Urethral Catheter (Disposable Foley Catheter)  Class B Shelf Life: 5 Years  Sizes: (2way) 6fr, 8fr, 10fr, 12fr, 14fr, 16fr, 18fr, 20fr, 22fr, 24fr (3way) 16fr, 18fr, 20fr, 22fr, 24fr	Disposable Latex Foley Balloon Catheter, Sterile	<b>Approved</b> subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
3.	-do- <b>(MDB-11)</b>	-do-	K&K Zenith Disposable Endotracheal Tube, Sterile Without Cuff  Class B Shelf Life: 5 Years	Disposable Trachea Cannula	<b>Approved</b> subject to inspection of manufacturer abroad under Rule 71 of MDR 2017.
4.	-do- <b>(MDB-13)</b>	<b>Legal Manufacturer:</b> Suzhou Lingyan Medical Technology Co., Ltd 99 Maopeng RD, Xujiang Industrial Park, Wuzhong District Suzhou, China.  FSC Valid till 08-04-2022)	Perfect Disposable I.V. Catheter, Sterile  ( Sizes: 18G, 20G, 22G, 24G)  Class B Shelf Life: 05 Years	Disoposable I.V. Catheter, Sterile	<b>Approved</b> subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if

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

**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 13<sup>th</sup> meeting held on 05-08-2019 and approved as mentioned against each:-

S.No.	Name and Address of Establishment	Manufacturer detail	Name of Medical Device.	Brief Description	Decision of MDB
1.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051)	<b>Manufacturer:</b> M/s Shandong Wuzhou Medical Equipment Co., Ltd., Dingtao (YanTai)	ST Classic Disposable Sterile Insulin Syringe  Class B	Disposable Insulin Syringe U-100 Sterile	<b>Approved</b> subject to foreign inspection of manufacturer abroad. The 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-	<b>-do-</b>	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	<b>Approved</b> 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-	<b>-do-</b>	ST Classic Intravenous Infusion Sets with Burette  Class B  Shelf Life: 5 Years  100ml, 150ml  Rs.25,000/-	IV Infusion Set	<b>Approved</b> 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.



4.	-do-	-do-	ST Classic Disposable Sterile Syringes  Class B  Shelf Life: 5 Years  1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml  Rs.25,000/-	Disposable Syringes	<b>Approved</b> 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.
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**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:-

<b>S.#</b>	<b>Regn. No.</b>	<b>Name of Medical Device</b>	<b>Existing Name of importer on Registration/ Enlistment letters</b>	<b>Proposed Name of Importer on Registration/ Enlistment letters</b>
1.	MDIE-0000011	Leukomed (Absorbent Wound Dressing)	M/s BSN Medical (Pvt) Limited, 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 Wound 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) Limited 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 per detail mentioned below:-

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:-**

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, Quickbornstrabe 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 x10 2.0 x 15 2.5 x 15.

			4.0 x 30 , 4.0 x 34	
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**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 x10 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, Shahdman Colony, Gujrat.  CNIC # 33201-0429490-9.	Mr. Abdul Jabbar Qaureshi, PO Khas, Guliana, Kharian, District Gujrat. CNIC # 34202-5912261-1  (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-55, Shahdman Colony, Gujrat.	Mr. Abdul Jabbar Qureshi, PO Khas, Guliana, Kharian, District Gujrat. CNIC # 34202-5912261-1

CNIC # 33201-0429490-9.	(B.Pharmacy)
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**7. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES).**

S.#	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/ Shelf Life	Brief Description	Decision
1.	AGP Limited, B-23-C, SITE, Karachi (ELI-00571)	<b>Legal Manufacturer:</b> 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 0.05ml. Class B Claimed Shelf Life: 05-years.	Polypropylene syringe with latex free rubber gasket and stainless needle with sharp injury prevention	<b>Approved</b>
2.	<b>-do-</b>	<b>Legal Manufacturer:</b> 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	<b>Approved</b>

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

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

	Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi.  (ELI-00347)	Terumo BCT Ltd., Old Belfast Road, Millbrook, Larne, BT40 2SH, United Kingdom  <b>Manufacturing site:</b> 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)	Bag (with anticoagulant)  Class D Shelf Life: 36 Months  Codes: 2CD256E8 2CD356E0 2CD356E8 2CD356S8 2CD456E0 2CD456E8  Fee submitted: Rs. 50,000/	containers for single use only, and used for collection, processing, storage and transfusion of whole blood or blood components.	The firm shall submit valid full QA certificate at the time of issuance of registration letter
2.	-do-	<b>Legal Manufacturer:</b> Terumo BCT Ltd., Old Belfast Road, Millbrook, Larne, BT40 2SH, United Kingdom  <b>Manufacturing site:</b> 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)	Teruflex® CPDA-1 Single Blood Bag (with anticoagulant)  Class D  Shelf Life: 36 Months  Codes: 1CD256E8 1CD256E0 1CD356E8 1CD356E0 1CD456E8 1CD456E0  Fee submitted: Rs. 50,000/-	Sterile plastic collapsible containers for single use only, and used for collection, processing, storage and transfusion of whole blood or blood components.	<b>Approved</b>  The firm shall submit valid full QA certificate at the time of issuance of registration letter
3.	-do-	<b>Legal Manufacturer:</b> Terumo BCT Ltd., Old Belfast Road, Millbrook, Larne,	Teruflex® CPDA-1 Quadruple Blood Bag (with anticoagulant)	Sterile plastic collapsible containers for single use only, and used for	<b>Approved</b>  The firm shall submit valid full QA certificate at

