

**DECISIONS OF THE 22<sup>ND</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 22-10-2020**

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

The following firms have applied for grant of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The inspections were conducted according to the Checklist as already approved by the MDB.

S.No	Name of Establishment	Director/Proprietor/partners	Cold Chain (Yes/No)	Decision
1.	M/s Dynatis Pakistan, Plot No. 710, Sunder Industrial Estate, Lahore.	Mr..Zahid Saeed Mr. Khalid Saeed Mr. Anwar Saeed Mr.Saeed Ismail	No.	<b>Approved</b> for storage of room temperature medical devices without cold chain facility.

**2. CORRECTION IN ALREADY APPROVED ESTABLISHMENT LICENSE OF M/S PHARMA LIFE DISTRIBUTORS, RAWALPINDI TO IMPORT MEDICAL DEVICES.**

Sr. No	Name of Establishment	Director/Proprietor/partners	Cold Chain (Yes/No)	Decision
1.	M/s Pharma Life Distributors, Office No. CB-94/1, Cobline, Near Askari-11, Sajid Bukhari Road, Afshan Colony, Rawalpindi.	Mr. Imran Rasheed	No.	<b>Approved</b> for storage of room temperature medical devices.

**Decision:** The Board approved the inclusion of name of Director i.e. Mr. Shahid Rasheed for issuance of Establishment License to import medical devices.

### 3. REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till 26-05-2022)	ARCHITECT Rubella IgM Kit  Class C (i) ARCHITECT Rubella IgM Reagent Code: 6C18-25 Shelf Life: 12Months  (ii) ARCHITECT Rubella IgM Control Code: 6C18-10 Shelf Life: 12Months  (iii) ARCHITECT Rubella IgM Calibrator Code: 6C18-01 Shelf Life: 12Months Fee submitted: Rs. 50,000/-	CMIA for the qualitative detection of IgM antibodies to rubella virus in human serum and plasma	<b>Approved.</b>
2.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till 26-05-2022)	Alinityi CMV IgG Kit  Class C (i) Alinityi CMV IgG Reagent Kit Code: 07P4222 Shelf Life: 12Months  (ii) Alinityi CMV IgG Reagent Kit Code: 07P4232 Shelf Life: 12Months  (iii) Alinityi CMV IgG Calibrators Code: 07P4201 Shelf Life:	CMIA used for the qualitative detection and semi-quantitative determination of IgG antibodies to Cytomegalovirus virus in human serum and plasma	<b>Approved.</b>

			12Months  (iv) Alinityi CMV IgG Controls Code: 07P4210 Shelf Life: 12Months  Fee submitted: Rs. 50,000/-		
3.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till 26-05-2022)	ARCHITECT CMV IgG Kit  Class C (i) ARCHITECT CMV IgG Reagent Code: 6C15-20 Shelf Life: 14Months  (ii) ARCHITECT CMV IgG Reagent Code: 06C15-25 Shelf Life: 14Months  (iii) ARCHITECT CMV IgG Reagent Code: 06C15-30 Shelf Life: 14Months  (iv) ARCHITECT CMV IgG Calibrator Code: 06C15-01 Shelf Life: 14Months  (v) ARCHITECT CMV IgG Control Code: 06C15-10 Shelf Life: 14Months  Fee submitted: Rs. 50,000/-	CMIA used for the qualitative detection and semi-quantitative determination of IgG antibodies to Cytomegalovirus virus in human serum and plasma	<b>Approved.</b>
4.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines,	Abbott RealTimeCT/NG Kit  Class C	An invitro PCR assay for direct qualitative detection of the plasmid DNA of C.	<b>Deferred</b> for provision of following documents/clarification:- (i) Provide Free Sale

