DECISIONS OF THE 27th MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 21-01-2021

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

S.No	Name of Establishment	Director/Proprietor/ partners	Cold Chain (Yes/No)	Decision
1.	M/s Pharmakon International Enterprises, Office 23 & 26, 2nd Floor, Aries Tower, Shamsabad, Murree Road, Rawalpindi **Godown**: Same as Above.	Mr.Muhammad Abid Naeem Mr. Usman Naeem	Yes	**Approved** for room temperature and cold storage veterinary tet kits.
2.	M/s Greenz Pharmaceuticals, 568-J, Johar Town Lahore. **Godown**: Same as Above.	Mr. Ejaz Ahmed Hafeez	No.	**Approved** for storage of non cold chain medical devices.
3.	M/s Al-Kareem Medical Techonologies 5/F Islam Road, Old Muslim town, Lahore. **Godown**: Same as Above	Muhammed Imran House No. 4-S-91, Mohalla Faiz Madina, Kamoke, District Gujranwala 34102-8346344-7 2.Muhammed Khalid	No	**Approved** for storage of non temperature sensitive medical devices.
4.	M/s Star Agencies, B-71, Sector 4-C, Surjani Town, Karachi. **Godown**: Same as Above.	Asghar Ali	No	**Approved** for storage of non cold chanin medical devices.

5.	M/s Iqbal Enterprise, 1/4 –C, Block-6, P.E.C.H.S., Karachi. **Godown**: Same as Above	Mr. Zafar Iqbal	No.	**Approved** for storage of non cold chanin medical devices.
6.	M/s T&Y Care Pharma (Pvt) Ltd., **Head Office:** Office No.19, Second Floor, Al-Hameedd Mall, Sector G-11 Markaz, Islamabad. **Godown Address:** Mena Banda Salim Khan Road, Near Zaid Bin Haris Masjid, District Swabi.	Mr. Yasir Shahzad. Mr. Ahmad Tilal.	No	**Approved** for storage of non cold chain medical devices.
7.	M/s B.N Trading Company, 2nd Floor Office No.207, Makkah Tower Namak Mandi, Peshawar.	Mr. Burhan Ud Din	No	**Approved** for storage of non cold chain medical devices.
8.	M/s Lab Care International, **Address:** Office No. 10-11-C (3rd Floor) Karachi Market Khyber Bazar, Peshawar. **Godown Address:** D-3, 4th Floor Karachi Market Khyber Bazar, Peshawar.	Mr. Amjad Ali	No	**Approved** for storage of non cold chain medical devices.
9.	M/s The Lab House, **Address:** Shop No. GF-34, Pak Medical Center Khyber Bazar, Peshawar **Godown Address:**	Mr. Rizwanullah	No	**Approved** for storage of non cold chain medical devices.

	M/s GF-75, Pak Medical Center Khyber Bazar, Peshawar			

2. APPROVAL OF SITE FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

2.1.

M/s Chawala Enterprises, Faisalabad has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the **Unit is located at 3.5 K.M, Jhumra Road, Khurrianwala, Faisalabad.**

Decision: The Board approved the site of M/s Chawala Enterprises, located at 3.5 K.M, Jhumra Road, Khurrianwala, Faisalabad for establishment of manufacturing unit of medical devices.

3. POST LICENSE VARIATIONS.

M/s AGP Limited, B-23-C, SITE, Karachi has requested for approval of change of technical person in their ELI-00571 issued on 29-07-2020 as per detail given below:-

Current Technical Person	**Proposed Technical Person**
Ms. Jawaria Naeem, House No. 5/1274, Mohallah Shah Faisal Colony, Karachi CNIC # 42201-1316843-2	Ms. Wajiha Mateen, House No.12/25-C-III, MOhallah Nazimabad-3, Karachi. CNIC # 42101-9241638-8 Pharm-D

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

Previous Technical Person	**New Approved Technical Person**
Ms. Jawaria Naeem, House No. 5/1274, Mohallah Shah Faisal Colony, Karachi CNIC # 42201-1316843-2	Ms. Wajiha Mateen, House No.12/25-C-III, MOhallah Nazimabad-3, Karachi. CNIC # 42101-9241638-8 Pharm-D

4. POST REGISTRATION VARIATIONS.

4.1.

M/s Premier Sales (Private) Limited, Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi has requested for change of Establishment name and address on their following registered medical devices for import:-

S.No	Registration Number	Name of Medical Device (s)
1.	MDIR-0000487	BD Micro-Fine TM + Pen Needle (8MM).
2.	MDIR-0000488	BD Ultra-Fine TM Pen Needle (4MM).
3.	MDIR-0000489	BD Micro-Fine TM + Pen Needle (5MM).
4.	MDIR-0000001	BD Unltra Fine TM II Insuline Syringe (1ml)

Decision: The Board approved the change of establishment name and address on registration letter for their above mentioned registered medical devices for import.

4.2.

M/s Nisa SF Private Limited, Shaikhupura has requested to grant them additional sizes of their following already registered medical devices for local manufacture as mentioned below:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDMR-000009	BM Disposable Syringe	1ml with 26Gx½"(0.45mm x 13mm) 1.5ml with 26g X1½ (0.45MM X 13MM) 2ml with 24Gx1" (0.55mm x 25mm) 2.5ml with 24Gx1" (0.55mm x 25mm) 3ml with 24G X1"(0.55mm x 25mm) 3ml with 23G X1"(0.6mm x 25mm) 5ml with 23G X1 " (0.6mm x 25mm) 10ml with 21G X1½"(0.8mm x 38mm) 20Ml with 20G X 1½"(0.9mm x 38mm) 30Ml with 20G X 1½"(0.9mm x 38mm) 50Ml with 20G X 1½"(0.9mm x 38mm) 60Ml with 20G X 1½"(0.9mm x 38mm)	1ml with 22G (0.7mm x 30mm) 2ml with 22G (0.7mm x 40mm) 10ml with 21G X1¼" (0.8mm x 32mm)

Decision: The Board approved the additional size of BM Disposable Syringe of 1ml with 22G (0.7mm x 30mm), 2ml with 22G (0.7mm x 40mm) **and 10ml with 21G X1¼" (0.8mm x 32mm) (Registration No.MDMR-000009) for local manufacture.**

4.3.

M/s Physiomed (Pvt) Limited, Office No.268/3, Kamal Road, Saddar, Rawalpindi has stated that there is an error in the address of the manufacturing site of the below mentioned registered medical device in registration letter and requested for correction of manufacturing site address as per detail given below:-

S.#	Regn. No.	Name of Medical Device	Existing address of manufacturing site	Correct address of manufacturing site
1.	MDIR-0000726	CPS Aim TM SL (Sittable Inner Catheter) with integrated valve.	St. Jude Medical Coodination Center BVBA, The Corporate Village, Da Vincilaan 11 box F1, 1935 Zaventem, Belgium (Application Certificate).	St. Jude Medical, Cardiac Ryhthm Management Division, 15900 Valley View Court, Sylmar, California, 91342, USA.

Decision: The Board approved the correction of address of manufacturing site of M/s Physiomed (Pvt) Limited, Rawalpindi of their below mentioned medical advice as mentioned below subject to submission of differential fee of 15000/-

Regn. No.	Name of Medical Device	Previous address of manufacturing site	New Approved Corrected address of manufacturing site
MDIR-0000726	CPS Aim TM SL (Sittable Inner Catheter) with integrated valve.	St. Jude Medical Coodination Center BVBA, The Corporate Village, Da Vincilaan 11 box F1, 1935 Zaventem, Belgium (Application Certificate).	St. Jude Medical, Cardiac Ryhthm Management Division, 15900 Valley View Court, Sylmar, California, 91342, USA.

4.4.

M/s Atco Pharma International (Pvt) Limited, B-18, S.I.T.E, Karachi has requested for addition of new manufacturing site of their already registered medical device namely Cre8 Amphilimus Eluting Coronary Stent (Regn. No. MDIR-0000042) as per detail mentioned below: -

Regn. No.	Name of Medical Devices.	Existing Manufacturing Site	Proposed Additional Manufacturing Site.
MDIR-0000042	Cre8 Amphilimus Eluting Coronary Stent	M/s CID S.P.a, Strade per Crescentino s/n, 13040 Saluggia (VC), Italy.	M/s Tibbi Urunler San. Ve Dis. Ticaret, A.S. Istanbul Trakya Serbest Bolgesi Ferhatpasa Mah. Ataturk Bulvari Manolya Sok No.7, 34540, Catalca, Istanbul, Turkey.

Decision: The Board approved the additional manufacturing site for below mentioned medical advice of M/s Atco Pharma International (Pvt) Limited, Karachi as mentioned below:-

Regn. No.	Name of Medical Devices.	Existing Manufacturing Site	New Approved Additional Manufacturing Site.
MDIR-0000042	**Cre8 Amphilimus Eluting Coronary Stent**	**M/s CID S.P.a, Strade per Crescentino s/n, 13040 Saluggia (VC), Italy.**	**M/s Tibbi Urunler San. Ve Dis. Ticaret, A.S. Istanbul Trakya Serbest Bolgesi Ferhatpasa Mah. Ataturk Bulvari Manolya Sok No.7, 34540, Catalca, Istanbul, Turkey.**

5. <u>VIOLATION OF LABELING REQUIREMENTS BY M/S ALI GOHAR & COMPANY (PVT) LTD, KARACHI.</u>

Decision: The Board discussed the matter at length and decided as under:

i) Allowed the stocks ordered 'not to dispose off' to be used after complying with labelling requirements in their licensed premises;

ii) Exemption from labeling rules is not acceded to by the MDB;

iii) For future the principal (manufcturer) should comply with labeling rules before dispatch of consignments.

