# Government of Pakistan Ministry of National Health Services, Regulation & Coordination Drug Regulatory Authority of Pakistan

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# $\frac{\text{DECISIONS OF THE 35}^{\text{TH}} \text{ MEETING OF THE MEDICAL DEVICE BOARD (MDB)}}{\text{HELD ON } 14\text{-}07\text{-}2021}$

# Item No. II. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

S.#	Name of Establishment	r/partners	Cold Chain (Yes/No)	Decision
1.	M/s Shafia Enterprises 2 <sup>nd</sup> floor, Nigar Center, Patiala Ground link Mcleod Road, Lahore	Mr. Shahzad Ahmed	No	<b>Approved</b> for storage of non cold chain medical devices.
2.	M/s Maven Healthcare House no. 11, Canel Park Gulberg II, Lahore.	Mr. Ayaz Ahemd	No	Approved for storage of non cold chain medical devices.
3.	M/s Biliness (SMC ) Private Limited, Ground Floor Hameed Building, Bakkar Mandi, Band Road Lahore.	Muhammad Usama	No	Approved for storage of non cold chain medical devices.
4.	M/s Zhong Pak Facilitators, KandiArbab Sikandar Khan Khalil,Tehkal Bala, Peshawar.	Arbab Shafiq Ahmed Khan Arbab Daud Khan	No	<b>Approved</b> for storage of non cold chain medical devices.
5.	M/s. ZH Traders, House no. 16, Street No. 03, Sharif Park Begum Pura Lahore.	Mirza Maqbool Baig	No	<b>Approved</b> for storage of non cold chain medical devices.

6.	M/s Digitronics, 17, 7 <sup>th</sup> Floor, Rimpa Plaza, M.A. Jinnah Road, Karachi.	Ahmed Iltemas Usmani	No	<b>Rejected.</b> The firm has storage facility on 7 <sup>th</sup> Floor. Storage facility consists of 10' x 10' room, also office sitting arrangementat same room. No any appropriate ventilation and exit/ entrance.
7.	M/s Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Indutrial Area, Karachi.	Mr. Aleem Ahmed	No	Approved for storage of non cold chain medical devices.
8.	M/s T.K. Medical Instruments Company Plot No. C/2, Punjabi Colony, Federal Capital Area, Liaqatabad No. 4, Karachi.	Nirmila Namwer Lal	No	Approved for storage of room temperature medical devices
9.	M/s. 3C International 1620, Main Doubel Road, Sector I-10/1, Islamabad.	Mr. Sharafat Ali Muhammad Waqas	No	Approved for storage of warm range ofmedical devices
10.	M/s Hanson International, Office No.57-D, , Block DHA, EME Multan Road, Lahore.	Muhammad Shafiq	No	Approved for storage of room temperature medical devices
11.	M/s Techsource Enterprises B-36, Karachi University Employees Co-operative Housing Society, Madras Chowk, Gulzar-e-Hijri, Karachi.	Shariq Hassan	No	Rejected, the firm have valid DSL, however firm requested 15 days time to improve documentation and to arrange dedicated storage facility for room temperature and temperature sensitive medical devices as per GDPMD checklist.  Still no compliance shown by the firm till date 26-06-2021 even after several reminders.
12.	M/s. Koncept Technologies	Mr. Adnan Kamil	No	Approved for storage of room temperature and temperature

	A1-198, Block 13A, Railway Society, Gulshan-E-Iqbal, Karachi.	Mirbaz Khan		sensitive medical devices
13.	M/s Asfand Traders 402, 4th floor, Marium Heights, K.C.H.S, Block 7&8, CCA Area Near Baloch Colony Flyover, Shahrah-e- Faisal, Karachi.	Asfand Yar Wali	No	<b>Rejected,</b> the firm has requested to shift the premises for storage of medical devices for suitable area as current storage facility is located on 4 <sup>th</sup> floor of building having no passenger /cargo lift not commence to lift the medical equipment at that place, for this firm required 15 days time but no compliance shown by the firm after 15 days.
14.	M/s. Sanabal Ventures (Pvt) Ltd, 13-L, Model Town Lahor	Mr. Ikram ul Haq Qureshi Mr. Umiar Ikram Mr. Mohammad Ali Qureshi Mr. Uzair Ikram Qureshi Mr. Osama Ikram Qureshi	No.	Approved for storage of room temperature medical devices.