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

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



8.	-do-	<p><b>Legal Manufacturer</b> Johnson &amp; Johnson International c/o European Logistics Centre Leonardo Da Vincilaan 15, BE- 1831, Diegem Belgium.</p> <p>FSC Belgium Issuance Date 02-07- 2019</p>	<p>VICRYL (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture</p> <p>Class D</p> <p>Shelf Life: 05 Years</p> <p>Rs.50,000/-</p> <p>Codes &amp; Sizes as per FSC</p>	<p>VICRYL Sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2mm diameter.</p>	<p><b>Approved.</b></p>
9.	<p>M/s. Noor international, 29-D, Block 6, PECHS, <u>Karachi</u>, ELI-00061.</p>	<p><b>Legal Manufacturer:</b> M/s Hitec Medical Co., Ltd, No.703, Hengnan RD 1328, Minhang District 201114, Shanghai, China. FSC China Valid Till (14-10-2021)</p>	<p>HITEC CARE Tracheobronchial Tube.</p> <p><b>Class-B.</b></p> <p>claimed shelf life: 05-years.</p> <p>Codes &amp; Sizes as per FSC.</p>	<p>Tracheobron-- hial Tube.</p>	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• Original &amp; valid free sale certificate of country of origin and SRA <b>OR</b> CE- Mark Certifications of Product Quality Assurance and Production Quality Assurance to the manufacturer.</li> <li>• The provided GMP certificate is concluded as non- conformance of directives</li> </ul>

					93/42/EEC & ISO 13485, hence it is advised to submit the conformance/ follow-up report.
10.	-do-	<p><b>Legal Manufacturer:</b> M/s Hitec Medical Co., Ltd, No.703, Hengnan RD 1328, Minhang District 201114, Shanghai, China. FSC China Valid Till (14-10-2021)</p>	<p>HITEC CARE Tracheostomy Tube. <b>Class-B</b> claimed shelf life: 05-years. Codes &amp; Sizes as per FSC.</p>	Tracheostomy Tube.	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• Original &amp; valid free sale certificate of country of origin and SRA <b>OR</b> CE- Mark Certifications of Product Quality Assurance and Production Quality Assurance to the manufacturer.</li> <li>• The provided GMP certificate is concluded as non-conformance of directives 93/42/EEC &amp; ISO 13485, hence it is advised to submit the conformance/ follow-up report.</li> </ul>

11.	-do-	<p><b>Legal Manufacturer:</b> M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China;</p> <p>FSC China Valid Till (07-02-2020)</p> <p>FSC Germany: Date of Issuance: 05-01-2019.</p>	<p><b>MEDCAPTAIN</b> (Syringe pump) <b>Class-C</b></p> <p>Codes &amp; Sizes as per FSC.</p> <p><b>Class-B.</b> claimed shelf life: 05-years.</p>	Syringe pump	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• Original &amp; valid free sale certificate of country of origin duly notarized by the embassy as per 4(xiv) of Form-7A.</li> <li>• Provide the original &amp; valid agency agreement AND valid certificate of ISO-13485.</li> </ul>
12.	-do-	<p><b>Legal Manufacturer:</b> M/s Medcaptain Medical Technology Co., Ltd, 1w2th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan 518055 Shenzhen, Guangdong, China;</p> <p>FSC China Valid Till (07-02-2020)</p> <p>FSC Germany: Date of Issuance: 05-01-2019.</p>	<p><b>MEDCAPTAIN</b> (Infusion pump) Codes &amp; Sizes as per FSC.</p> <p><b>Class-B.</b> claimed shelf life: 05-years.</p>	Infusion pump	<p><b>Deferred</b> for provision of following documents:-</p> <ul style="list-style-type: none"> <li>• Original &amp; valid free sale certificate of country of origin duly notarized by the embassy as per 4(xiv) of Form-7A.</li> <li>• Provide the original &amp; valid agency agreement AND valid certificate of ISO-13485.</li> </ul>

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

			Codes & Sizes as per FSC		
18.	M/s Usmanco International, 220, Block: 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121)	<b>Legal Manufacturer:</b>  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)	Thoracic Catheter  Thoracic Catheter without Trocar  Class B Shelf Life: 5 Years  Sizes & Codes as Per FSC 18012011 18016011 18024011 18028011 18032011, 18036011,18040011	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.	<b>Deferred</b> for provision of Free Sale Certificate of any reference country OR CE mark documents.
19.	-do-	<b>Legal Manufacturer:</b>  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 microaggregates from 1-2 units of red blood cells or whole blood during blood transfusion.	<b>Deferred</b> for provision of Free Sale Certificate of any reference country OR CE mark documents.
20.	-do-	<b>Legal Manufacturer:</b> 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.	<b>Approved.</b>

		FSC US FDA valid till 03-11-2021	ET Tube cuffed 101302, 101303, 101304, 101305, 101306, 101307, 101308, 101309, 101310, 101311, 101312, 101313. 101314.		
21.	-do-	<b>Legal Manufacturer:</b>  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)	Feeding Catheter/ tube  Feeding Catheter  Class B Shelf Life: 5 Years  Sizes & Codes as Per FSC 19704201 19705201 19706201 19708201 19710201 19712201	Feeding tubes are placed into the stomach or the duodenum for diagnostic and/ or therapeutic purposes.	<b>Deferred</b> for provision of Free Sale Certificate of any reference country OR CE mark documents.
22.	-do-	<b>Legal Manufacturer:</b>  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 16803001 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.	<b>Deferred</b> for provision of Free Sale Certificate of any reference country OR CE mark documents.
23.	-do-	<b>Legal</b>	Nelaton Catheter	Nelaton	<b>Deferred</b> for