		IL 60018, USA  (EXPORT ONLY certificate USFDA Valid Till 13-05-2020)	i) Abbott RealTime CT/NG Control Kit Code: 2G28-80 Shelf Life: 18 Months  ii) Abbott RealTime CT/NG Amplification Reagent Kit (4x48 Tests) Code: 2G28-91 Shelf Life: 18 Months  Rs.50,000/- (Challan:0580489)	trachomatis and the genomic DNA of N.gonorrhoeae in female endocervical or vaginal swab specimens, male urethral swab specimens, or in male and female urine specimens	Certificate in country of origin duly attested by Embassy of Pakistan.  (ii) Depositor copy of fee challan required to confirm fee.
5.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA  (EXPORT ONLY certificate USFDA Valid Till 13-05-2020)	Abbott RealTime CMV Kit  Class C  i) Abbott RealTime CMV Calibrator Kit Code: 5N23-70 Shelf Life: 18 Months  ii) Abbott RealTime CMV Control Kit Code: 5N23-80 Shelf Life: 18 Months  iii) Abbott RealTime CMV Amplification Reagent Kit Code: 5N23-90 Shelf Life: 18 Months  Rs.50,000/- (Challan:0580491)	An invitro PCR assay for quantitation of cytomegalovirus (CMV) DNA in human plasma or whole blood.	<b>Deferred</b> for provision of following documents/ clarification:- (i) Provide Free Sale Certificate in country of origin duly attested by Embassy of Pakistan. (ii) Depositor copy of fee challan required to confirm fee.
6.	-do-	Manufacturer: M/s Abbott Molecular Inc., 1300 East	Abbott RealTime EBV Kit  Class C	An invitro PCR assay for quantitation of Epstein-Bar	<b>Deferred</b> for provision of following documents/

		Touhy Avenue Des Plaines, IL 60018, USA  (EXPORT ONLY certificate USFDA Valid Till 13-05- 2020)	i) Abbott RealTime EBV Calibrator Kit Code: 08N54-070 Shelf Life: 18 Months  ii) Abbott RealTime EBV Code: 08N54-085 Shelf Life: 18 Months  Rs.50,000/- (Challan:0580493)	Virus (EBV) DNA in human plasma or whole blood.	clarification:- (i) Provide Free Sale Certificate in country of origin duly attested by Embassy of Pakistan. (ii) Depositor copy of fee challan required to confirm fee.
7.	-do-	<b>Manufacture r:</b> Abbot GmbH & Co, KG Max-Planck- Ring 2 65205 Wiesbaden Germany.  (FSC Germany Issuance 19- 07-2018)	Alinity EBV VCA IgM Kit Class C  1. Alinity EBV VCA IgM Reagent Kit Code: 09P2222 Shelf life: 11 Months  2. Alinity EBV VCA IgM Reagent Kit Code: 09P2232 Shelf life: 11 Months  3. Alinity EBV VCA IgM Calibrators: Code: 09P2201 Shelf life: 17 Months  4. Alinity EBV VCA IgM Controls Code: 09P2210 Shelf life: 18 Months  Fee submitted: Rs.50,000/-	CMIA used for the qualitative detection of IgM antibodies to Epstein-Bar Virus (EBV) Viral Capsid Antigen (VCA) in human serum and plasma	<b>Approved.</b>
8.	-do-	Legal Manufacturer:	Alinity c CRP Vario Reagent Kit	Alinity c CRP Vario Reagent,	<b>Approved.</b>

		M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	Alinity c CRP Vario Wide Range Calibrator Kit Alinity c CRP Vario High Sensitivity Calibrator Kit Alinity c CRP Vario HS Control Kit Alinity c Immuno Control-1 Kit Alinity c Immuno Control 2 Kit Alinity c Immuno Control Set Codes & Sizes as per FSC of SRA.	control and its Calibrator Kit are used for QN assay of C- reactive protein in human serum or plasma. • Claimed Shelf-life: 18months.	
9.	-do-	Legal Manufacturer: M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	CRP Vario CRP Calibrator Set CRP Calibrator WR CRP Calibrator HS CRP Control HS Immuno Control 1 Immuno Control 2 Immuno Control Set  Codes & Sizes as per FSC of SRA.	CRP Vario Calibrator and immune control Kit are used for QN assay of C- reactive protein in human serum or plasma. • Claimed Shelf-life: 24- months.	<b>Approved.</b>
10.	-do-	Legal Manufacturer: M/s Alere Scarborough, Inc. 10 Southgate Road, Scarborough, ME 04074, USA.  FSC USFDA Valid Till (31-05-2020)	BinaxNOW Malaria  Codes & Sizes as per FSC of SRA.	BinaxNOW Malaria test for QL detection of <i>P. Falciparum</i> , <i>P. Pan</i> & <i>P.</i> <i>vivax</i> . Via ICT method. • Claimed Shelf-life: 24- months	<b>Approved.</b>
11.	-do-	M/s Abbott Diabetes Care Ltd. Range Road, Witney, Oxon OX29 0YL, UK	FreeStyleOptium <b>B-Ketone Test</b> Strips  Codes & Sizes as per FSC of SRA.	• To measure the ketone bodies from human serum or plasma. • Claimed	<b>Deferred</b> for provision of following:- 1. Manufacturing and QC details. 2. EPSP