# Item No.II. POST LICENSE VARIATIONS.

# Case No.1.

M/s Meritorius Business Solutions (Pvt) Ltd, Office 202, 2<sup>nd</sup> Floor, 153-D,Civic Center, Phase-4, Bahria Town,Rawalpinndi has requested for approval of change of their qualified technical person in their ELI-00208 issued on 18-10-2018 as per detail given below:-

<b>Existing Qualified Technical Person</b>	Proposed Qualified Technical Person		
Mr.Nazeer-ud-din Ahsan, House No.	Muhammad Haris Muteeb Baig, House		
609, StreetNo.4, Setor I-9/4, Islamabad.	No.31/CA, Mohallah Chihtian Abad Pindora,		
CNIC No.61101-8131531-7	Rawalpindi.		
	CNIC No.37405-7830700-7		
	B.Sc BiomedicalEngineering.		

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

<b>Previous Qualified Technical Person</b>	New Approved Qualified Technical	
	Person	
Mr.Nazeer-ud-din Ahsan, House No.	Muhammad Haris Muteeb Baig, House	
609, StreetNo.4, Setor I-9/4,	No.31/CA, Mohallah Chihtian Abad	
Islamabad.	Pindora, Rawalpindi.	
CNIC No.61101-8131531-7	CNIC No.37405-7830700-7	
	B.Sc Biomedical Engineering.	

### Case No.2.

M/s Bain Medical (SMC-Pvt) Ltd, Shop No.2,Ground Floor, Plot 58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi has requested for approval of change of establishment name in their ELI-00614 issued on 03-12-2020, as per detail given below:-

Existing name and address of Etablishment	Proposed name and address of Etablishment
M/s Bain Medical (SMC-Pvt) Ltd, Shop	M/s Bain Medical Private Limited, Ground
No.2, Ground Floor, Plot -58-C, Street No.24,	Floor with Mezzanine, Plot -58-C, Street No.24,
Touheed Commerial Area, Phase-5, DHA,	Touheed Commerial Area, Phase-5, DHA,
Karachi	Karachi

Decision: The Board acceded to the request of the firm /company and approved the change of title of the firm as mentioned below:-

Previous name and address of Etablishment	New Approved name and address of Etablishment		
M/s Bain Medical (SMC-Pvt) Ltd,	M/s Bain Medical Private Limited, Ground		
Shop No.2, Ground Floor, Plot -58-C,	Floor with Mezzanine, Plot -58-C, Street		
Street No.24, Touheed Commerial	No.24, Touheed Commerial Area, Phase-5,		
Area, Phase-5, DHA, Karachi	DHA, Karachi		

### Case No.3.

M/s Mars Enterprises, Office No.4, Jason Center,2<sup>nd</sup> Floor, BC-8, Block-9,Clifton, Karachi has requested for approval of change of office address in their ELI-00097, issued on 03-08-2018, as per detail given below. There is no change in godown address:-

<b>Existing office address of Etablishment</b>	Proposed office address of Etablishment
M/s Mars Enterprises, Office No.4, Jason	Office No.S-43, GlassTower, 2 <sup>nd</sup> Floor, Block-
Center,2 <sup>nd</sup> Floor, BC-8, Block-9, Clifton,	8, Frere Tower, Clifton, Saddar Town, Karachi-
Karachi	South.

Decision: The Board acceded to the request of the firm /company and approved the change of office address as mentioned below:-

Existing	office	address	of	Proposed office address of Etablishment
Etablishme	ent			
M/s Mars Enterprises, Office No.4,				Office No.S-43, GlassTower, 2 <sup>nd</sup> Floor,
Jason Cente	er,2 <sup>nd</sup> Floor	, BC-8, Block	-	Block-8, Frere Tower, Clifton, Saddar Town,
9,Clifton, I	Karachi			Karachi-South.