		<p><b>Manufacturer:</b></p> <p>Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye.</p> <p>(FSC Turkey Valid 36 Month from date of issuance 20-05-2020)</p>	<p>Nelaton Catheter-Line 40 cm</p> <p>Nelaton Cathetor-Line 40 cm</p> <p>Class B Shelf Life: 5 Years</p> <p>Sizes &amp; Codes as Per FSC 19506011 19508011 19510011 19512011 19514011 19516011 19518011 19520011 19522011 19524011</p>	<p>catheter is a single use, sterile medical device, consisting of a flexible tube, which can be fitted with a connector to a urine drainage system, in order to provide drainage and/ or flushing of the bladder.</p>	<p>provision of Free Sale Certificate of any reference country OR CE mark documents.</p>
24.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Bicakcilar Tibbi cih Azlar Sanayi ve Ticaret A.S. (Osmangazi Mah. Gazi Cad. No: 21/ Esenyurt/ Istanbul/ Turkiye.</p> <p>(FSC Turkey Valid 36 Month from date of issuance 20-05-2020)</p>	<p>Thoracic Catheter with Trocar</p> <p>Class B Shelf Life: 5 Years</p> <p>Sizes &amp; Codes as Per FSC 18212011 18216011 18220011 18224011 18228011 18232011</p>	<p>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.</p>	<p><b>Deferred</b> for provision of Free Sale Certificate of any reference country OR CE mark documents.</p>
25.	M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore  ELI: 00150	<p><b>Legal Manufacturer</b></p> <p>M/s Dragerwerk AG &amp;CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany</p> <p><b>Manufacturing Site:</b> Dragerwerk AG&amp;Co.</p>	<p>Drager O2Star Non-rebreather Oxygen Mask</p> <p>Class-B</p> <p>Shelf Life: 3 years</p> <p>Sizes:</p>	<p>For inhalation and insufflation of breathing gas with increased O2 concentration. Only to be used on patients with</p>	<p><b>Approved.</b></p>

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



		<p>Logistic Centre Futian Free Trade Zone Shenzhen, Guangdong, China 518045.</p> <p><b>FSC US FDA valid till 23-09-2021.</b></p>	<p>rechargeable commonly used in wrist watches and other electronic equipment. Battery is replaceable.</p> <p>Model: KardiaMobile 6L (Six Leads)</p>	<p>single channel or two channel ECG rhythm recordings. The device utilizes the computing power of Apple, Inc., iOS or Google LLC, Android-based smartphones to obtain and analyze single-channel ECG.</p>	<p>embassy attested documents as the provided documents are without attestation and notarization.</p> <ul style="list-style-type: none"> <li>• FQA certificate.</li> <li>• Manufacturing and QC processes documents.</li> </ul>
28.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><b>Legal Manufacturer:</b></p> <p>M/s Sentinel CH. SpA Robert Koch, 2-20152 Milano Italy.</p> <p>(FSC Italy issuance 12-10-2018)</p>	<p>Alinity c HBDH, Clinical Chemistry</p> <p>Class B</p> <p>Shelf Life: 15 Months</p> <p>Sizes &amp; Codes as Per FSC</p> <p>Alinity c HBDH Reagent Kit 01R0122</p> <p>Alinity c Clinical Chemistry Calibrator Kit 08P6503</p> <p>Alinity c Clinical Chemistry Control 1 Kit 08P6515</p> <p>Alinity c Clinical Chemistry Control 2 Kit 08P6516</p>	<p>The Alinity c HBDH assay is used for the kinetic determination of a-hydroxybutyrate dehydrogenase (HBDH) according to the Deutsche Gesellschaft für Klinische Chemie (DGKC) 1 recommendation in serum or plasma on the Alinity c analyzer.</p>	<p><b>Approved.</b></p>
29.	<p>M/s. Remington Pharmaceutical Industries (Pvt) Ltd</p>	<p><b>Legal Manufacturer:</b></p> <p><b>URSAPHARM</b></p>	<p>HYLO GEL Sodium Hyaluronate 2</p>	<p>Sodium Hyaluronate 2 md/ml, eye</p>	<p><b>Approved.</b></p>

	ELI-00395	<b>Arzneimittel GmbH Industriestraße 35 66129 Saarbrücken Germany.</b>  FSC Germany  Date of issue 17.01.2019 (original)	md/ml, eye drops  (44237 Lubricant, eye)  Class B  Shelf Life: 3 years.	drops	
<b>30.</b>	M/s Elite Traders Office 342-B 1 <sup>st</sup> Floor,B-Block Satellite Town Rawalpindi.  ELI-00193	<b>Legal Manufacturer: IMPLANTCAST GmbH :imenirger Schanze 26D-21614 Buxtehude Germany</b>  FSC: Germany (Original)  Date of issue 07.03.2019	<b>HIP IMPLANTS</b>  (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.	<b>Approved.</b>
<b>31.</b>	M/s Meher Traders, Office No. A-21-22 First Floor Zeenat Medecine Market North Nappier Road, Karachi.  (ELI-00128)	<b>Manufacturer: Hunan Luzhou Huikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China.</b>  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.	<b>Deferred</b> for provision of Free Sale Certificate of any Reference Country or CE mark documents.
<b>32.</b>	-do-	<b>Legal Manufacturer:  Nanchang Kaimed</b>	WellMed  Endotracheal Tube	Tracheal tubes may also be used as a route for	<b>Deferred</b> for provision of Free Sale Certificate of any Reference