6. <u>ISSUANCE OF IMPORT PERMIT (FORM-10).</u>

- Mr. Abdullah Ahmed of NUST, H-12, Islamabad, Research Assistant has requested for grant of permit to import following medical devices manufactured by M/s Nanjing Pars Biochem Co. Ltd., China through M/s Progressive Trade Company, B-586, Akbar Plaza, Commercial Market, Satellite

Town, Rawalpindi for the purpose of research at ASAB, National University of Science& Technology (NUST), Islamabad: -

Sr.No.	Name of Medical Device.	Quantity
1.	Human Anti-Thrombin III.ELISA Kit	01 Pcs
2.	Human Mannanbinding lectin (MBL) Kit	01 Pcs
3.	Human Alpha-fetoprotein (AFP) Kit	01Pcs

Decision: The MDB discussed the matter at length and decided to approve the issuance of import permit for above mentioned medical devices as quantity mentioned against each to the applicant for research purpose at ASAB, National University of Science& Technology (NUST), Islamabad.

7. CANCELLATION OF REGISTRATION OF ABC REVITAL AND DCK AUTO DISABLE SYRINGES WITH REUSE PREVENTION FEATURE 5 ML Reg. No. 069510.

Decision: The Board discussed the matter at length and decided to issue show cause notice and giving an opportuinity of hearing to M/S AJ Mirza Pharma (Pvt) Ltd., 7-Ground Floor, Shafi Court, Merewether Road, Civil Lines, Karachi for why there product, namely, ABC Revital and DCK Auto disable syringe with reuse prevention feature 5 ml (Reg.No. 069510) manufctured by M/s Revital Healthcare (EPZ) Ltd, Mumbasa, Kenya registered on 17th January, 2011 should not be cancelled as the manufacturer had cancelled their Agency Agreement / contract or Authorization for the said product.

8. SUBMISSION OF DOCUMENTS OF DEFERRED/APPROVED CASES FOR REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

The following applications for registration of Medical Device for import were placed before the MDB in its 26th meetings held on 6th January, 2021 and deferred for provision of document. Now the firm has submitted documents

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Decision
1.	M/s. Hashir Surgical Services,	**Manufacturer:** M/s. USM Healthcare	Favocath U (Set of I.V Catheter and Injection stopper)	**Approved** on the basis of CE marked submitted documents.

	Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar.	Medical Devices Factory JSC Lot I-4b-1.3, N3 Street, Saigon Hi-tech Park, Long Thanh My Ward, District 9, Ho Chi Minh City, Vietnam, FSC Vietnam valid till 06-10-2022.	Class B Code:- Codes as per FSC Vietnam dated 07-10-2019 Shelf Life: 5 years. Fee submitted: Rs. 25,000/-	
2.	M/s Grace Pharmaceuticals office # 102, First floor, The plaza, Block-9 Clifton, Karachi.	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Auto Disable Syringe. Class B Sizes as per FSC 0.5ml, 1ml, 2ml, 5ml Shelf Life: 05 Years	**Approved** on the basis of CE marked submitted documents.
3.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Scalp Vein Set Class B Sizes as per FSC 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm 0.9mm, 1.2mm	**Approved** on the basis of CE marked submitted documents.
4.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd.	**ALPHA** IV Cannula Class B Sizes as per FSC 0.6x16mm (26Gx0.63IN),	**Approved** on the basis of CE marked submitted documents.

		No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	0.6x19mm (26Gx0.75IN) 0.7x19mm (24Gx0.75IN) 0.9x19mm (22Gx0.75IN) 0.9x25mm (22Gx1.00IN) 1.0x32mm (20Gx1.25IN) 1.0x25mm (20Gx1.00IN) 1.0x30mm (20Gx1.16IN) 1.1x48mm (20Gx1.88IN) 1.3x30mm (18Gx1.16IN) 1.3x48mm (18Gx1.88IN) 1.6x55mm (16Gx2.17IN) 2.0x55mm (14Gx2.17IN) Model: Two-way Connector Type, (Pen type or with injection port) Y-connector type size : 0.6x16mm (26Gx0.63IN)	
5.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Blood Transfusion Set Class B Codes & Sizes as per FSC.	**Approved** on the basis of CE marked submitted documents.
6.	-do-	**Legal Manufacturer:** JianxiHongda Medical	**ALPHA** Infusion Set	**Approved** on the basis of CE marked submitted documents.

		Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	Class B Codes & Sizes as per FSC.	
7.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Disposable Insulin Syringe Class B Codes & Sizes as per FSC.	**Approved** on the basis of CE marked submitted documents.
8.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Disposable Syringes (3ml, 5ml, 10ml and 20ml) Class B Codes & Sizes as per FSC.	**Approved** only 10ml & 20ml on the basis of CE marked submitted documents.
9.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd.	**ALPHA** Brutte Chamber 100 ml Class B Codes & Sizes as per FSC.	**Approved** on the basis of CE marked submitted documents.

		No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)		
10.	-do-	**Legal Manufacturer:** JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	**ALPHA** Disposable Syringes (50ml) Class B Codes & Sizes as per FSC.	**Approved** on the basis of CE marked submitted documents.

9. CORRECTION OF SHELF LIFE OF ALREADY APPROVED MEDICAL DEVICES (TYPOGRAPHICAL ERROR).

The below mentioned applications of M/s Hashir Surgical Services, Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar was placed before the MDB in its 20th and 26th meeting held on 21st September, 2020 and 6th January, 2021 respectively and approved subject to provisions of documents:-

1.	M/s Hashir Surgical Services 1. Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar. 2. Office No.05, 2nd Floor, Syed's Tower,	**Legal Manufacture:** M/s LR No.5025/1239 Msumarini-Mombasa-Malindi Rd P.O BOX 80713-80100 Mombasa-Kenya FSC Kenya valid till (31-12-2019)	REVITAL CADY Auto Disable Syringes for immunization 0.05ml, 0.1ml, 0.5ml, 2ml, 5ml, 10ml Class B **Shelf Life: 12 months**	Auto Disable Syringes for immunization

	University Road, Peshawar. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar **Evaluator:** AD-III [114-P]		Rs.25,000/-	
2.	M/s Hashir Surgical Services Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar. Office No.05, 2nd Floor, Syed's Tower, University Road, Peshawar. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar ELI: 00075 **Evaluator:** AD-III	**Legal Manufacturer:** M/s Revital Healthcare (EPZ) limited, LR No.5025/1239 Msumarini-Mombasa-Malindi Rd P.O BOX 80713-80100 Mombasa-Kenya. FSC: Kenya Date of issue: 31st December, 2019 WHO Prequalified	REVITAL Re-use prevention syringes **Shelf Life: 12 months** Sizes: 2ml, 5ml, 10ml Class B	Provides access to a vein of a patient in order to sample blood, inject medication.

Now the firm has provided documents and **It is further submitted that the shelf life of the above mentioned medical devices was inadvertantly written in agenda as 12 months while the correct shelf life is 05 years.**

Decision: The Board discussed and approved the above mentioned medical devices of M/s Hashir Surgical Services, Peshawar on the basis of CE marked documents and WHO pre-qualification with 05 years shelf life for aforementioned medical devices.

10. NOC FOR IMPORT OF MEDICAL DEVICES

It is submitted that DRAP Office, Lahore has forwarded a case wherein it has been stated that M/s Chughtai Lab (Pvt) Ltd, Lahore applied for the grant of NOC for import of "qualitative realtime PCR Systems-Zip-96V" 05 units, Manufactured by M/s Zybio Inc. China through M/s Ayan Molecular products, Lahore. As per Medical Device Rules, 2017 and letter No. F.4-21/2020 IE dated 26-06-2020 import of medical device for private blood Testing Laboratory use is not mentioned in above said rules.

Decision: The MDB did not agree with granting NOCs for import of unregistered /un-enlisted medical devices / equipments for private laboratories. The import of unregistered / un-enlisted medical devices should be allowed for government / private hospitals, institutes or trusts under Rule 24(d) of Medical Devices Rules, 2017.

11. REGISTRATION OF UMBILIZER OF M/S FEROZSONS (PVT) LTD.

Decision: The Board discussed the matter at length and decided as under:

i) Approved / authorized UMV-001 EUA (Emergency Resuscitator) for its import and usage on similar terms and conditions as authorized by FDA under Emergency Use Authorization;

ii) The authorization for import and usage of product in Pakistan shall be terminated or revoked, if its authorization is terminated or revoked by FDA under EUA;

iii) The firm shall file a fresh application for registration UMV-001 EUA (Emergency Resuscitator) if the said product is approved or granted 510K by FDA.

The importer is further advised to adhere to the following advisory:

a) Provide complete list and updates on usage of number of units of the device along with names of hospitals / institutes where it is used;

b) Monitor the service aspects of the product;

c) Submit quarterly report of any adverse event occurring due to device or otherwise.