### Item No.III. POST REGISTRATION VARIATIONS

#### Case No.01.

M/s B.Braun Pakistan (Pvt) Ltd, The Forum, Shite 216, Khayaban-e-Jami, Clifton Block-9, Karachi has stated with reference to renewalletter dated 10<sup>th</sup> March, 2021 for products category (IVC's), as stipulated in the Medical Devices Rule, 2017, clause 19 sub clause (4) which states that labeling information has to include license number, registration number, maximumretail price, as approved for the purpose of enlistment or registration of medical device shall be clearly specified in the labeling.

They have further stated that renewal of registration of below mentioned products, they have communicated to their Global Production /Site that registration numbers have to be changed after renewal of products under Medical Devices Rules, 2017:-

S.No.	Prouct Name	Old Regn.	New Regn.
		Number	Number
1.	Introcan	062281	MDIR-0002279
2.	Introcan Safety	062280	MDIR-0002276
3.	Introcan -W with In-Stopper	062282	MDIR-0002278
4.	Vasofix Braunule	062283	MDIR-0002277
5.	Vasofix Safety	062284	MDIR-0002275

Furthermore, according to their Company's Global SOP, the process of updating labels is a lengthy and time-consuming process as one product label is used in different countries. Moreover, several delays are caused by the pandemic.

Therefore, we M/s B. Braun Pakistan (Pvt) Ltd, Karachi have no choice but to continue to use previous registration number on the labels during the transition phase of label change. Once the labels are updated, they will inform MDMC Division for availability of new updated labels for their above mentioned products.

Decision: The Board after deliberation deferred the case and asked the firm to indicate the time line for which they want to have a waiver from labelling rules and what sort of waiver they would like to have.

#### Case No.02.

M/s Popular International, 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi., has requested for addition of new manufacturing site and additional sizes of their already registered medical devices as per detail mentioned below: -

Regn.	Name of	Existing	<b>Proposed Additional</b>	<b>Demanded</b> Additional
No.	Medical	Manufacturing	Manufacturing Site.	Sizes/Codes
	Devices.	Site		
MDIR-	SOFSILK	M/s Coviden LLC,	M/s Polysuture	SP15430, SP11440
0000852	(Wax Coated	15 Hampshire	Industria e Comercio	SP12450, SP13440
	Braided Silk	Street Mansfield,	Ltda., Av. Vereador	SP15401, SP15410
	Silicone	MA 02048, USA	Gabriel Ramos da	SP15420, SP15430
	Coated		Silva, 1245-Sao	SP21460, SP23440
	Braided Silk)	Manufacturing	Sebastiao do Paraiso-	SP23450, SP24410
		Site:	MG- Brazil	SP24420, SP24430
		M/s Coviden, 60		SP24440, SP24450
		Middletown Ave		SP25410, SP25420
		North Haven, CT		SP26401, SP26410
		06473, USA		SP401, SP401E
				SP402, SP410
		M/s Coviden, Zona		SP410E, SP41460
		Franca DE San		SP420, SP420E
		Isidro Carretera		SP42430, SP42440
		San Isidaro, Km		SP430, SP430E
		17, Santo Domingo		SP43420, SP43430
		Dominican		SP43440, SP43450
		Republic		SP43460, SP440
				SP44410, SP44420
				SP44430, SP45401
				SP45410, SP46401
				SP46402, SP48440
				SP53430, SP53430E
				SP6060, SP6070
				SP6080, SP6580
				SP82430, SP82430E
				SP82440, SP82440E
				SP82460, SP86420 SVB6580,SP23440D,
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				, ,
				SP24430D, SP26401D, SP41460D, SP86420D,
				SP401ED, SP410ED
				SP401ED, SP410ED SP420ED, SP430ED
MDIR-	Ticron Coated	-do-	-do-	3PLB750, PL15720,
0000849	Braided	-uo-	-uo-	PL24710, PL24720,
00000 <del>1</del> 7	Polyester			PL24730, PL27702,
	1 Olycsici			PL58701, PL710, PL720,
				PL730, PL740, PL7940,
				FL/30, FL/40, FL/940,