		<p>Medical Apprautus Co., Ltd. Jinxian Medical Device Industrial Area, Nanchang City, Jiangxi Province, 331700 China.</p> <p>(FSC valid till 01-06-2021)</p>	<p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Sizes &amp; 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, 8.5mm, 9.0mm, 9.5mm, 10.0mm</p>	<p>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 emergency medicine.</p>	<p>Country or CE mark documents</p>
33.	-do-	<p><b>Manufacturer:</b> Hunan Luzhou Huikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China.</p> <p>FSC China valid till 13-10-2021</p>	<p>Wellmed</p> <p>Disposable Syringe (with Needle) 1ml, 3ml, 5ml, 10ml</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes &amp; Codes as per FSC</p> <p>1ml. 3ml, 5ml, 10ml</p>	<p>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.</p>	<p><b>Deferred</b> for provision of Free Sale Certificate of any Reference Country or CE mark documents.</p>
34.	<p>M/s. Raffay Associate Office No 04, 2<sup>nd</sup> Floor Ahmed Plaza range, Road Rawalpindi.</p> <p>ELI 00021</p>	<p>Legal Manufacturer: Sewoon Medical Co., Ltd 60 Dorimgil, IPjang Myeon Seobuk-Gu Korea</p> <p>FSC – Korea Date of issue</p>	<p>BONASTENT BonashimStent Biliary stent</p> <p>(Self-Expandable Metallic Stent</p> <p>Class-C</p>	<p>BONASTENT are indicated for the palliative treatment of strictures caused by malignant and</p>	<p><b>Approved.</b></p>

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

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

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s. Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi ELI-00240.	<b>Legal Manufacturer:</b> 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 <b>Class-A.</b> claimed shelf life: N/A.	Adult Diaper	<b>Approved</b> 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)	<b>Manufacturer:</b> M/s Shanghai Yuechen Medical Supply Co., Ltd., 8 <sup>th</sup> 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, HW09, HW10, HW11, HW12, HW13, HW14, HA01, HA02, HA03, HA04, HA05, HA06, HA07, HA08,	Disposable ECG Electrodes	<b>Approved</b> 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 (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
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. 1601 ZhangdongR oad 201203; Shanghai.	FOXTORT™ NCPTCA Balloon Catheter. Codes & Sizes as per FSC of SRA. Class: D.	FOXTROT™ NC PTCA (Percutaneous Transluminal Coronary Angioplasty) 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	<b>Approved.</b>

				dilatation catheter to, and through the stenosis to be dilated.	
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### **11. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

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

<b>S.#</b>	<b>Name of Firm (s)/Importer</b>	<b>Name of Manufacturer</b>	<b>Name of Medical Device</b>	<b>Brief Description</b>
1.	M/s. Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi. (ELI-00034)	<b>Legal Manufacturer:</b> 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 <b>FSC Belgium</b> 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 guidewire 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)		
2.	-do-	<p><b>Legal</b></p> <p><b>Manufacturer:</b> 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</p> <p><b>FSC Belgium</b> <b>Issuance Date</b> (20-06-19)</p>	<p>RADIFOCUS OPTITORQUE Catheter. Class D Claimed Shelf Life: 36 Months Rs. 50,000/- Codes &amp; Sizes as per FSC</p>	<p>Catheter for Angiography. An angiographic or diagnostic catheter is intended for use in angiographic procedures. It 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.</p>

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

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

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
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1.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014)	Ortho Cot  Class A  Shelf Life: 05 Years  Rs.5000/-	Non-Absorbent Cotton Wool	<b>Approved.</b>
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### **13. RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)**

<b>Sr. No.</b>	<b>Name &amp; Address of Establishment</b>	<b>Name of Medical Devices With Size</b>	<b>Brief Description</b>	<b>Decision</b>
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.	<b>Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly basis.</b>
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.	<b>Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly basis.</b>
3.	-do-	Absorbent Cotton Wool BPC-1973 (Medi Cot)  Class A	Absorbent cotton wool comply with requirements in this monograph	<b>Approved, the firm will undertake to provide the stability study data for claimed shelf life on quarterly</b>