12. 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.	M/s SY'AH IMPEX, 1-6/15 Sector No. 5, Korangi Industrial Area Karachi Pakistan ELI: 00440	**Legal Manufacturer:** M/s Jiangyin Nanquan Macromolecule Product Co., Ltd No, 618 Jingxian Road, Xiagang Street, Jiang Yin City, Jiangsu, Province, China. **FSC: China** **Valid till: 2021.09.29**	SHIFA Auto Disable Syringes (Auto -disable syringes) Class -B Shelf Life: 5 years Sizes: 0.05cc, 0.1ml, 0.5ml, 1ml, 2ml	AD syringes include a reuse 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	**Approved** subject to provision of FSC from reference country duly attested.
2.	-do- (Renewal)	**Legal Manufacturer:** M/s Changzhou Tongda Medical Appliance Co., Ltd. Sanhekou Street, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China. **FSC MHRA issuance 06-12-2016** **FSC China** **Valid till: 2020.09.13**	Shifa Aotu-destructive Syringe Class-B Shelf Life: 3 years Sizes: 0.5cc, 1cc, 2cc, 3cc & 5cc	Auto-destructive syringes	**Approved.**
3.	M/s Intra Health, 56A Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049)	**Legal Manufacturer:** M/s Hunan Pingan Medical Device Technology Co. Ltd., Economic Development Zone, LI Country, Hunan Province, China. FSC China Issuance	Uniject Auto Disable Syringe Class-B Shelf Life: 05 Years Rs.5,000/-	Auto Disable Syringe	**Approved** subject to provision of following documents:- • Apply on Form-7A as the device falls in Class-B as per MDR, 2017. • Manufacturing

		Date (15-02-2019)			and QC processes in details. • Stability studies in details. • MRP of the device. • FSC in the country of origin, duly notarized. • As the product is not from reference country, provide FSC of reference country as per Rule 67 of Medical devices rules, 2017, duly attested. • Complete description of the device with intended use, risk and warnings. • FQA certificate mentioning the subject device, duly notarized. • Essential principles checklist. • Declaration of Conformity and labels.
4.	Rehman Medicine Co., 1&2 First Floor, H.J. Centre, Kutchi Gali No.2, Marriot Road, Karachi (ELI-00423)	**Legal Manufacturer:** M/s Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd., No. 2 Guanyin Road, Economic Development Zone, Taihu Country, 246400 Anqing, Anhui, China. FSC China Valid Till (22-07-2021)	Master A Auto Disable Syringe with Needle for Single Use Class B Shelf Life: 05 Years Rs.25,000/-	It is manual use that for fluid extraction during clinic or after liquid injection for immediate injection.	**Approved** subject to provision of following documents:- • Stability studies in details. • MRP of the device. • The subject device is not included in the FSC of country of origin. • As the product is

					not from reference country, provide FSC of reference country as per Rule 67 of Medical devices rules, 2017, duly attested. • Complete description of the device with intended use, risk and warnings. • FQA certificate mentioning the subject device, duly notarized. • Labels approved in the country of origin.
5.	M/s AB Enterprises, 192 block 7/8, K.M.C.H.S, Karachi	**Legal Manufacturer:** Heze Yinuo Medical Industry Co. Ltd, Dingtao County, Economic development Zone, Heze City, Shangdong, China.	AB Auto destructive syringe Class-B Shelf life: 5 years Codes & sizes: Not given	Auto-destructive syringes	**Approved** subject to provision of following documents:- • Credentials of manufacturer's abroad. • Manufacturing and QC processes in details. • Stability studies in details. • MRP of the device. • Only AB safety device is included in LOA. • FSC in the country of origin mentioning all the applied sizes and codes. • As the product is not from reference country, provide FSC of reference

					country as per Rule 67 of Medical devices rules, 2017, duly attested. • Complete description of the device with intended use, risk and warnings. • QMS ISO 13485 certificate. • FQA certificate mentioning the subject device, duly notarized. • Essential principles checklist. • Declaration of Conformity and labels.
6.	-do-	**Legal Manufacturer:** Heze Yinuo Medical Industry Co. Ltd, Dingtao County, Economic development Zone, Heze City, Shangdong, China.	AB Safety syringe Class-B Shelf life: 5 years Codes & sizes: Not given	Auto-destructive syringes	**Approved** subject to provision of following documents:- • Credentials of manufacturer's abroad. • Manufacturing and QC processes in details. • Stability studies in details. • MRP of the device. • Only AB safety device is included in LOA. • FSC in the country of origin mentioning all the applied sizes and codes. • As the product is not from reference country, provide

					FSC of reference country as per Rule 67 of Medical devices rules, 2017, duly attested. • Complete description of the device with intended use, risk and warnings. • QMS ISO 13485 certificate. • FQA certificate mentioning the subject device. • Essential principles checklist. • Declaration of Conformity and labels.
7.	M/s Samerian's Enterprise, 4-First Floor H. J Centre Kutchi Gali No. 2, **Karachi.** **ELI: 00425.**	M/s. JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD 78 # NORTH SUZHONG ROAD BAOYING YANGZHOU JIANGSU PROVICE P.R. CHINA.	**MASTER PLUS** Auto –Disable Syringes 1ML-2ML-5ML-10ML-20-ML **Class-B** Shelflife: 05-years.	Master Plus **Auto –Disable Syringes**	**Approved** subject to provision of the original and valid free sale certificate of SRA, CE certification or WHO pre-qualification as per MDR, 2017.

13. 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 Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore (ELI: 00150)	**Manufacturer:** Dragerwerk AG &Co. KGaA Moislinger Allee 53-55 D-23542 Lubeck, Germany FSC Germany issued on 08-07-2020	Drager Babylog VN800 (Neonatal Intensive Care Ventilator) Class: C Ref: 8422400	Intended for the ventilation of neonates from 0.4 kg up to 10 kg and pediatric patients from 5 kg up to 20 kg bodyweight.	**Approved.**

			Shelf Life: N/A Fee submitted: Rs. 50,000/-		
2.	-do-	**Manufacturer:** Dragerwerk AG &Co. KGaA Moislinger Allee 53-55 D-23542 Lubeck, Germany FSC Germany issued on 08-07-2020	Drager Evita V800 (Intensive Care Ventilator) Class: C Ref: 8422500 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for the ventilation of adults, adolescents, children, infants and neonates.	**Approved.**
3.	-do-	Legal Manufacturer: Dragerwerk AG & Co. KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaA Revalstrabe 1, 23560, Lubeck, Germany FSC Germany issued on 08-07-2020	Drager Atlan A350 (Anesthesia Workstation) Class C Ref: 8621500 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for use in anesthetizing adults, pediatric patients and neonates. Can be used for mechanical ventilation, manual ventilation, pressure-supported spontaneous breathing and spontaneous breathing	**Approved.**
4.	-do-	Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany FSC Germany issued on 08-07-2020.	Drager Fabius Plus XL (Anesthesia Workstation) Class C Ref: 8608555 Shelf Life: N/A	Specified for inhalational anesthesia and/or patient ventilation in accordance with the intended use during surgical or diagnostic interventions	**Approved.**

			Fee submitted: Rs. 50,000/-		
5.	-do-	Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany FSC Germany issued on 08-07-2020	Drager Fabius MRI (Anesthesia Workstation) Class C Ref: 8607300 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Indicated as a continuous flow anesthesia system useable in an MRI environment. May be used for manually assisted or automatic ventilation, delivery of gases and anesthetic vapor and monitoring of oxygen concentration, breathing pressure and respiratory volume.	**Approved.**
6.	-do-	Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany FSC Germany issued on 08-07-2020	Drager Evita V600 (Intensive Care Ventilator) Class: C Ref: 8422300 Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for the ventilation of adults, adolescents, children, infants and neonates.	**Approved.**
7.	-do-	Legal Manufacturer: Dragerwerk AG &Co, KGaA Moislinger Allee 53-55, 23542 Lubeck, Germany	Drager Babylog VN600 (Neonatal Intensive Care Ventilator)	Intended for the ventilation of neonates from 0.4 kg up to 10 kg and pediatric patients	**Approved.**

		Manufacturing site: Dragerwerk AG &Co, KGaA Revalstrabe 1, 23560, Lubeck, Germany FSC Germany issued on 08-07-2020	Class: C Ref: 8422200 Shelf Life: N/A Fee submitted: Rs. 50,000/-	from 5 kg up to 20 kg bodyweight.	
8.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Drager, Ventstar Breathing Bags (Breathing Bags disposable) Class-B Shelf Life: 3 years Codes & Sizes: Beg set 120 Beg set 150 Beg set (P) 110	Breathing Bags with connection hose is intended for use with anesthesia machines as a reservoir during automatic ventilation and as a manual breathing bag during manual ventilation. Intended for single use only.	**Approved.**
9.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany**	Drager O2Star Oxygen Nasal Cannula (Disposable 02 therapy accessories) Class-B Shelf Life: 3 years Sizes: Nasal Cannula Straight, S Nasal Cannula Straight, M	For inhalation and insufflation of breathing gas with increased O2 concentration. Only to be used on patients with spontaneous breathing in medical environment.	**Approved.**

		Date of issue: 15.10.19	Nasal Cannula Straight, L Nasal Cannula Straight, XL		
10.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Drager Care star (Breathing Filters accessories for anesthetic and respiratory use) Class-B Shelf Life: 3 years Sizes/ codes: Filter care star 45 Filter care star 40A Filter care star 30	Breathing Filters accessories for anesthetic and respiratory use	**Approved.**
11.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Drager Nova Star (Non-Invasive Ventilation Mask) Class- B Shelf Life: use up to 30 days on the same patient Codes/ sizes: TS NIV Mask, AAV, S TS NIV Mask, AAV, M TS NIV Mask, AAV, L TS NIV Mask, SE, S TS NIV Mask, SE, M TS NIV Mask, SE, L	Face mask	**Approved.**
12.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1	Drager (HME Filter Twin Star) (HME Breathing Filters accessories for anesthetic and respiratory use)	HME Breathing Filters accessories for anesthetic and respiratory use	**Approved.**

		23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Class-B Shelf Life: 3 years Sizes: Filter Twin star 90 Filter Twin star HEPA Filter Twin star 55 Filter Twin star 65A Filter Twin star 25 Filter Twin star 8 Filter Twin star 10A		
13.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Drager (HME Filter Safe Star) (Breathing Filters accessories for anesthetic and respiratory use) Class-B Shelf Life: 3 years Sizes: Filter 80 Filter 55 Filter 60A	Breathing system filter for anesthetic and respiratory use.	**Approved.**
14.	-do-	**Legal Manufacturer** M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany **Manufacturing Site:** Dragerwerk AG&Co. KGaA RevalstrBe 1 23560, Lubeck, Germany. **FSC: Germany** **Date of issue: 15.10.19**	Drager O2Star Oxygen & Aerosol Mask) (Disposable 02 therapy accessories) Class-B Shelf Life: 3 years Sizes: Oxygen and Aerosol mask, S Oxygen and Aerosol mask, M/L	Disposable O2 therapy accessory for inhalation and insufflation of breathing gas with increased O2 concentration and of aerosols. Only to be used on patients with spontaneous breathing in medical environment.	**Approved.**