	1			DY =0.50 DY =0.50 DY 0.50
				PL7950, PL7960, PL8750,
				PL88705, PL91750,
				PL92750, PL98705,
				PLN92720V, PLSK1720,
				PLSK2620, PL24720D,
				PL27702D
MDIR-	Surgipro	-do-	-do-	2PN81680, PP12650,
0000858	(Monofilament			PP13620, PP15620,
	Polypropylene)			PP15630, PP22630,
	1 orypropyrene)			PP22640, PP23620,
				PP23630, PP23640,
				PP24610, PP24620,
				· · · · · · · · · · · · · · · · · · ·
				PP24630, PP24640,
				PP25610, PP26601,
				PP26610, PP26620,
				PP27601, PP27610,
				PP43640, PP43640E,
				PP44620, PP44630,
				PP45601, PP45610,
				PP48602, PP48602E,
				PP6510, PP7510,
				PP83650, PP84610,
				PP84620, PP8510,
				PP87601, PP87610,
				PP9510, PP24610D,
				PP24620D, PP26601D,
				PP43640D, PP44620D,
				PP44630D, 2PPN12660V
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MDIR-	Monosof	-do-	-do-	2NP22340, 2NP22360,
0001200	Monofilament			3NP44340, 3NP45320,
	Nyon			3NP45330, 3NP47320,
				3NP69330, 3NP69340,
				3NP84330, 3NP84340,
				NB43340, NB43340E,
				NB52340, NB52350,
				NB83330, NB83340,
				NBXF52340,
				NBXF52350,
				NBXF81360,
				NBXF83340,
				NBXF83350, NP11350,
				NP12340, NP12350,
				NP13320, NP13330,
				NP13340, NP15010,
				NP15020, NP15030,
				NP15040, NP21350,
				NP22340, NP23320,
				NP23330, NP23340,

NP2350, NP24301, NP25010, NP25020, NP25030, NP43320E, NP43330, NP43330, NP43330E, NP43330, NP43330E, NP43300, NP43360E, NP43300, NP44330E, NP44330, NP44330E, NP44330, NP44340E, NP45301, NP45310E, NP45310E, NP45301, NP45310E, NP45300, NP4530E, NP45330, NP45330E, NP45330, NP45330E, NP45330, NP52350, NP52350, NP52350, NP52350, NP52350, NP52350, NP52350, NP52350E, NP52350, NP52350E, NP52350, NP52350E, NP52350, NP5330, NP54300, NP56930, NP6590, NP6710, NP5710, NP66930, NP66710, NP69300, NP6710, NP69300, NP6710, NP69340, NP69340E, NP69340, NP69340E, NP69340, NP69340E, NP69340, NP69340E, NP69340, NP83360, NP83360, NP83360, NP83300, NP83300, NP83300, NP83300, NP85330, NPM553400, NPM53400, NPM553400, NPM55			NID22270 NID24204
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		NP57301, NP86330,
		NBK83330V,
		NPK81360V,
		NPB10310D,
		2NPG10390D,
		NPXF81350D,
		NPXF81360D,
		NP43320D, NP84330D,
		NP83340D, NP82350D,
		NP43330D

Decision: The Board approved the additional manufacturing site and sizes of above mentioned medical devices as mentioned against each.