		Shelf Life: 05 Years Rs.5000/- Renewal Sizes as existing registration	for staple length and neps is suitable for cleaning	<b>basis.</b>
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#### **14. APPLICATION FOR RENEWAL/CONVERSION OF DML INTO ESTABLISHMENT 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 Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Jassh Pharma,	20 KM Ferozpur Road, Lahore.	Mr. Jamil Asghar Rana (Production Incharger) (B.Pharmacy )	Ms. Rehana Tabbasum 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 Scientific, FS House, Opposite Street No. 4,	<b>Legal Manufacturer &amp; Manufacturing Site:</b> Demeditec Diagnostic	5HIAA ELISA, Dopamine, Metanephrine Plasma ELISA, Metaephrine Urine ELISA, Normetanephrine Plasma	Enzyme Immunoassay for the quantitative determination.
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	<p>Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi.</p> <p>ELI-00209</p>	<p>GmbH Lise-Meitner Strasse 2, D-24145 Kiel Germany.</p> <p>FSC Germany Issuance 13-03-2019</p> <p><b>MDB-14</b></p>	<p>ELISA, Normetanephine Urine ELISA</p> <p>Class B</p> <p>DEE1900 5HIAA ELISA Shelf Life: 30 Months</p> <p>DEE6300 Dopamine Shelf Life: 19 Months</p> <p>DEE8100Metanephine Plasma ELISA Shelf Life: 24 Months</p> <p>DEE8400 Metanephine Urine ELISA Shelf Life: 36 Months</p> <p>DEE8200 Normetanephine Plasma ELISA Shelf Life: 24 Months</p> <p>DEE8500 Normetanephine Urine ELISA. Shelf Life: 36 Months</p> <p>Rs.25,000/-</p>	
2.	<p>M/s Muslim Trading Agencies, 3 Syed Moj Darya Road, Lahore.</p> <p>(ELI-00359)</p>	<p><b>Legal Manufacturer:</b></p> <p>Macherey-Nagel GmbH &amp; Co. KG Neumann-Neander str. 6-8, 52355 Düren, Germany</p> <p>FSC Germany Issued 22-06-2018</p> <p><b>MDB-14</b></p>	<p><b>Uryxxon® Relax</b></p> <p>Medi Test Urine analysis</p> <p><b>Medi-Test Glucose 93001, 93024</b> Shelf Life: 2.5 years</p> <p><b>Medi-Test Combi 3A 93007, 93030</b> Shelf Life: 2.5 years</p> <p><b>Medi-Test Combi 10 SGL 93067, 93077</b> Shelf Life: 2 years</p> <p><b>Medi-Test Uryxxon Stick 10 93068, 930872</b></p>	For Strips and controls N/A

			Shelf Life: 2 years  Class B  <b>Rs.25,000/-</b>	
3.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Plot No. 3, MCHS Society, Shaheed-e-Millat Road, Karachi (ELI-00274)	<b>Manufacturer:</b> M/s AESKU. Diagnostics GmbH & Co. KG Mikroforum Ring 2, D-55234, Wendelsheim, Germany  (FSC Germany Issue Date 27-04-2018)  <b>MDB-15</b>	AESKUSLIDES 1. AESKUSLIDES ANA - HEp-2 Kit 120 tests Ref: 51.100 Shelf life: 2 years  2. AESKUSLIDES ANA-HEp-2 Kit 600 tests Ref: 51.100.Bulk5 Shelf life: 2 years  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	Indirect immuno fluorescence assays to detect autoantibodies in human serum

			<p>8. AESKUSLIDES EMA IgG Kit 100 tests Ref: 512.101 Shelf life: 18 months</p> <p>9. AESKUSLIDES rLKS (wrapped) Kit 50 tests Ref: 517.050 Shelf life: 18 months</p> <p>10. AESKUSLIDES rLKS (separated) Kit 50 tests Ref: 517.051 Shelf life: 18 months</p> <p>11. AESKUSLIDES rLKS (separated) Kit 100 tests Ref: 517.100 Shelf life: 18 months</p> <p>12. AESKUSLIDES rLKS (wrapped) Kit 100 tests Ref: 517.101 Shelf life: 18 months</p> <p>13. AESKUSLIDES nDNA (Crithluc) Kit 100 tests Ref: 53.100 Shelf life: 24 months</p> <p>14. AESKUSLIDES ANCA Ethanol (Crithluc) Kit 60 tests Ref: 54.050 Shelf Life: 24 months</p> <p>15. AESKUSLIDES ANCA Formalin Kit 60 tests Ref: 54.051 Shelf life: 18 months</p>	
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			<p>16. AESKUSLIDES ANCA Ethanol Kit 120 tests Ref: 54.100 Shelf Life: 24 months</p> <p>17. AESKUSLIDES ANCA Formalin Kit 120 tests Ref: 54.101 Shelf life: 18 months Class B Fee submitted: Rs. 25,000/-</p>	
4.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. (ELI-00209)	<p><b>Legal Manufacturer:</b> DemedittecDiagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance 13-03-2019 )</p> <p><b>MDB-15</b></p>	<p>DEMEDITEC Androstenedione ELISA KIT DEMEDITEC Dihydrotestosterone ELISA KIT DEMEDITEC Testosterone free</p> <p>Androstenedione ELISA Dihydrotestosterone ELISA Testosterone free Class B Shelf Life: 9 Months Codes As per FSC Rs.25,000/-</p> <p>DE3265 Androstenedione ELISA DE2330 Dihydrotestosterone ELISA DE2924 Testosterone free</p>	<p><b>The DEMEDITEC Androstenedione ELISA</b> is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of Androstenedione in serum and EDTA plasma.</p>
5.	-do-	<p><b>Legal Manufacturer:</b> Demedittec Diagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Issuance 13-03-2019 )</p> <p><b>MDB-15</b></p>	<p><b>DEMEDITEC Androstenedione ELISA</b> <b>Dihydrotestosterone ELISA</b> <b>Testosterone free</b> Androstenedione ELISA Dihydrotestosterone ELISA Testosterone free Class B Shelf Life: 9 Months Codes : DE3265</p>	<p><b>The DEMEDITEC Androstenedione ELISA</b> is an enzyme immunoassay for the quantitative in vitro diagnostic measurement of Androstenedione in serum and EDTA plasma.</p>