		FSC UK Issuance Date (10-04-2018)		Shelf-life: 18months	3. Brochures. 4. Sample of packaging 5. Stability studies 6. Correction/ clarification of GMDN with reference
12.	-do-	Legal Manufacturer: M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	UIBC, Iron IVD Testing reagent kit.  Codes & Sizes as per FSC of SRA.	Multigent iron assay for direct colorimetric detection of Iron in human serum or plasma. • Claimed Shelf-life: 18months.	<b>Approved.</b>
13.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy. FSC Italy Issuance Date (18-06-2018)	Alinity c Ceruleplasmin Reagent Kit Alinity c Plasmaproteins Cal 3x Kit. Codes & Sizes as per FSC of SRA.  <b>Class-B</b>	Alinity c Ceruleplasmin Reagent kit used for the quantitative determination of plasma protein in human serum and plasma.	<b>Approved.</b>
14.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy. FSC Italy Issuance Date (18-06-2018)	Creatinine (Enzymatic)  Codes & Sizes as per FSC of SRA. <b>Class-B</b>	Creatinine Enzymatic reagent kit used for quantitative determination of creatinine in human serum and plasma.	<b>Approved.</b>
15.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy	Alinity c Dibucaine (CHE) Reagent Kit Alinity c Cholinesterase Reagent Kit Alinity c Clinical Chemistry Control 1 Kit Alinity c Clinical	Alinity c Dibucaine (CHE) Reagent Kit used for quantitative determination of c Dibucaine (CHE) pseudo cholinesterase in human serum	<b>Approved.</b>

		Issuance Date (18-10-2018)	Chemistry Control 2 Kit Codes & Sizes as per FSC of SRA. <b>Class-B</b>	and plasma.	
16.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	Alinity c Creatinine (Enzymatic) Reagent Kit Codes & Sizes as per FSC of SRA. <b>Class-B</b>	Alinity c Creatinine Enzymatic reagent kit used for quantitative determination of creatinine in human serum and plasma.	<b>Approved.</b>
17.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	Alinity c UIBC Reagent Kit  Alinity c UIBC Calibrator Kit  Alinity c Iron Reagent Kit  Codes & Sizes as per FSC of SRA. <b>Class-B</b>	UIBC Reagent Kit reagent kit used for quantitative determination of UIBC, iron in human serum and plasma.	<b>Approved.</b>
18.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-10-2018)	Alinity c Total Bile Acids Reagent Kit Alinity c Total Bile Acids Calibrator Kit  Codes & Sizes as per FSC of SRA. <b>Class-B</b>	Total Bile Acids Reagent Kit used for quantitative determination of Total Bile Acids in human serum and plasma.	<b>Approved.</b>
19.	-do-	<b>Legal Manufacturer:</b> M/s Abbott Ireland Diagnostics Division, Fininklin Business Park, Sligo, Ireland. FSC Ireland Valid Till (28-05-2024)	Alinity I B.R.A.H.M.S PCT  Codes & Sizes as per FSC of SRA.	The assays are chemiluminescent microparticle immunoassays (CMIA) for the QN determination of procalcitonin (PCT) in human serum and plasma (lithium heparin and	<b>Approved.</b>



				K2EDTA) on the Alinityi and ARCHITECT analyzers.	
20.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-06-2018)	Dibucaine (CHE) Cholinesterase ClinChem Cal ClinChem Control 1 ClinChem Control 2  Codes & Sizes as per FSC of SRA. Class-B	Dibucaine (CHE) used for quantitative determination of Dibucaine (CHE), Cholinesterase, ClinChem in human serum and plasma.	<b>Approved.</b>
21.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-06-2018)	Ceruloplasmin Copper Plasmaproteins Cal 3x  Codes & Sizes as per FSC of SRA.	Ceruloplasmin Copper Reagent kit used for the quantitative determination of plasma protein in human serum and plasma.	<b>Approved.</b>
22.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-06-2018)	Cystatin C Cystatin C Calibrator Cystatin C Control Set Fructosamine Fructosamine Control 1 Fructosamine Control 2. Codes & Sizes as per FSC of SRA.	Cystatin C Reagent kit used for the quantitative determination of Cystatin C in human serum and plasma.	<b>Approved.</b>
23.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.	HBDH ClinChem Cal ClinChem Control 1 ClinChem Control 2.  Codes & Sizes as per FSC of SRA.	HBDH Reagent kit used for the quantitative determination of HBDH, ClinChem in human serum and plasma.	<b>Approved.</b>