# Item No.IV. <u>EXEMPTION FROM LABELLING REQUIREMENT UNDER MDR, 2017</u> <u>Case No.01.</u>

M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio PakitanTransmission Center, Hyderabad Road, Landhi, Karachi has requested to consider exemption of additional label requirements for their following registered medical devices: -

S.No.	Name of Medical Device	Registration No.
1.	PanbioCOVID-10 Ag Rapid Test Deice	MDIR-0001928
	(Nasopharyngeal)	
2.	Panbio COVID-19 IgG/IgM Rapid Test Device	MDIR-0002494
	(FingerstickcWholecBlood/Venous Whole Blood/	
	serum/plasma)	
3.	Panbio COVID-19 Ag Rapid Test Device (Nasal)	MDIR-0002495

They have further stated that due to fact that the Legal manufacturer names as Abbott Rapid Diagnostic Jena GmbH of Germany is unable to fulfil additional labelling requirements until December, 2022 due to heavy workload to manage COVID-19 related need throughout the globe.

Decision: The Board after deliberation deferred the case and asked the firm to specify the waivers from labelling rules they would like to have and to further clarify whether they had got any waivers from labelling in other counties or not?

# Item No.V. PRODUCT SPECIFIC INSPECTION TO CHECK THE FACILITY FOR REGISTRATION OF LOCALLY MANUFACTURED VENTILATOR

Decision: The Board after deliberation approved already licensed facility of M/s Alsons Industries (Pvt) Limited, Karachi for manufacture of ICU ventilators.

# Item No.VI. REQUIREMENTS FOR MANUFACTURING OF NON-STERILE PPES INTENDED FOR MEDICAL USE.

Following requirements for manufacturing of non-sterile PPEs has been drafted and reproduced below for consideration of MDB please.

# REQUIREMENTS FOR MANUFACTURING OF NON-STERILE PPEs INTENDED FOR MEDICAL USE

## **General Part**

Sr. #	Description	
1	Name of manufacturing unit	
2	Address of manufacturing unit	
3	Name of owner / partner / CEO /MD. Copy of CNIC is also required	
4	Name of person in-charge of production. Copy of CNIC is also required	
5	Name of person in-charge of Quality Control. Copy of CNIC is also required	
6	Name of facilities to be inspected	
7	Drug Manufacturing License #, if applicable	

### **Technical Part**

Sr.#	Description			
1	Location and surroundings			
	Area: It shall be appropriate for the intended product			
	Location:			
	Site to be verified.			

Requirements for site verification:application on cover letter, Fee of Rs. 5,000/-, land and ownership documents. Note:

- a) It shall preferably be in industrial area (no site verification inspection required).
- b) It shall not be in residential or commercial area
- c) In case of unclassified area, then site verification inspection will be performed.

# 2 Building design and construction

- a) Adequate size and suitable design in accordance with manufacturing process flow.
- b) Fire alarm system to signal evacuation.
- c) Fire extinguishers, hoses and/or hydrants
- d) First aid kits
- e) Emergency exits
- f) Acceptable Quality of ventilation in the facility

#### 3 Services

Electrical supply, lighting, pest control arrangements, temperature and humidity controls.

HVAC not mandatory for non-sterile PPEs, however, manufacturing shall be carried out in hygienic environment and cleanliness is to be ensured by the manufacturer.

### 4 Storage areas (raw material store, in-process store and finished goods store)

Maintain appropriate storage conditions as per requirement of the material and product

### 5 Production

Manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications.

Manufacturer shall conform to the following international standards for development and production of medical devices: -

- a. ISO-13485 (Quality management system for the manufacturing of medical devices).
- b. ISO-14971 (Risk management for processing and development of medical devices).