15.	M/s Medtronics Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Adapta™ (Single chamber rate responsive pacemaker,) (Model: ADSR01) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000/-	Implantable pulse generator indicated for use to improve cardiac output, prevent symptoms or protect against arrythmias related to cardiac impulse formation or conduction disorders. Sterile, single-use.	**Approved..**
16.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera™ S VR (Single chamber implantable cardioverter defibrillator) (Model: DVBC3D1) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000/-	Intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatning ventricular tachyarrhythmias. Sterile, single-use	**Approved.**
17.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Solara Quad™ CRT-P MRI SureScan™ (Dual Chamber, Implantable Pulse Generator with Cardiac Resynchronization therapy) (Model: W4TR06) Class D	A multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia	**Approved.**

			Shelf Life: 18 Months Fee submitted: Rs.50,000/-	pacing, sequential biventricular pacing, and atraial tachyarrhythmia therapies. Sterile, single-use, MR Conditional	
18.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera MRI™ S DR SureScan™ (Dual Chamber Implantable Cardioverter Defibrillator) (Model: DDMC3D4) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000/-	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use. MR Conditional	**Approved.**
19.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Viva™ XT CRT-D (dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy) (Model: DTBA2D1) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000/-	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use.	**Approved.**

20.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC US FDA valid till 15-08-2021)	Azure™ S DR MRI SureScan™ (Dual Chamber Implantable Pulse generator) (Model: W3DR01) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	A multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing. Sterile, single-use, MR Conditional	**Approved.**
21.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Viva ™ Quad XT CRT-D (dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy) (Model: DTBA2QQ) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use.	**Approved.**
22.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case	Evera ™ S DR (Dual chamber implantable cardioverter defibrillator) (Model: DDBC3D4)	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated	**Approved.**

		postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use.	
23.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Compia MRI ™ Quad CRT-D Surescan ™ (Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy) (Model: DTMC2QQ) Class D Shelf Life: 18 Months. Fee submitted: Rs. 50,000/-	Intended to provide ventricular antitachycardia pacing, cardioversion and defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias. Sterile, single-use, MR Conditional	**Approved.**
24.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera ™ S VR (Single chamber implantable cardioverter defibrillator) (Model: DVBC3D4) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias. Sterile, single-use.	**Approved.**

25.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera MRI ™ S VR SureScan ™ (Single chamber implantable cardioverter defibrillator) (Model: DVMC3D4) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias. Sterile, single-use, MR Conditional.	**Approved.**
26.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera™ XT DR (Dual Chamber Implantable Cardioverter Defibrillator) (Model:DDBB2D1 Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use.	**Approved.**
27.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131	Viva ™ Quad S CRT-D (dual chamber implantable cardioverter defibrillator with cardiac resynchronization	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-	**Approved.**

		Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	therapy) (Model: DTBB2Q1) Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	threatening ventricular tachyarrhythmias. Sterile, single-use.	
28.	-do-	Legal Manufacturer: MEDTRONIC INC., 710 Medtronic Pkwy, Minneapolis, MN USA 55432. Manufacturer: Lake Region Medical 340 Lake Hazeltine Dr CHASKA, MN USA 55318 (FSC USFDA valid till 06-12-2019)	AchieveAdvance ™ Mapping Catheter Class D Shelf Life: 2 Years Codes: 2ACH15 2ACH20 2ACH25 Fee submitted: Rs. 50,000/-	An intra-cardiac electrophysiology (EP) recording catheter indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e recording or stimulation only. Sterile, single use.	**Approved.** The firm shall provide valid FSC before issuance of registration letter.
29.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Compia MRI ™ CRT-D Surescan ™ (Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy) (Model: DTMC2D1) Class D Shelf Life: 18 Months	Intended to provide ventricular antitachycardia pacing, cardioversion and defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias. Sterile, single-use, MR Conditional	**Approved.**

			Fee submitted: Rs. 50,000/-		
30.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Viva™ S CRT-D (implantable cardioverter defibrillator with cardiac resynchronization therapy) (Model: DTBB2D1) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-threatening ventricular tachyarrhythmias. Sterile, single-use.	**Approved.**
31.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera MRI™ XT VR SureScan™ (single chamber implantable cardioverter defibrillator) (Model: DVMB2D1) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000/-	Intended to provide ventricular antitachycardia pacing and defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias. Sterile, single-use, MR Conditional	**Approved.**
32.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131	Evera™ S DR (Dual Chamber implantable cardioverter defibrillator) (Model:DDBC3D1 Class D	Intended to provide atrial and/or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and/or life-	**Approved.**

		Tolochenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Shelf Life: 18 Months Fee submitted: Rs.50,000/-	threatening ventricular tachyarrhythmias. Sterile, single-use.	
33.	M/s Meditec Instruments Co., Suit No. 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi (ELI-00233)	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	EasyLyte Electrodes (Cluster) Class B Codes: 2101, 2102, 2103, 2106, 2113, 2150, 2151,2152 Shelf Life: 12 Months Fee submitted: Rs. 25,000/-	Electrolyte Electrodes to be used with EasyLyte analyzer	**Approved.** Firm shall submit separte application for other electrodes.
34.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	EasyLyte Electrolyte Reagents (Cluster) Class B Codes: 2028, 2026, 2109, 2120, 2112, 2121 2115, 2122, 2114, 2123,2124 Shelf Life: 24 Months Fee submitted: Rs. 25,000/-	Electrolyte Reagents to be used with EasyLyte analyzer	**Approved.** The firm shall submit separae application for Reagents of other analyzers.
35.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730.	EasyRA Analyzer-ISE; LIS (Ref No: 10360) Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Designed for clinical laboratory use to provide quantitative results on analytes indicative of hepatic, renal, metabolic,	**Approved.** The firm shall submit separate application for other models.

		FSC US FDA valid till 19-06-2021		electrolyte and other physiological disturbances.	
36.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	EasyElectrolyte Analyzer Na/K/Cl (Ref No: 4002) Class B Shelf Life: N/A Fee submitted: Rs.5,000/-	Designed for clinical laboratory use, making direct quantitative measurements of sodium, potassium and chloride in serum, plasma, whole blood and urine samples	**Approved.** The firm shall submit separate application for other models.
37.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	EasyBlood Gas Analyzer (Ref No: 6001) Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Designed for clinical laboratory use, making direct measurements of pH, partial pressure of carbon dioxide and partial pressure of oxygen	**Approved.** .
38.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	EasyLyte Plus Na/K/Cl Analyzer (Ref No: 2014) Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Designed for clinical laboratory use for measurement of sodium, potassium and chloride in serum, plasma, whole blood and urine samples .	**Approved.** The firm shall submit separate application for other models.
39.	-do-	**Manufacturer:** M/s Medica Corp., 5 Oak Park Drive,	EasyStat Analyzer (Ref No: 7001) Class B	Designed for clinical laboratory use making direct measurements of pH, partial	**Approved.**

		Bedford, MA USA 01730. FSC US FDA valid till 19-06-2021	Shelf Life: N/A Fee submitted: Rs. 25,000/-	pressure of carbon dioxide, partial pressure of oxygen, hematocrit, sodium, potassium and ionized calcium on whole blood samples from syringes or capillary tubes	
40.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** M/s Abbott Diabetes Care Ltd., Range Road, Witney, Oxon, OX29 0YL, UK (FSC UK issuance 10-04-2018)	FreeStyle Optium Neo H Blood Glucose Test Strips Class C Shelf Life: 18 Months Codes: 71312-75		**Approved.**
41.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	**Legal Manufacturer:** The Surgical Company International B.V. Beeldschermweg 6F 3821 AH Amersfoort the Netherlands. (FSC Issue 24-12-2018)	Fluido® Compact Warming Unit Fluido® Compact Disposable Set Class C Shelf Life: 7 Sizes & Codes as Per FSC 650100 650200	A main Electricity AC – powered device designed for in-line heating of banked blood, blood products, and intravenous IV Solution, typically from about 4 C to near body temperature before infusion, through the convection of heat.	**Approved.**
42.	-do-	**Legal Manufacturer:** The Surgical Company International B.V. Beeldschermweg 6F 3821 AH Amersfoort The Netherlands. (FSC Issue 24-12-2018)	Mistral-Air Warming Unit Class-C Shelf Life: 7 Years Sizes & Codes as Per FSC	A non-sterile underlay or overlay through which heated or cooled air is circulated to heat or cool a patient typically in surgical and	**Approved.**

			MA1100-EU (Warming unit) MA1200-EU (Plus warming unit 220-240)	intensive care settings.	
43.	-do-	**Legal Manufacturer:** The Surgical Company International B.V. Beeldschermweg 6F 3821 AH Amersfoort the Netherlands. (FSC Issue 24-12-2018)	Fluido® Air Guard System Fluido Air Guard System Class C Shelf Life: 7 Years Sizes & Codes as Per FSC: 651230 660400 660200A 660300 660500-B	A metal rod with two or more hooked bars intending horizontally from its top from which various fluid delivery devise bags or bottles can be suspended for the administration of intravenous fluids medication to the patient.	**Approved.**
44.	-do-	**Legal Manufacturer:** The Surgical Company International B.V. Beeldschermweg 6F 3821 AH Amersfoort the Netherlands. (FSC Issue 24-12-2018)	Fluido® Compact Warming Unit Fluido® Compact Disposable Set Class C Shelf Life: 7 Sizes & Codes as Per FSC 650100 650200	A main Electricity AC – powered device designed for in-line heating of banked blood, blood products, and intravenous IV Solution, typically from about 4 C to near body temperature before infusion, through the convection of heat.	**Approved.**
45.	-do-	**Legal Manufacturer:** SunMed Holdings, LLC (dba Ventlab, LLC, dba Thox Medical, LLC, dba SunMed, LLC) 2710 Northrigdge Drive NW, Suite A Grand Rapids, Mi USA 49544	Sunmed Airflow Manual Disposable Resuscitator Class B Shelf Life: 5 Years	Bag: Oval Shaped holed bag where oxygen and or air mix are acuumulated and later squeezed to provide oxygen /air to the patient lungs.	**Approved.**