		FSC Italy Issuance Date (18-06-2018)			
24.	-do-	<b>Legal Manufacturer:</b> M/s Sentinel CH. Spa Via Robert Koch 2-20152 Milano, Italy.  FSC Italy Issuance Date (18-06-2018)	Ammonia Ultra Ammonia Controls  Codes & Sizes as per FSC of SRA.	Ammonia Ultra Reagent kit used for the QN determination of Ammonia in human serum and plasma.	<b>Approved.</b>
25.	-do-	<b>Legal Manufacturer:</b>  Abbott GmbH & Co, Kg Max-Planck- Ring 2 65205 Wiesbaden Germany.  (FSC Germany issue 19-07-2018)	Alinityi SCC Kit  Class C  Sizes & Codes as Per FSC Alinityi SCC Calibrators 09P3301 Shelf Life: 24 Months  Alinityi SCC Controls 09P3310 Shelf Life: 24 Months  Alinityi SCC Reagent Kit (2x100 tests) 09P3322 Shelf Life: 12 Months  Alinityi SCC Reagent Kit (2x600 tests) 09P3332 Shelf Life: 12 Months	The Alinityi SCC assay is used for the quantitative determination of squamous cell carcinoma antigen (SCC Ag) in human serum and plasma on the Alinityi analyzer.	<b>Deferred</b> for provision of stability studies.
26.	-do-	<b>Legal Manufacturer:</b>  M/s Abbott	FreeStyleOptium Blood Glucose Test Strips  Class C	Blood Glucose Test Strips	<b>Deferred</b> for provision of Stability studies, Labels and Codes required which are not

		Diabetes Care Ltd., Range Road, Witney, Oxon, OX29 0YL, UK  (FSC UK issuance 10-04-2018)	Shelf Life: 18 Months  Sizes & Codes as Per FSC  99052-75, 99054-77		mentioned in FSC.
27.	-do-	<b>Legal Manufacturer:</b>  Abbott Ireland Diagnostics Division LisnamuckLongford Co. Longford Ireland.  (FSC Ireland issue 03-09-2023)	Alinityi 25-OH Vitamin D Alinityi B12  Alinityi 25-OH Vitamin D Alinityi B12  Class B  Alinityi 25-OH Vitamin D 15 Months Alinityi B12 11 Months	Alinityi 25-OH Vitamin D Alinityi B12  Alinityi 25-OH Vitamin D Alinityi B12	<b>Deferred</b> for provision of PQMS certificate, Label of Alinityi Vitamin B-12 Reagent kit (07P67-32) and MRP of the device.
28.	M/s Vertex Medical PvtLTd, 70-B-1, Gulberg-II Lahore ELI: 00150	Legal manufacturer  ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö Sweden  FSC: Sweden  Valid till 25.05.2020	Enterprise 9000X  (Acute Care Electrical Hospital Bed)  Class: A  Service Life:10 years	Acute Care Electrical Hospital Bed	<b>Approved.</b>
29.	-do-	Legal manufacturer  ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö Sweden  FSC: Sweden	Enterprise 8000X  (Acute Care Electrical Hospital Bed)  Class: A  Shelf Life:10 years	Acute Care Electrical Hospital Bed	<b>Approved.</b>