			Androstenedione ELISA DE2330 Dihydrotestosterone ELISA DE2924 Testosterone free Rs.25,000/-	
6.	M/s. Global Marketing Services. 111, Hali Road Westridge1, Rawalpindi ELI-00109	Legal Manufacturer: BioMerieux, Inc. 100 Rodolphe Street, Durham, North Carolina, 27712, USA  Manufacturing site: BioMerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042  FSC France issued on 25-07-2018  <b>MDB-15</b>	VITEK® 2 AST Cards  Class B  Codes: <b>Vitek 2 AST-XN05</b> Ref No: 413230 Shelf Life: 548 days Contents: SAM, ATM, FEP, CFM, CRO, CXM, C, CS, ESB, LEV, MEM, MNO, MXF, PIP, TE, TCC, TGC, TMP No. of Cards: 20 Cards <b>Vitek 2 AST-GN81</b> Ref No: 413438 Shelf Life: 548 days Contents: AN, AMC, AM, CZ, FEP, FOX, CAZ, CRO, CIP, ETP, GM, LEV, MEM, FT, TZP, TE, TM, SXT No. of Cards: 20 Cards  <b>Vitek 2 AST-GN84</b> Ref No: 413410 Shelf Life: 548 days Contents: AMC, AM, ATM, CZ, FEP, CRO, CIP, ETP, ESB, GM, IPM, LEV, MEM, FT, TZP, TE, SXT No. of Cards: 20 Cards  <b>Vitek 2 AST-GP67</b> Ref No: 22226 Shelf Life: 548 days Contents: AM, P, OXSF, CIP, CM, E, GM, HLG, ICR, LEV, LNZ, MXF, FT, OX1, QDA, RA, HLS, TE, TGC, SXT, VA No. of Cards: 20 Cards	Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents  Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents  Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative 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

			<p><b>Vitek 2 AST-GP74</b>  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</p> <p><b>Vitek 2 AST-N204</b>  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</p> <p><b>Vitek 2 AST-N222</b>  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</p> <p><b>Vitek 2 AST-N235</b>  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</p> <p><b>Vitek 2 AST-N374</b>  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</p>	<p>Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents</p> <p>Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents</p> <p>Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents</p> <p>Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents</p> <p>Gram Negative Susceptibility Card intended to determine the susceptibility of clinically significant</p>
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			<p><b>Vitek 2 AST-P580</b>  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</p> <p><b>Vitek 2 AST-P592</b>  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</p> <p><b>Vitek 2 AST-YS05</b>  Ref No: 411945  Shelf Life: 548 days  Contents: CAS, FLU, VRC  No. of Cards: 20 Cards</p> <p><b>Vitek 2 AST-YS07</b>  Ref No: 414967  Shelf Life: 548 days  Contents: AB, CAS, FLU, FCT, MCF, VRC  No. of Cards: 20 Cards</p> <p><b>Vitek 2 AST-YS08</b>  Ref No: 420739  Shelf Life: 548 days  Contents: AB, CAS, FLU, FCT, MCF, VRC  No. of Cards: 20 Cards</p> <p><b>Vitek 2 AST-ST01</b>  Ref No: 410028  Shelf Life: 548 days  Contents AM, P, CTX, CRO, CM, E, ICR, LEV, LNZ, TE, SXT, VA</p>	<p>aerobic gram-negative bacilli to antimicrobial agents.</p> <p>Gram Positive Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents.</p> <p>Gram Positive Susceptibility Card intended to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae to antimicrobial agents.</p> <p>Fungal Susceptibility Card intended to determine the susceptibility of clinically significant yeasts to antifungal agents</p> <p>Fungal Susceptibility Card intended to determine the susceptibility of clinically significant yeasts to antifungal agents</p>
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			<p>No. of Cards: 20 Cards</p> <p><b>Vitek 2 AST-ST03</b>  Ref No: 421040  Shelf Life: 548 days  Contents: AM, P, CTX, CRO, C, CM, E, GM, ICR, LEV, LNZ, MXF, RA, TEC, TE, TGC, SXT, VA  No. of Cards: 20 Cards</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>Fungal Susceptibility Card intended to determine the susceptibility of clinically significant yeasts to antifungal agents</p> <p>Streptococcus Susceptibility Card intended to determine the susceptibility of S. pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus to antimicrobial agents</p> <p>Streptococcus Susceptibility Card intended to determine the susceptibility of S. pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus to antimicrobial agents</p>
7.	<p>M/s Roche Pakistan Limited,  1st floor,  37-B,  Block-6,  P.E.C.H.S,  Karachi.   (ELI-00009)</p>	<p><b>Manufacturer:</b>  Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim,  Germany   (FSC Germany issued on 15-03-2017)  (FSC Germany issued on 22-02-2018)   <b>MDB-16</b></p>	<p>Cobas ® Thyroid Cluster   Class B  1. cobasElecsys T3  Size: 200 Tests  Code: 11731360122  Shelf life: 18 months  2. cobasElecsys T3  Size: 300 Tests  Code: 07027869190  Shelf life: 18 months  3. cobasElecsys T3 Calset  Code: 11731548122  Shelf life: 24 months  4. cobasElecsys T4  Size : 200 Tests</p>	<p>1. Immunoassay for the in vitro quantitative determination of total triiodothyronine in human serum and plasma.  2. Immunoassay for the in vitro quantitative determination of total triiodothyronine in human serum and plasma</p>