		SunMed holdings, LLC 2710 Northdrige Dr Nw Ste A Grand Rapids, Mi USA 49544 **Manufacuturing Site:** Sunmed Ap, Ltd, 6-9 Zhufeng Rd., Qiannan Industrial Park Qianwu Town, Doumen District Zhuhai, Guangdong China. (FSC Valid 11-02-2021)	Sizes & Codes as Per FSC AF1100MB AF2100MB AF3100MB AF4100MB AF5100MB		
46.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch Slide** **(**Sterile powder free latex surgical gloves) Codes & Sizes as per FSC. **Class-B.** claimed shelf life: 05-years.	Sterile powder free latex surgical gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE Certification as per NANDO Databse or WHO Pre-qualification.
47.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch** **(**Sterile powder free latex surgical gloves) Codes & Sizes as per FSC. **Class-B.** claimed shelf life: 05-years.	Sterile powder free latex surgical gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE Certification as per NANDO Databse or WHO Pre-qualification.
48.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar,	**iNtouch Sense-** **(**Sterile powder free latex surgical gloves) Codes & Sizes as per FSC. **Class-B.**	Sterile powder free latex surgical gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE

		42100 Klang, Selangor, Malaysia.	claimed shelf life: 05-years.		Certification as per NANDO Databse or WHO Pre-qualification.
49.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch Micro (**Sterile powder free latex microsurgical gloves) Codes & Sizes as per FSC. **Class-B.** claimed shelf life: 05-years.	Sterile powder free latex microsurgical gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE Certification as per NANDO Databse or WHO Pre-qualification.
50.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch** (Sterile powdered latex surgical gloves) Codes & Sizes as per FSC. **Class-B.** claimed shelf life: 05-years.	Sterile powdered latex surgical gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE Certification as per NANDO Databse or WHO Pre-qualification.
51.	-do-	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch V-Synthetic** (Sterile powder free nitrile examination gloves) Codes & Sizes as per FSC. **Class-B.** claimed shelf life: 05-years.	Sterile powder free nitrile examination gloves.	**Approved** subject to provision of original & valid free sale certificate of any SRA or CE Certification as per NANDO Databse or WHO Pre-qualification.
52.	M/s KASBN International, 422-A-1 GULBERG III NEAR GHALIB MARKET LAHORE (ELI-00434)	**Legal Manufactuer:** NOUVAG AG LOCATED at St. Gallerstrasse 23-25, 9403, Goldach, Switzerland. FSC: Switzerland	**(NOUVAG)** Vacuson SUCTION PUMP Class B Shelf Life: N/A	The Vacuson suction pump is sensible and precisely integrated liposuction device, combining	**Approved.**

		Valid till 30.07.2022	Codes: 4227-115-4227-230-	infiltration and suction for protective tissue treatment with or without local anesthetic tumescence.	
53.	M/s. Fresenius Kabi Pakistan Private Limited. First Floor, Tanwir Ahmed Medical Center (TAMC), MM Alam Road, 27-C/3, Gulberg III, Lahore, Pakistan. (ELI-00266)	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	P1YA White Blood Cell Set Class-B Shelf Life: 3 Years Model/ Code: (9400431)	The Cell Separator disposables are sterile, pyrogen free used for collection of blood components from donors, for the therapeutic apheresis and for therapeutic plasma exchange. Intended to be used for single donor/ patient.	**Approved** subject to provision of valid Letter Of Authorization.
54.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 23-08-2019	AT3 Autotransfusion Set (Disposables for Autotransfusion) Class-B Shelf Life: 3 Years Model/ code: (9005103)	The C.A.T.S. (Continuous Autotransfusion System) is an Autotransfusion device intended for the processing of autologous shed blood collected intra-operatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it is intended for peri-operative separation of blood into Packed Red Cells, Plasma	**Approved** subject to provision of valid Letter Of Authorization.

				and Platelet Rich Plasma.	
55.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 23-08-2019	ATF 120 Fast Start Kit Class-B Shelf Life: 3 Years Model/ code: (9108501)	The C.A.T.S. (Continuous Autotransfusion System) is an Autotransfusion device intended for the processing of autologous shed blood collected intra-operatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it is intended for peri-operative separation of blood into Packed Red Cells, Plasma and Platelet Rich Plasma.	**Approved** subject to provision of valid Letter Of Authorization.
56.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	C5L Platelet Set (5-day Storage) Class-B Shelf Life: 3 Years Code: (9400201)	The Cell Separator disposables are sterile, pyrogen free used for collection of blood components from donors, for the therapeutic apheresis and for therapeutic plasma exchange. Intended to be used for single donor/ patient.	**Approved** subject to provision of valid Letter Of Authorization.

57.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	RVY White Blood Cell Set Class-B Shelf Life: 3 Years Model/ code: (9400361)	The Cell Separators use centrifugal force to separate blood components. For the different indications various treatment programs can be selected on the Cell Separators. The programs can be seen in the following table with a description of the program and the type of Apheresis and Cell Separation Disposable that can be used.	**Approved** subject to provision of valid Letter Of Authorization.
58.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	S5L Platelet Set (5-day Storage) SN Class-B Shelf Life: 3 Years Model/ code: (9400211)	The Cell Separators use centrifugal force to separate blood components. For the different indications various treatment programs can be selected on the Cell Separators. The programs can be seen in the following table with a description of the program and the type of Apheresis and Cell Separation Disposable that can be used.	**Approved** subject to provision of valid Letter Of Authorization.
59.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany	C4L Platelet Set (5-day Storage) Class-B Shelf Life: 3 Years	The Cell Separators use centrifugal force to separate blood components. For the different	**Approved** subject to provision of valid Letter Of Authorization.

		Physical Manufacturer: Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	Model/ code: (9400371)	indications various treatment programs can be selected on the Cell Separators. The programs can be seen in the following table with a description of the program and the type of Apheresis and Cell Separation Disposable that can be used.	
60.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG61346 Bad Homburg, Germany **Physical Manufacturer:** Fresenius HemoCare Netherlands B.V. Runde ZZ 41, 7881 HM EMMER-COMPASCUUM, THE NETHERLANDS. FSC: Germany Date of Issue: 24-06-2019	PL1 Plasma Exchange Set (9400401) Class-B Shelf Life: 3 Years Model/code: AF1100MB	The Cell Separators use centrifugal force to separate blood components. For the different indications various treatment programs can be selected on the Cell Separators. The programs can be seen in the following table with a description of the program and the type of Apheresis and Cell Separation Disposable that can be used.	**Approved** subject to provision of valid Letter Of Authorization.
61.	-do-	**Legal Manufacturer:** M/s. Fresenius Kabi AG 61346 Bad Homburg Germany **Physical Manufacturer:** Fresenius Kabi Horatev CZ s.r.o. Horatev 104,298 13 CZECH Republic	**Name of Product:** ACD-A 500ml Class-C Shelf Life: 24 months Model/ code: (TS14005)	Transfusion Accessories ACD-A are sterile processing solutions for use in blood bank and for use in apheresis applications. ACD-A is a clear, colorless and sterile solution	**Approved.**

		FSC Germany Date of Issue: 06-03-2019		filled in PVC containers. The steam sterilized transfusion accessories have a sterile and non-pyrogenic fluid path. They are wrapped in an individual over-wrap/flow wrap and are protected by a corrugated shipping carton. The marking on the labels and cartons indicates the storage conditions and the products can be used until the expiry date mentioned on the label. GMDN Code: 46812 – Blood storage solution, anticoagulation A blood preservation fluid used during the collection and storage of blood and blood components in a healthcare and/or a blood bank facility (typically in a laboratory associated with the collection of blood or during apheresis procedures that result in the collection of blood), to prevent blood clotting. It is supplied in a container (e.g., a	

				polypropylene bag) and is not for direct intravenous infusion. This is single-use device.	
62.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078)	**Legal Manufacturer:** M/s Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe, Hyogo, 651-0073, Japan **Manufacturing Site:** M/s Eiken Chemical Co., Ltd., Nogi Plant 143 Nogi, Nogi-machi, Shimotsuga-gun, Tochigi, 329-0114, Japan (Meditape) M/s Sysmex Corporation Kakogawa Factory 314-2 Kitano, Noguchi-cho, Kakogawa, Hyogo 675-0011, Japan. M/s Sysmex Corporation i-Square 262-11, Mizuashi, Noguchi-cho, Kakogawa, Hyogo 675-0011, Japan	**SYSMEX FULLY AUTOMATED**Urine Chemistry Analyzer. Codes & Sizes as per FSC Class-D. Shelflife: 05-years.	Fully Automated Urine Chemistry Analyzer.	**Approved.** Firm shall provide Full QA certificate and Undertaking on stamp paper. Firm asked for separate application for each type of medical device.
63.	-do-	**Legal Manufacturer:** M/s Japan Lyophilization Laboratory, 1-5-21 Otuska, Bunkyo-ku, Tokyo 112-0012, Japan **Manufacturing Site:** M/s Japan Lyophilization Laboratory, Kiyose Factory 3-1-5 Matsuyama, Kiyose-shi, Tokyo 204-0022, Japan. M/s Sysmex international Reagents Co., Ltd., Seishin	**SYSMEX** HISCL Anti-TP Assay Kit. Class-C. Shelflife: 12-months. Codes & Sizes as per FSC	Anti-TP Assay Kit.	**Approved**. Firm shall provide Full QA certificate and Undertaking on stamp paper.