		Valid till 25.05.2020			
30.	-do-	Legal manufacturer  ArjoHuntleigh AB Hans Michelsensgat an 10 211 20 Malmo Sweden  FSC: Sweden  Valid till 25.05.2020	Enterprise 5000X  (Acute Care Electrical Hospital Bed)  Class: A  Shelf Life:10 years	Acute Care Electrical Hospital Bed	<b>Approved.</b>
31.	-do-	Legal manufacturer  Soluscope SAS 100 Rue du Gauge -ZI, les Paluds 13400 AUBAGNE France  FSC: France  Date of issue: 10-07-2019	SOLUSCOPE GTA  (Disinfectant)  Class- C  Shelf Life: 35 months Codes & sizes: SL-V1-GTA SOLUSCOPE SERIE 1	Cleaner for Endoscope	<b>Deferred</b> for provision of original and valid letter of Authorization and QMS certificate.
32.	-do-	Legal manufacturer  Soluscope SAS 100 Rue du Fauge - Z.I.LesPaluds 13400 Aubange- France  FSC: France Date of issue: 10.07.2019	SOLUSCOPE EZ  (Cleaner for Endoscope)  Code: SL-V1-PA SOLUSCOPE SERIE 1  Class: A  Shelf Life: 36 months	Cleaner for Endoscope	<b>Deferred</b> for provision of original and valid letter of Authorization and QMS certificate.
33.	-do-	Legal Manufacturer  MIMP Mammendorfe r Institute fur Physik un Medizin GmbH Oskar-	EZ Pad MRI  Class-A  Shelf Life: not mentioned  Codes & sizes: 5300202 (S)	Single use ECG Electrodes	<b>Deferred</b> for provision of Stability studies and Essential principles of safety & performance.

		von-Miller Str. ^ 82291 Mammendorf, Germany  FSC: Germany  Date of issue: 20-04-2020.	5300203 (L)		
34.	-do-	Legal manufacturer  Soluscope SAS 100 Rue du Fauge - Z.I.LesPaluds 13400 Aubange- France  FSC: France Date of issue: 10.07.2019	Soluscope SERIE 1 (Endoscope Washer/Disinfecto r)  Code & Sizes: Not mentioned  Class- C  Shelf Life: 35 months	Endoscope Washer/Disinfe ctor	<b>Deferred</b> for provision of original and valid letter of Authorization, QMS certificate and labels .
35.	-do-	Legal Manufacturer Dragerwerk AG &Co, KGaAMoislin gerAllee 53- 55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstr abe 1 23560 Lubeck, Germany.  FSC: Germany Date of issue: 15-10-2019	Ergo Star  Tracheal Tube Adapter  Class B  Shelf Life: 3 years Codes & sizes: CM 40, CM 45, CM 50, CM 55, CM 60, CM 90, CM 95	Purpose of device is not clear.	<b>Deferred</b> for provision of following documents  1. Notarized credentials of manufacturer abroad 2. Stability studies supporting claimed shelf life 3. IFU and device description 4. Essential principles of safety and performance
36.	-do-	Legal Manufacturer Dragerwerk AG &Co, KGaAMoislin	Drager Water Lock 2  Class-B	Drager Water Lock safely stops water from getting into the multi-	<b>Deferred</b> for provision of following documents  1. Notarized

		gerAllee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany.  FSC: Germany Date of issue: 15-10-2019	Shelf Life: 5 years Codes & sizes: Not mentioned	gas sensor.	credentials of manufacturer abroad 2. Stability studies supporting claimed shelf life 3. IFU and device description 4. Essential principles of safety and performance 5. Clarification of grouping of applied device in family (Infinity ID water lock 2 & Water Lock 2)
37.	-do-	Legal Manufacturer Dragerwerk AG & Co, KGaAMoislingerAllee 53-55 23542 Lubeck, Germany Manufacturing site: Dragerwerk AG & Co. KGaARevalstrabe 1 23560 Lubeck, Germany.  FSC: Germany Date of issue: 15-10-2019	Drager  Infinity ID Flow sensor  Class-B  Shelf Life: Not mentioned Codes & sizes: 5x	Flow sensor	<b>Deferred</b> for provision of following documents  1. Notarized credentials of manufacturer abroad 2. Stability studies supporting claimed shelf life 3. IFU and device description 4. Essential principles of safety and performance Moreover the firm shall apply separately for Spirolog & Spirolife.
38.	-do-	Legal Manufacturer M/s Sorin Group Italia S.r.l., 1340 Saluggia (VC), Italy FSC: Italy Date of issue: 02-03-18	Carbomedics Supra Annular Aortic (Top Hat) Class D Shelf Life: 05 Years Rs. 50,000/- Codes & sizes: S5-019, S5-021, S5-023, S5-025, S5-027	Carbomedics Aortic	<b>Deferred:</b> Board observed that heart valves of Sorin Group Italia are already registered in the name of M/s Pharma Consultant Pakistan, Lahore and therefore deferred the case for clarification of sole agency from the manufacturer abroad