			<p>Code : 12017709122 Shelf life: 18 months 5. cobasElecsys T4 Size:300 Tests Code: 07027885190 Shelf life: 18 months 6. cobasElecsys T4 Calset Code:12017717122 Shelf life: 18 months 7. cobasElecsys FT3 III Size: 200 Tests Code: 06437206190 Shelf life: 18 months 8. cobasElecsys FT3 III Size: 300 Tests Code: 07027362190 Shelf life: 18 months 9. Roche cobasElecsys FT3 III Calset Code: 06437222190 Shelf life: 18 months 10. cobasElecsys FT4 II Size:300 Tests Code:07027397190 Shelf life: 18 months 11. cobasElecsys FT4 II Calset Code: 06437290190 Shelf life: 18 months 12. cobasElecsys FT4 III Size:200 Tests Code:07976836190 Shelf life: 15 months 13. cobasElecsys FT4 III Calset Code:07976879190 Shelf life: 18 months  14. cobasElecsys TSH Size:400 Tests Code:11731459122 Shelf life: 18 months  15. cobasElecsys TSH Size:300 Tests Code:07028091190 Shelf life: 18 months</p>	<p>3. T3 CalSet is used for calibrating the quantitative Elecsys T3 assay on the Elecsys and cobas e immunoassay analyzers 4. Immunoassay for the in vitro quantitative determination of thyroxine in human serum and plasma. 5. Immunoassay for the in vitro quantitative determination of thyroxine in human serum and plasma. 6. T4 CalSet is used for calibrating the quantitative Elecsys T4 assay on the Elecsys and cobas e immunoassay analyzers 7. Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and plasma. 8. Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and plasma. 9. FT3 III CalSet is used for calibrating the quantitative Elecsys FT3 III assay on the Elecsys and cobas e</p>
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			<p>16. cobasElecsys TSH Calset Code: 04738551190 Shelf life: 18 months</p> <p>17. cobasPreciControlThyro Sensitive Code:06445918190 Shelf life: 36 months</p> <p>18. cobasElecsysTg Size:100 Tests Code:06445896190 Shelf life: 15 months</p> <p>19. cobasElecsysTgCalset Code:06445900190 Shelf life: 18 months</p> <p>20. cobasElecsys T-Uptake Size:100 Tests Code:07028105190 Shelf life: 18 months</p> <p>21. cobasElecsys T-Uptake Size:200 Tests Code:11731394122 Shelf life: 18 months</p> <p>22. cobasElecsys T-Uptake Calset Code:06528309190 Shelf life: 24 months</p>	<p>immunoassay analyzers.</p> <p>10. Immunoassay for the in vitro quantitative determination of free thyroxine in human serum and plasma.</p> <p>11. FT4 II CalSet is used for calibrating the quantitative Elecsys FT4 II assay on the Elecsys and cobas e immunoassay analyzers</p> <p>12. Immunoassay for the in vitro quantitative determination of free thyroxine in human serum and plasma.</p> <p>13. CalSet FT4 III is used for calibrating the quantitative ElecsysFT4 III assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>14. Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma.</p> <p>15. Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma.</p> <p>16. TSH CalSet is used for calibrating</p>
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				<p>the quantitative Elecsys TSH assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>17. PreciControlThyro Sensitive is used for quality control of the Elecsys TSH and ElecsysTg II immunoassays on the Elecsys and cobas e immunoassay analyzers</p> <p>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.</p> <p>19. Tg II CalSet is used for calibrating the quantitative ElecsysTg II assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>20. Immunoassay for the in vitro quantitative determination of thyroxine-binding capacity (TBC or T-uptake) in human serum and plasma.</p> <p>21. Immunoassay for the in vitro quantitative</p>
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				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-	<p><b>Manufacturer:</b> Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany.</p> <p><b>Manufacturing Site:</b> Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany.</p> <p>(FSC Germany issued on 15-3-2017) (FSC Germany issued on 22-02-2018)</p> <p><b>MDB-16</b></p>	<p>Cobas® Elecsys Thyroid antibodies and Anti-CCP Cluster</p> <p>Class B</p> <p>1. Anti-TSHR Shelf Life: 18 Months Size 100 Tests Code: 04388780</p> <p>2. Anti-TSHR Shelf Life: 18 Months Sizes: 300 Test Code: 07026951190</p> <p>3. Anti-TPO Shelf Life: 15 months Sizes 100 Test Code: 06368590</p> <p>4. Anti-TPO Shelf Life: 15 months Sizes 300 Test Code: 07026935190</p> <p>5. Anti-TPO Calset Shelf Life: 18 Months Code: 06472931</p> <p>6. Anti-TG Shelf Life: 15 Months Size: 100 Tests</p>	<p>1. Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used as an aid in the differential diagnosis of Graves' disease.</p> <p>2- Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used in the assessment of</p>