		Factory 4-3-2 Takatsukadai, Nishi-ku, Kobe-shi, Hyogo 651-2271, Japan. M/s Sysmex International Reagents Co., Ltd., Ono Factory 17 Takumidai, Ono-shi, Hyogo 675-1322, Japan.			
64.	-do-	Legal Manufacturer: M/s Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe, Hyogo, 651-0073, Japan Manufacturing Site: M/s Sysmex international Reagents Co., Ltd., Seishin Factory 4-3-2 Takatsukadai, Nishi-ku, Kobe-shi, Hyogo 651-2271, Japan. M/s Sysmex International Reagents Co., Ltd., Ono Factory 17 Takumidai, Ono-shi, Hyogo 675-1322, Japan **FSC Japan** Issuance Date: (24-05-2018)	**SYSMEX** HISCL HIV Ag+Ab Assay Kit Class-C. Shelflife: 18-months. Codes & Sizes as per FSC	HIV Ag+Ab Assay Kit	**Approved**. Firm shall provide Full QA certificate and Undertaking on stamp paper.
65.	-do-	**Legal Manufacturer:** M/s Sysmex Corporation, 1-5-1 Wakinohama - Kaigandori, Chuo-ku, Kobe, Hyogo, 651-0073, Japan **Manufacturing Site:** M/s Sysmex Corporation Kakogawa Factory 314-2 Kitano, Naguchi-cho, Kakogawa, Hyogo 675-0011 Japan. M/s Sysmex Corporation i-Square	**UF-4000** Fully Automated Urine Particle Analyzer. Codes & Sizes as per FSC Class-D. Shelflife: N/A.	Fully Automated Urine Particle Analyzer.	**Approved**. Firm shall provide Full QA certificate and Undertaking on stamp paper. Firm asked for separate application for each type of medical device.

		262-11, Mizuashi, Noguchi-cho, Kakogawa, Hyogo 675-0019, Japan. M/s Sysmex RA Co., Ltd., 1850-3 Hirooka-nomura, Shiojiri, Nagano, 399-0702, Japan.			
66.	-do-	**Legal Manufacturer:** M/s Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe, Hyogo, 651-0073, Japan **Manufacturing Site:** M/s Sysmex Corporation Kakogawa Factory 314-2 Kitano, Naguchi-cho, Kakogawa, Hyogo 675-0011 Japan M/s Sysmex Corporation i-Square 262-11, Mizuashi, Noguchi-cho, Kakogawa, Hyogo 675-0019, Japan M/s Sysmex RA Co., Ltd., 1850-3 Hirooka-nomura, Shiojiri, Nagano, 399-0702, Japan.	**SYSMEX** Automated Hematology Slide Preparation. Codes & Sizes as per FSC Class-D. Shelflife: N/A.	Hematology Slide Preparation system.	**Approved**. Firm shall provide Full QA certificate and Undertaking on stamp paper. Firm asked for separate application for each type of medical device.
67.	-do-	**Legal Manufacturer:** M/s Sysmex Corporation, 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe, Hyogo, 651-0073, Japan **Manufacturing Site:** M/s Sysmex Corporation Kakogawa Factory 314-2 Kitano, Naguchi-cho, Kakogawa, Hyogo 675-0011 Japan. M/s Sysmex Corporation i-Square	**SYSMEX** Automated Hematology Analyzer XN-L Series. Class-D. Shelflife: N/A. Codes & Sizes as per FSC	Hematology Analyzer.	**Approved**. Firm shall provide Full QA certificate and Undertaking on stamp paper. Firm asked for separate application for each type of medical device.

		262-11, Mizuashi, Noguchi-cho, Kakogawa, Hyogo 675-0019, Japan. M/s Sysmex RA Co., Ltd., 1850-3 Hirooka-nomura, Shiojiri, Nagano, 399-0702, Japan.			
68.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109	Legal Manufacturer: M/s Taiwan Advanced Nanotech Inc. 10F, No, 95, Xinpu 6th St., Taoyuan Dist., Taoyuan City 330 Taiwan. FSC: TAIWAN Valid till: 24.09.2021	**TAN bead** (Nucletic Acid Extraction Kit & Analyzer) Class-B Shelf Life: 1.5 years	Automatic nucleic acid extration system for the extraction of Viral DNA or RNA from human biological specimens such as serum, plasma and other cell-free fluids.	**Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.**
69.	-do-	Legal Manuacturer M/s Taiwan Advanced Nanotech Inc, 10F., No, 95, Xinpu 6th St. Taoyuan Dist., Taoyuan City 330, Taiwan FSC: Taiwan Date of Issue:29.01.2019	**MAELSTROM 9600** Nucleic Acid Extraction Kit & System (Nucleic Acid Extraction Kit & Analyzer) Model: 665A46-665S46-765S46-665S32-665046-665S24-665A46-KEI-665S46-KEI Class-B Shelf Life: 18 months	Maelstrom 9600 is an automated nucleic acid platform designed for high-throughput applications. Specialized spin tips enable superb mixing efficiency of magnetic beads and larger processing volume. With intuitive interface and flexible program, Maelstrom 9600 can boost laboratory productivity by transforming routine operations into a walk-away solution.	**Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.**
70.	M/s. Hope Pharma Address: Office # 1-B Guldasht Town, Zarar	**Legal Manufacturer:** M/s. **Medas Inc**	**Border PTCA Guide-Wire** PTCA guide wire	PTCA Guide wires are intended to facilitate the	**Deferred** for provision of original free sale certificate

	Shaheed Road Cantonment Lahore.	12550 Biscayne Blvd, Suite 405, North Miami, FL 33181. FSC USA (copy) 25.08.2021	Class: D Shelf Life: 02 years. Rs. 50,000/-	placement of balloon dilatation cathetrs during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) The MEDAS PTCA Guide Wire arenot to be used in the neuro vasculature.	(embassy attested), agency agreement (notarized) and justifiable stability study.
71.	M/S Verizon. 60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore. (ELI-00087)	Manufacturer: M/s COOK, INC. 750 DANIELS WAY Bloomington, IN USA 47404 FSC USFDA valid till 18-09-2020	Polyvinyl Alcohol Foam Embolization Particles Code: PVA-100, PVA-1000, PVA-1500, PVA-200, PVA-2000, PVA-300, PVA-500, PVA-700 Class D Shelf Life: Not mentioned Fee submitted: Rs. 50,000/-	Intended for embolization of the blood supply to hypervascular tumors, and arteriovenous malformations, including use in intracranial embolization. Sterile, single-use	**Approved** subject to provision of valid FSC, Stability studies and manufacturing details.
72.	-do-	Manufacturer: COOK, INC. 750 DANIELS WAY Bloomington, IN USA 47404 FSC US FDA valid till 16-09-2020	Transseptal Needle Class D Code: TSNC-18-71.0 TSNC-19-56.0 Shelf Life: 05 years Fee submitted: Rs. 50,000/-	Intended for transseptal left heart access in both diagnostic and interventional procedures. Sterile, single use	**Approved** subject to provision of valid FSC, Stability studies and manufacturing details.

73.	-do-	Manufacturer: Cook Ireland Limited O'Halloran Road, National Technology Park, Limerick, Ireland FSC Ireland valid till 13-08-2023	ECHOTIP® ULTRA Endoscopic Ultrasound Needle Code: ECHO-19, ECHO-1-22, ECHO-25 Class B Shelf Life: 03 years Fee submitted: Rs. 50,000/-	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope. Sterile, single-use	**Approved.**

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

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce of Commerce Building, St No-2/A, Block 9, KDA Scheme-5, Clifton, Karachi (ELI-00259)	Manufacturer: M/s. 3M Company, 3M Centre, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN USA 55144 Manufacturing site: WAHL CLIPPER CORP. 2900 NORTH LOCUST ST. Sterling, IL USA 61081 FSC US FDA valid till 12-01-2022	3M Surgical Clipper with Pivoting Head (9661L) (clipper handle) Class A Shelf Life: N/A Fee submitted: Rs. 5,000/-	Cordless, rechargeable battery-operated hair clipper that uses disposable assemblies to remove body hair from patients in preparation for surgery or other times when hair removal is required	**Approved.**

2.	-do-	Manufacturer: M/s. 3M Company, 3M Centre, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN USA 55144 Manufacturing site: WAHL CLIPPER CORP. 2900 NORTH LOCUST ST. Sterling, IL USA 61081 FSC US FDA valid till 12-01-2022	3M Surgical Clipper Blade Assembly (9660) Class A Shelf Life: N/A Fee submitted: Rs. 5,000/-	Single-use pivoting clipper blade assembly to be used with 3M Surgical Clipper with Pivoting Head to remove body hair from patients in preparation for surgery or other times when hair removal is required	**Approved.**
3.	-do-	**Legal Manufacturer:** M/s 3M Company, 3M Health Care, 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN USA 55144, USA **Manufacturing Facility:** M/s 3M Company, 5400 Paris Rd Columbia, MO, USA 65202 **FSC USA valid till 23-05-2021**	3M™ Littmann® Classic III™ Stethoscope Codes: 5620, 5621, 5622, 5623, 5627, 5630, 5633, 5803, 5806, 5807, 5809, 5811, 5812, 5831, 5832, 5835, 5839,5861, 5862, 5863, 5864, 5868, 5870, 5871, 5872, 5873, 5874, 5875, 5959, 5960, 5962 Class A Shelf Life: N/A Fee submitted: Rs.5,000/-	Used for auscultation of heart, lung and other body sounds. It is use by healthcare professionals for medical diagnostic purposes only	**Approved**
4.	-do-	**Legal Manufacturer:**	3M™ Littmann® Classic II™	Used for auscultation of	**Approved**