					to be provided by the firm.
39.	M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092)	<b>Legal Manufacturer:</b> Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12 <sup>th</sup> Floor, No. 588 Yingkou Road, Shanghai. China.  (FSC Issuance 20-06-2018)	Kinmed auto Disable Syringe  1ml, 3ml, 5ml, 10ml, 20ml  Class B Shelf Life: 5 Years	Auto Disable Syringe	<b>Deferred</b> for the provision of FSC, LOA and all relevant documents for AUTO-DISABLE syringes
40.	M/s. RA Healthcare (SMC-PVT) Limited 2 <sup>nd</sup> Floor, Building# 50, Mir Arcade, Mini Commercial, Phase 7, BahriaTown, Islamabad. (ELI-00482)	<b>Legal Manufacturer:</b> Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ High-Tech Park, Shanghai, P.R. China. <b>Manufacturer Site(s):</b> Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Road 201203; Shanghai, P.R. China. 1. Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road 201203;	<b>FIREFIGHTER™</b> PTCA Balloon Catheter <b>Class: D.</b> Codes & Sizes as per FSC of SRA.	Firefighter™ PTCA Balloon Catheter is a semi-compliant Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange System that consists of an integrated shaft and a balloon at the distal end of the catheter.	<b>Approved</b> subject to provision of real time stability data for shelf life.

		<p>Shanghai, P.R. China.</p> <p><b>Sterilization site:</b> Shanghai MicroPort Medical (Group)Co. Ltd. Building 4 No, 51 Hangfan Road 201316; Shanghai P.R. China.</p>			
41.	-do-	<p><b>Legal Manufacturer:</b> Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ High-Tech Park, Shanghai, P.R. China.</p> <p><b>Manufacturer Site(s):</b> Shanghai MicroPort Medical (Group) Co, Ltd 501 Newton Road 201203; Shanghai, P.R. China.</p> <p>2. Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road 201203; Shanghai, P.R. China.</p> <p><b>Sterilization site:</b> Shanghai MicroPort</p>	<p><b>FOXTORT™</b> NC PTCA Balloon Catheter.</p> <p>Codes &amp; Sizes as per FSC of SRA.</p> <p><b>Class: D</b></p>	<p><b>FOXTROT™</b> 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 dilatation catheter to, and through the stenosis to be dilated. The dilatation catheter is coated with</p>	<p><b>Deferred</b> for provision of stability data of the product.</p>



		Medical (Group)Co. Ltd. Building 4 No, 51 Hangfan Road 201316; Shanghai P.R. China.		hydrophilic coating.	
42.	-do-	<p><b>Legal Manufacturer:</b> Shanghai MicroPort Medical (Group) Co., Ltd. 501 Newton Rd, ZJ High-Tech Park, Shanghai, P.R. China.</p> <p><b>Manufacturer Site(s):</b> Shanghai MicroPort Medical (Group) Co., Ltd 501 Newton Road 201203; Shanghai, P.R. China.</p> <p>3. Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road 201203; Shanghai, P.R. China.</p> <p><b>Sterilization site:</b> Shanghai MicroPort Medical (Group)Co. Ltd. Building 4 No, 51 Hangfan Road 201316;</p>	<p><b>FOXTORT™ PROPTCA</b> Balloon Catheter. <b>Class: D</b> Codes &amp; Sizes as per FSC of SRA.</p>	<p>FOXTROT™ PRO PTCA (Percutaneous Transluminal Coronary Angioplasty) balloon catheter has an integrated shaft system balloon near the distal tip. The shaft has a combination of single lumen and dual lumens tubing. One lumen is used for inflation of the balloon with contrast medium, and the second lumen in the distal shaft, permits the use of a guide-wire to facilitate advancement of the dilatation catheter to, and through the stenosis to be dilated. The dilatation catheter is coated with hydrophilic coating.</p>	<p><b>Approved</b> subject to provision of real time stability data.</p>

		Shanghai P.R. China.			
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**4. CASES WHICH WERE APPROVED IN PREVIOUS MDB MEETINGS SUBJECT TO PROVISION OF DOCUMENTS.**