			<p>Code: 06368697</p> <p>7. Anti-TG Shelf Life: 15 Months Sizes: 300 Tests Code” 07026919190</p> <p>8. Anti-TG CalSet Shelf Life: 15 Months Code: 06368603</p> <p>9. PreciControlThyro AB Shelf Life: 15 Months Size: 100 Tests Code: 05042666</p> <p>10.Anti-CCP Shelf Life: 7 Months Size: 100 Tests Code: 05031656</p> <p>11.Anti-CCP Shelf Life: 7 Months Size: 100 Tests Code: 07251670190</p> <p>12. PreciControl Anti-CCP Shelf Life: 36 Months Code: 05031664</p>	<p>patients with suspect Graves' disease (autoimmune hyperthyroidism).</p> <p>3- Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.</p> <p>4- Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases</p> <p>5- Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>6- Immunoassay for the in vitro</p>
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				<p>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.</p> <p>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.</p> <p>8- Anti-TgCalSet is used for calibrating the quantitative Elecsys Anti-Tg assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>9- PreciControlThyro AB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays on the Elecsys and cobas e immunoassay analyzers.</p>
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				<p>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.</p> <p>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.</p> <p>12- PreciControl Anti-CCP is used for quality control of the Elecsys Anti-CCP immunoassay on the Elecsys and cobas e immunoassay analyzers.</p>
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9.	<p>M/s Roche Pakistan Limited, 1st floor, 37-B, Block-6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009)</p>	<p><b>Manufacturer:</b> Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany.</p> <p>(FSC Germany issued on 15-03-2017) (FSC Germany issued on 22-08-2018) (FSC Germany issued on 19-09-2016) (FSC Germany issued on 09-01-2019) (FSC Germany issued on 09-07-2019-Not Embassy attested)</p> <p><b>MDB-17</b></p>	<p>Diabetes Assay CPS (Centralized and Point of Care Testing Solutions) Cluster</p> <p>Class B</p> <p>1. Elecsys C-Peptide Shelf life: 19 months Size:100 Tests Code: 03184897</p> <p>2. Elecsys C-Peptide Shelf life: 19 months Size:100 Tests Code: 07027168190</p> <p>3. C-Peptide CalSet Shelf life: 18 months Code:03184919</p> <p>4. Elecsys Insulin Shelf life: 19 months Size: 100 Tests Code: 12017547</p> <p>5. Elecsys Insulin Shelf life: 19 months Size:100 Tests Code: 07027559190</p> <p>6. Insulin CalSet Shelf life: 18 months Code:12017504</p> <p>7. cobas HbA1c (Hemoglobin A1c) Test Shelf life: 22 months Size:10 Tests Code:06378676</p> <p>8. A1C-3 Tina-quant Hemoglobin A1c Gen.3 Shelf life: 22 months Size: 150 Tests. Code: 05336163190</p> <p>9. A1C-3 cobas c111 Tina-</p>	<p>1-Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion</p> <p>2-Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion.</p> <p>3- C-Peptide CalSet is used for calibrating the quantitative Elecsys C-Peptide assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>4-Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate</p>
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			<p>quant Hemoglobin A1c Gen.3 Shelf life: 18 months Size: 2 x 100 Tests. Code: 05336180190</p> <p>10. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3. Shelf life: 18 months Size: 200 Tests Code:08445699190</p> <p>11. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3 Shelf life: 18 months Size: 500 Tests Code: 08056668190</p> <p>12. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3 Shelf life: 18 months Size: 500 Tests Code: 07559674190</p> <p>13. cobas HbA1c Control. Shelf life: 18 months Code: 06380204</p> <p>14. A1CD2 cobas c111 Hemolyzing Reagent Gen.2 Shelf life: 18 months Code:05007232</p> <p>15. A1CD2 Hemolyzing Reagent Gen.2 Shelf life: 18 months Size:51 mL. Code: 04528182</p> <p>16. A1CD Hemolyzing Reagent Shelf life: 18 months Size: 50 mL Code: 08463107190</p> <p>17. A1CD Hemolyzing Reagent Shelf life: 18 months</p>	<p>metabolism, including diabetes mellitus and hypoglycemia.</p> <p>5-Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia</p> <p>6-Insulin CalSet is used for calibrating the quantitative Elecsys Insulin assay on the Elecsys and cobas e immunoassay analyzers.</p> <p>7- The cobas b 101 is an in vitro diagnostic test system designed to quantitatively determine the % hemoglobin A1c (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in human capillary and venous whole blood by photometric transmission measurement. An estimated average glucose level (eAG) is calculated by the cobas b 101 system.</p>
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			<p>Size:98 mL. Code:07224648190 18. C.f.a.s. HbA1c Shelf life: 24 months Code: 04528417190</p> <p>19. PreciControl HbA1c norm Shelf life: 19 months Code: 05479207190</p> <p>20. PreciControl HbA1c path Shelf life: 19 months Code: 05912504190</p> <p>21. Hemolyzing Reagent Roche/Hitchi Shelf life: 18 months Size: 1000 mL. Code: 11488457122</p>	<p>The system is intended for professional use in a clinical laboratory setting, or point of care (PoC) locations</p> <p>8-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.</p> <p>9-In vitro test for the quantitative 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 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</p> <p>10-In vitro test for</p>
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				<p>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.</p> <p>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</p>
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				<p>is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes</p> <p>12. 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.</p> <p>13- cobas HbA1c Control solution is used for performing quality control of HbA1c with cobas HbA1c reagent discs on the cobas b 101 instrument</p> <p>14-The hemolyzing reagent is used as diluent for the</p>
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				<p>Tina-quant Hemoglobin A1c assays on the cobas c 111 system.</p> <p>15 -The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on cobas c systems.</p> <p>16-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on cobas c systems.</p> <p>17-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1cDx Gen.3 assay on the cobas c 513 system.</p> <p>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.</p> <p>19-Preci Control HbA1c norm is for use in quality control by monitoring accuracy and precision for the quantitative methods as</p>
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				<p>specified in the value sheets.</p> <p>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.</p> <p>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.</p>
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**Decision: The MDB approved the products at Sr. No.1-9 in current fee structure of clusters as applicable of today.**

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