		M/s 3M Company, 3M Health Care, 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN USA 55144, USA **Manufacturing Facility:** M/s 3M Company, 5400 Paris Rd Columbia, MO, USA 65202 **FSC USA valid till 23-05-2021**	Pediatric Stethoscope Codes: 2113, 2113R, 2119, 2122, 2153 Class A Shelf Life: N/A Fee submitted: Rs.5,000/-	heart, lung and other body sounds. It is use by healthcare professionals for medical diagnostic purposes only	
5.	-do-	**Legal Manufacturer:** M/s 3M Company, 3M Health Care, 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN USA 55144, USA **Manufacturing Facility:** M/s 3M Company, 5400 Paris Rd Columbia, MO, USA 65202 **FSC USA valid till 23-05-2021**	3M Littmann® Cardiology IV™ Stethoscope Codes: 6151, 6152,6153, 6154, 6155, 6516, 6158, 6159, 6162, 6163, 6164, 6165, 6166, 6167,6168, 6170, 6171, 6176, , 6179, 6190, 6200, 6201, 6202, 6203, 6204, 6205, 6206, 6232, 6234, 6238, 6240, 6241, 6242 Class A Shelf Life: N/A Fee submitted: Rs.5,000/-	Used for auscultation of heart, lung and other body sounds. It is use by healthcare professionals for medical diagnostic purposes only	**Approved**
6.	M/s Mubarik Vision, Basement 32-A, Usman Center, Shah Alam Market, Lahore	**Legal Manufacturer:** France Chirurgie Instrumentation SAS 20/22 Rue Louis	**J.A Bernard Lacrimal Probe** **Class A**	J.A Bernard Lacrimal Probe Single use instrument	**Approved** the product in the name of M/s

	ELI-00045	Arman (75015) Paris, France **Manufacturer Site** France Ghirurgie Instrumentation SAS, (FCI S.A.S 2 RUE CARL ZEISS 25000 BESANCON FCS Paris, France Date of issue 28.01.2019	**Shelf Life: Five years** **Codes & sizes:** **A8.4060** **SI.4025** **S1.4030**	indicated for lacrimal duct exploration	Mubarik Vision.
7.	M/s. Noor international, 29-D, Block 6, PECHS, **Karachi.** ELI-00061.	Legal Manufacturer: Kossan International Sdn Bhd Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 ¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.	**iNtouch V Natural** (Sterile powder free latex examination gloves) Codes & Sizes as per FSC. **Class-A.** claimed shelf life: 05-years.	Sterile powder free latex examination gloves.	**Approved.** Firm shall provide original & valid free sale certificate and agency agreement before issuance of registration letter.

15. RENEWAL OF 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 B.Braun Pakistan (Pvt) Ltd., The Forum, Suite No. 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006)	**Legal Manufacturer:** M/s B.Braun Melsungen AG Carl-Braun-Straβe 1 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia FSC Germany issued on 27-08-2019	Vasofix® Safety I.V. Cannulae (with injection port) Class: B Shelf life: 5 years Codes as per FSC Germany dated 27-08-2019 Fee submitted: Rs. 12,500/-	Shielded, indwelling I.V. cannula with injection port designed to minimize inadvertent needle sticks. Sterile, single-use	**Approved.**
2.	-do-	**Legal Manufacturer:** M/s B.Braun Melsungen AG Carl-Braun-Straβe 1 34212	Introcan Safety ® I.V. cannulae	An I.V. cannula without injection port	**Approved.**

		Melsungen, Germany **Manufacturing Site:** M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia FSC Germany issued on 27-08-2019	Class: B Shelf life: 5 years Codes as per FSC Germany dated 27-08-2019 Fee submitted: Rs. 12,500/-	that has safety shield which covers the needle after use to reduce the risk of accidental needle sticks. Sterile, single-use	
3.	-do-	**Legal Manufacturer:** M/s B.Braun Melsungen AG Carl-Braun-Straβe 1 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia FSC Germany issued on 27-08-2019	Vasofix® Braunule® I.V. cannulae (with injection port) Class: B Shelf life: 5 years Codes as per FSC Germany dated 27-08-2019 Fee submitted: Rs. 12,500/-	Indwelling I.V. cannula with injection port. Sterile, single-use	**Approved.**
4.	-do-	**Legal Manufacturer:** M/s B.Braun Melsungen AG Carl-Braun-Straβe 1 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia FSC Germany issued on 27-08-2019	Introcan®-W With In-stopper I.V cannulae Class: B Shelf life: 5 years Codes as per FSC Germany dated 27-08-2019 Fee submitted: Rs. 12,500/-	Indwelling I.V. cannula with wings and in-stopper. Sterile, single-use	**Approved**.
5.	-do-	**Legal Manufacturer:** M/s B.Braun Melsungen AG Carl-Braun-Straβe 1 34212 Melsungen, Germany	Introcan® I.V. cannulae (without injection port and wings)	Indwelling I.V cannula without wings and without	**Approved.**

		Manufacturing Site: M/s B. Braun Medical Industries Sdn. Bhd. Bayan Lepas Free Industrial Zone, 11900 Penang, Malaysia FSC Germany issued on 27-08-2019	Class: B Shelf life: 5 years Codes as per FSC Germany dated 27-08-2019 Fee submitted: Rs. 12,500/-	injection port. Sterile, single-use	

16. <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 19th meetings and deferred for provision of document. Now the firm has provided documents:-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision
1.	M/s Mana & Co., Office No. 401, 4th floor, Masood chamber Shahrah e Liaqat, Karachi., Karachi (ELI-00280) [2820]	**Legal Manufacturer:** M/s Xiamen Ants-bro Technology Co., Ltd, 4F, 5th Building, Technology Business Establishing Center, No.289 Wengjiao Road, Haicang District, Xiamen City, Fujian Province China FSC China Valid Till(07-04--2022) **FSC MHRA issuance 20-11-2020**	Medisign Digital Thermometer Class B Shelf Life: 04 Years Rs. 25,000/- Models: TM-2011 TM-3002	Digital Thermometer	**Approved.**
2.	M/s Global Marketing Services, 111, Hali Road Westridge 1,	**Legal Manufacturer:** M/s Copheid 904 Caribbean Drive	Xpert® FII & FV Xpert Factor II & Factor V Assay Class C	It is intended for qualitative in vitro diagnostic genotyping	**Approved.**

	Rawalpindi	Sunnyvale, CA 94089 USA (FSC USFDA Valid Till 17-12-2020)	 Shelf Life: 24 Months GXFIIFV-10	test for the detection of factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood.	
3.	-do-	**Legal Manufacturer:** M/s BioMerieux SA 376 Chemin De l' Orme 69280 Marcy I'Etolie, France **Manufacturing Site:** M/s BioMerieux SA 3 Route de Port Michand 38390 La Balme Les Grottes, France (FSC France Issuance Date: 05-07-2019)	E-Test Class B Shelf Life: 24 Months Codes & Sizes as per FSC	Etest is quantitative technique for determining the antimicrobial susceptibility of Gram-negative and Gram-positive aerobic bacteria such as enterobacteria cea.	**Approved.**
4.	-do-	**Legal Manufacturer:** M/s BioMerieux SA, 376 Chemin de l'Etoile, France (FSC France Issuance Date 13-12-2017)	VIDAS Total 05-OH Vitamin D (25-hydroxy Vitamin D IVD) Class B Shelf Life: 15 Months (455 Days) 30463	It is an automated quantitative test for use on the instruments of the VIDAS family for the determination of 25-hydroxyvitamin D total in human serum or plasma using ELFA Technique.	**Approved.**
5.	M/s. Schazoo SPL Consumer Health Care71 B/C2, Gulberg 3, Lahore.	**Legal Manufacturer:** Apharm S.R.L, Italy.	Vijoint hcc60 mg/3ml. (Hyaluronic acid Sodium Salt, Chondroitin	The Device is a synovial fluid substitute for use in joints	**Approved.**

	[ELI-00095]	**Manufacturing Site**: SOTHEMA, 1 Bousloura Casablanca Morrocco. Scanned copy of FSC of Italy (attested by embassy) provided.	Sulfate, Cyclodextrin) Claimed Shelf Life: 02-years Class C Rs.50,000/-	with degenerative or mechanical joint disese causing pain or impaired mobility.	
6.	M/s Imtiaz Brothers, Suits#7B, 2nd Floor, Abrar Business Center, 25-Main Wahdat Road, Lahore. ELI: 00133.	**Legal Manufacturer** M/s Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China FSC: China. Valid Till: 07-06-2020	STERILE SURGICAL Face Mask. Class-A. Shelflife: 05 years.		**Approved.**
7.	-do-	**Legal Manufacturer M/s** Guangzhou Fuzelong Hygiene Material Co., Ltd 12 # Guancum Road Jiangpu Street Conghua District Guangzhou City Peoples Republic of China. FSC: China Valid Till: 07-06-2020.	DISPOSABLE SURGICAL Gown Class- A. Shelflife: 05 years.		**Approved.**

17. <u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).</u>

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision
1.	M/s Schazoo SPL Consumer Healthcare, 71 B/C2, Gulberg 3, Lahore ELI: 00095	Legal Manufacturer: PCL Inc, Korea 701 Star Valley, Gasan Digital Complex Seoul, Korea	PCL Covid-19 Speedy RT-PCR Class- C Shelf life: As per stability study	PCL Covid 19 Speedy RT-PCR	**Approved** subject to provision of following documents:- • Full QA certificate. • Original and valid certificate with the status of Free Sale of country of origin. • Freeale Certificate of any SRA or CE certification as per NANDO Database or WHO pre-qualification of the subject product.
2.	-do-	Legal Manufacturer: PCL Inc, Korea 701 Star Valley, Gasan Digital Complex Seoul, Korea FSCL Korea	PCL Covid-19 Ag Gold Saliva Class-C Shelf life: As per stability study	PCL Covid 19 Ag Gold Saliva	**Approved** subject to provision of following documents:- • Full QA certificate. • Original and valid certificate with the status of Free Sale of country of origin. • Free Sale Certificate of any SRA or CE certification as per NANDO Database or WHO pre-qualification of the subject product.