Following applications for enlistment/registration were approved in previous MDB meetings (Meeting No. tabulated below) for want a certain document/information on part of the applicant firms. The desired information has been provided by the firms and submitted for information of MDB before issuance of enlistment/registration letter to the applicant firms: -

<b>Sr.#</b>	<b>Name and Addresses of Applicant.</b>	<b>Manufacture Details</b>	<b>Name of Medical Device with sizes /Class/Shelf Life, Description</b>	<b>Decision</b>
<b>1.</b>	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019)	<b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)	Tobramycin (Kit) Class C 1. Tobramycin Code: 7F93-20 Shelf life: 12 months  2. Tobramycin Calibrators Code: 7F93-01 Shelf life: 15 months  Rs.50,000/- (Challan: 0580474) Intended for the quantitative determination of tobramycin in human serum or plasma on the Architect c Systems.	<b>Approved</b>
<b>2.</b>	-do-	<b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)	Amikacin (Kit) Class C Amikacin Code: 6L35-20 Shelf life: 12 months  Rs.50,000/- (Challan:0580480) Intended for the quantitative	<b>Approved</b>

			determination of amikacin in human serum or plasma on the Architect c Systems	
3.	-do-	<p><b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)</p>	<p>Valproic Acid (Kit) Class C 1. Valproic acid Code: 1E13-20 Shelf life: 12 months Rs.50,000/- (Challan:0580478) Valproic Acid assay is used for the quantitative in vitro measurement of valproic acid in human serum or plasma on the architect c System.</p>	<b>Approved</b>
4.	-do-	<p><b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)</p>	<p>Vancomycin (Kit) Class C Vancomycin Code: 6E44-21 Shelf life: 12 months Rs.50,000/- (Challan:0580483) Intended for the quantitative determination of vancomycin in human serum or plasma on the Architect c System</p>	<b>Approved</b>
5.	-do-	<p><b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)</p>	<p>Gentamicin (Kit) Class C Gentamicin Code: 1E11-20 Shelf life: 12 months Rs.50,000/- (Challan:0580481) Intended for the quantitative determination of gentamicin in human serum or plasma on the Architect cSystem.</p>	<b>Approved</b>

## 6. DEFERED CASES OF REGISTRATION/ENLISTMENT FOR IMPORT.

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

Sr.#	Name and Addresses of Applicant.	Manufacture Details	Name of Medical Device with sizes /Class/Shelf Life, Description	Decision
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	<b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)	Phenytoin (Kit) Class C Phenytoin Code: 5P08-21 Shelf life: 18 months Rs.50,000/- (Challan:0580477) Intended for the quantitative measurement of phenytoin in human serum or plasma on the Architect c System	Approved
2.	-do-	<b>Manufacturer:</b> M/s. Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA valid till 06-11-2020)	Quinidine (Kit) Class C Quinidine Code: 6L31-20 Shelf life: 12 months Rs.50,000/- (Challan:0580482) Intended for the quantitative determination of quinidine in human serum or plasma on the Architect c System.	Approved
3.	-do-	<b>Legal Manufacturer:</b> Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea.  (FSC Republic of Korea Issuance 11-03-2019)  Authorization valid	SD BIOLINE Chlamydia, Device  (Rs: 50000/-) Class C Shelf Life:18 Months (Cat.No. 09FK10) Product license no. 14-2088 The SD Bioline Chlamydia is a solid phase immunochromatographic assay for the rapid, qualitative detection of	The Board approved withdrawal of application

		till 21-03-2024.	Chlamydia antigen directly from endocervical swab and cytology brush specimens. This test is intended for professional use as an aid in the presumptive diagnosis of chlamydial infection.	
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**7. REGISTRATION OF COVRAID ARTIFICIAL INTELLIGENCE-BASED XRAY SOFTWARE TOOL FOR DETECTION OF COVID-19.**

**Decision:**

**The Board after profound discussion approved the product for secondary detection of COVID-19. However, M/s NECOP is required to submit quarterly reports for next two years of the diagnostic tool to be presented in MDB meetings. The Board also directed M/s NECOP to forward the said software i.e., the COVRAID (medical device) for its software validation processes to the Center of Artificial Intelligence, Punjab within period of 3 months.**

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