3.	-do-	Legal Manufacturer: PCL Inc, Korea 701 Star Valley, Gasan Digital Complex Seoul, Korea FSCL Korea	PCL Covid-19 IgG/1gM Rapid Gold Class-C Shelf life: As per stability study	PCL Covid 19 IgG/1gM Rapid Gold	**Approved** subject to provision of following documents:- • Full QA certificate. • Original and valid certificate with the status of Free Sale of country of origin. • Free Sale Certificate of any SRA or CE certification as per NANDO Database or WHO pre-qualification of the subject product.
4.	-do-	Legal Manufacturer: PCL Inc, Korea 701 Star Valley, Gasan Digital Complex Seoul, Korea FSCL Korea	PCL Covid-19 Ag Rapid FIA. Class-C Shelf life: As per stability study	PCL Covid 19 Ag Rapid FIA	**Approved** subject to provision of following documents:- • Full QA certificate. • Original and valid certificate with the status of Free Sale of country of origin. • Free Sale Certificate of any SRA or CE certification as per NANDO Database or WHO pre-qualification of the subject product.
5.	Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8,	**Legal Manufacturer:** Siemens Health	**SIEMENS ATELLICA** IM	The **ATELLICA** IM SARS-CoV-2 Total (COV2T)	**Approved.** Firm shall provide

	Korangi Creek Industrial Park, Karachi (ELI-00037)	Care Diagnostics Inc. 511 Benedict Ave. Tarrytown NY 10591 USA	SARS-CoV-2 Total Kit. Class C Shelf life: 12 Month Codes & Sizes as per FSC	assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the **ATELLICA** IM Analyzer.	QC details of subject product before issuance of registrtion letter.
6.	-do-	**Legal Manufacturer:** Siemens Health Care Diagnostics Inc. 511 Benedict Ave. Tarrytown NY 10591 USA	ADVIA Centaur SARS-CoV-2 kit. Class C Shelf life: 12 Month. Codes & Sizes as per FSC	The ADVIA Centaur SARS-CoV-2 Total (COV2T) assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.	**Approved.** Firm shall provide QC details of subject product before issuance of registrtion letter.
7.	Excel Corporation, 435 BYJ Society, Bahadurabad, Karachi (ELI-00110)	**Legal Manufacturer:** M/s Vega Technologies Inc. 11F-13, No.100 Chang Chun Road 104, Taipei, **Taiwan.** **Manufacturing Site:** M/s Vega Technologies Inc. Yang Wu District, Da lang Town, Dong Guan City,	Senoir Mist Compressor Nebulizer Class B Service Life: Not provided Rs. 25,000/- Code : CN 02 MD	it is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders.	**Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.**

		Guang Dong, China **FSC Spain Issuance Date (Not mentioned & FSC is in Spanish)**			
8.	-do-	**Legal Manufacturer:** M/s Dongguan Aidisy Machinery & Electronic Equipment Co., Ltd., Part B 3rd F, Block A, Wentang Industrial Park, Longhua Road, Zhouwu Dongcheng District Dongguan City, Guangdong Province, P.R. China. FSC China Valid Till (09-04-2022)	Safety Nebusil-Compressor Nebulizer Class B Service Life: not mention Rs. 25,000/- Code: MCN-S600A	The Nebulizer Compressor is Intended to Provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for the treatment of respiratory disorders in conscious patients. It is not intended for life support nor does it provide anu patient monitering capabilities.	**Approved** subject to provision of following documents:- • Original (Sole Agency agreement, • FSC of country of origin, • ISO 13485, Production Quality Assurance system certificate. • Credentials of manufacturer and DoC.)
9.	-do-	**Legal Manufacturer:** M/s Jiangsu Zhiyu Medical Instrument Co., Ltd No. 88, Nanyuan Road, Industrial Park, West Taizing City, Jiangsu Province, China. FSC China Valid Till (02-04-2021)	Star Disposable Medical Face Mask Class A Shelf Life: N/A Rs. 5,000/- Codes & Sizes : 17.5*9.5	It is intended to prevent spread of germs and for protection against microbs, body fluids or large particles in air. It is also used during surgery, medical examination & diagnostic procedure.	**Approved** subject to provision of following documents:- • Original Sole Agency agreement, • FSC of country of origin, • ISO 13485, • Credentials of manufacturer, • DoC and EPSP.

10.	M/s New Pakistan Traders, Office No.306/1, Trade Tower, New Challi Road, Karachi (ELI-00161)	**Legal Manufacturer:** M/s Shanghai kinmed Import & Export Co., Ltd. Suit L, 12th Floor, NO. 588 Yingkou Road, Shanghai, China,\. FSC Germany , (Issuance date: 09-05-2016)	Green Face Masks Class A Shelf Life: N/A Rs. 5,000/- Codes & Sizes as per FSC	It is intended to prevent spread of germs and for protection against microbs, body fluids or large particles in air. It is also used during surgery, medical examination & diagnostic procedure.	**Approved** subject to provision of following documents:- • FSC of country of origin. • Credentials of manufacturer, • DoC, EPSP. • Original Sole Agency agreement, • ISO 13485, Production quality assurance system certificate.) • Copy of FSC of Germany with generic name of the product issued to the Kingdom of Saudi Arabia provided.(copyp rovided) FSC with brand name attested from the embassy of Pakistan is required.
11.	**M/s Roche Pakistan** Ltd., 1st Floor, 37-B, Block 6, PECHS, Karachi (ELI-00009)	Legal Manufacturer: M/s SD Biosensor, Inc. C-4th& 5th,16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si Gyeonggi-do 16690, Republic of Korea Manufacturing site: 74, Osongsaengmye	SARS-COV-2 Rapid Antigen Test (Device Kit) Class C Shelf Life: 24 Months (ongoing) Size: 25 tests Ref: 9901-NCOV-01G (Cat No: 09327592190)	Rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in human nasopharynx. Intended to detect antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19. This product is strictly intended for	**Deferred** for clarification of Sole Agency Agreement of the applied product from manufacturer abroad.

		ong 4-r0, Osongeup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea FSC Germany Issuance Date 19.11.2020 Certificate of Korea issued on 28-10-2020	Fee submitted: Rs.50,000/-	professional use in laboratory and point of care environments.	

18. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (FORM 6)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Unisa (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak, District Nowshera	UNIFEED (Sterile Single Use Plastic Syringes) 30mL/cc, 50mL/cc, 60mL/cc Class A Shelf Life: 05 Years Rs. 5,000/-	Sterile Single Use Plastic Syringes	**Approved** subject to provision of undertaking to submit stability studies data.
2.	M/s Lab Diagnostic Systems (SMC) Pvt Ltd, 111, Hali Road, Westridge 1, Rawalpindi (ELM-00028)	COVID-19 Collection & Transport Kit Class A Shelf Life: Transport Medium 12 Month from the manufacture date when stored at +2° C to + 30° C. Swab: Store at 2° C to 30°C	Viral specimen transfers solution / medium **Source:** M/s Jiangsu Kangjie Medical Devices Co., Ltd., Shengao Town People Village, Jiangyan District, Taizhou, Jiangsu, 225500, China	**Approved** subject to provision of undertaking to submit stability studies data.

		Expiry: 3years from the manufacturing date Rs. 5,000/-		

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19. 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 Global Marketing Services, 111, Hali Road Westridge1, Rawalpindi ELI: 00109	Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany FSCGermany issued on 10-08-2020	Enticos 4 DR (Dual Chamber Pacemaker-MR Conditional) Code: 407155 Class: D Shelf Life: 19 months Fee submitted: Rs. 50,000/-	Implantable pacemaker, MR conditional, sterile, single-use	**Approved** subject to provision of original and notarized Letter of Authorization, MRP. The firm shall subject separate application for other models.
2	M/s Global Marketing Services, 111, Hali Road Westridge1, Rawalpindi ELI: 00109	Manufacturer: Laboratorios Grifols, S.A Calle Can Guasch, 2. Poligono Industrial Levante, 08150 Parets del Valles (Barcelona) Spain FSC Spain issued on 06-2019	Leucored Grifols CPD-SAG-M WB (Blood bags containing anti-coagulant) Class:D Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Blood bags intended for collection of blood and preparation of red blood cell concentrates and plasma with pre-storage leukoreduction . Sterile	**Approved** subject to provision of Free Sale Certificate of Spain with English translation and MRP. The firfm shall submit separate application for other types.

20. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (FORM-7)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
	M/s Unisa (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak, District Nowshera	UNITUBE Disposable Feeding Tube. As applied. Class-B Shelf Life: 05 Years Rs. 20,000/-	Used to provide nutrition to people who cannot obtain through mouth.	**Approved** subject to provision of undertaking to submit stability studies data.

21. GRANT OF ESTABLIMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

Decision: The Board approved the Establishment License to Manufacture Medical Devices and futher advised M/s Pak Electron Beam Irradiation (Pvt) Limited, Karachi to establish microbiology laboratory for verification of sterility.

22. EXPORT-PERMIT FOR THE PURPOSE OF CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.

M/s Defence Science & Technology Organization (DESTO), Islamabad have applied for export of small quantities of medical devices or accessories or components for the purpose of clinical investigations, examination, test or analysis and requested for issuance of export permit for **Surgical Masks (Qty.150)** to be sent to **M/s Henan Mammoth, China** re-confirming the results taken in PPEs Testing Lab established in DESTO.

Decision: The Board approved the permit to export Surgical Masks (Qty.150) manufactured by M/s Defence Science & Technology Organization (DESTO), Islamabad to M/s Henan Mammoth, China for the purpose of test or analysis of mask manufactured by them subject to submission of Fee of Rs.1000/- and undertaking on stamp paper.

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

S.No	Name of Establishment	Director/Proprietor/ partners	Cold Chain (Yes/No)	Decision of MDB.
1.	M/s Johnson Mathew Pakistan (Pvt) Limited, Unit C-304, Falak Tower, Fere Town, Karachi. **Godown Address:** C-51, Fblock-3 (South Sector), Darul Aman Society, Haider Ali Road, Near Hill Park, Karachi.	Syed Muhammad Amir Ali Jafri. Mr. Almas Jafri.	No	**Approved** for storage of non cold chain medical devices.

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