#### **Personnel:** Production in charge

- a) Qualification: as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government)
- b) Experience: as determined by MDB as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government)

**Equipment**: As per the PPE intended to be manufactured. The identity of individual major equipment items and lines must be identified

## **6 Quality Control Department**

### **Personnel**: Quality control in charge

- a) Qualification: as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government)
- b) Experience: as determined by MDB as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of

	approval from Federal Government)						
	Equipment: As per the PPE intended to be manufactured.						
	<b>Testing</b> : As per applicable International standards of the PPE intended to be manufactured						
7	Labelling						
	Labelling shall be in accordance with Chapter VI of the Medical Devices Rules, 2017.						
8	Documentation						
	a) Written standard operating procedures of each step from the procurement of raw material till the final dispatch and the associated records of actions taken shall be available.						
	b) Manufacturer shall clearly document the responsibility and authority of all						
	personnel involved in the process and maintain training record						
	c) Written procedures/SOPs for emergency exits and alarms						
	d) Accurate evacuation plan posted on each floor						
	e) Employees medical record keeping						
9	Health and safety						
	a) Electrical cables properly covered						
	b) Electrical outlets and switches properly installed						
10	Environmental						
	a) Waste manage system to dispose of hazardous wastes.						
	b) Waste water treatment facility						
11	Trainings						
	a) ISO13485						
	b) ISO14971						
	c) Batch processing						
	d) Emergency evacuation drills and on usage on firefighting equipment						
	e) Disposal, storage and handling of wastes						

Decision: The Board approved the above mentioned requirements for manufacture of nonsterile PPEs intended for medical use.

Item No.VIII. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical	Brief Description	Decision
			Devices.	Description	
1.	M/s. Tech	Legal	DORT-A	Hemovac	Deferred
	Zone,	Manufacturer:	Medical	Drain is used	for
	Ground Floor	Dort-A Tip	(Hemo-vac	to remove any	provision of
	Weal House, 8	Malzemeleri	Drain)	fluid from	original
	Faiz Road,	Sanayi Ithalat	Claimed Shelf	body after	agency
	Lahore.	Ihracat Ticaret	life:	surgery. It	agreement

2.	ELI-00040.	Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	03-years. Class: B	consists of perforated tubing connected to a portable vacuum unit called reservoir.	and FSC of any reference country or CE mark documents.
2.	-do-	Legal Manufacturer:  Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey  FSC: Turkey Date of issue: 15.03.2021	DORT-A Medical (Drain with Resevoir) Claimed Shelf life: 03-years. Class: B	Hemovac Drain is used to remove any fluid from body after surgery. It consists of perforated tubing connected to a portable vacuum unit called reservoir.	for provision of original agency agreement and FSC of any reference country or CE mark documents.
3.	-do-	Legal Manufacturer:  Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey  FSC: Turkey Date of issue: 15.03.2021	DORT-A Medical (Chest Drainage Device) Claimed Shelf life: 03-years. Class: B	Chest Drainage Device.	for provision of valid certificates of ISO-13485, FQA, QC details and CoA of the subject product and FSC of any reference country or CE mark documents.
4.	-do-	Legal Manufacturer:  Dort-A Tip	DORT-A Medical (Thoracic Drain Catheter)	Drain catheter is used to remove any	<b>Deferred</b> for provision of original and

		Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey  FSC: Turkey Date of issue: 15.03.2021	03-years. Class: B	fluid from body after surgery. It consists of perforated tubing connected to a portable vaccum unit called reservoir.	valid agency agreement, valid ISO- 13485 and FQA and FSC of any reference country or CE mark documents.
5.	-do-	Legal Manufacturer:  Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey  FSC: Turkey Date of issue: 15.03.2021	4-A Medikal (YANKUER Set) Claimed Shelf life: 03-years. Class: B	Yankuer set is a suction Catheter used to prevent aspiration.	for provision following documents:- Original & valid agency agreement.  Registration status or free sale certificate of any SRA.  Provide technical details of QC along with CoA of respective product(s,  Provide the justifiable stability study data and protocols that suffice the claim of shelf life.  Provide

					complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA)
6.	-do-	Legal Manufacturer:  M/s Jiangsu weikang Jiejing Medical Apparatus Co., Ltd 18 # Wenzhou Rd. Economical Development District, Shuyang 223600, China FSC: China Valid Till: 2023.03.22	WERACON (Nasogastric Tube) Claimed Shelf life: 03-years. Class: B	A Nasogastric tube (NG Tube) is a special tube that carries food and medicine to the stomach through the nose.	for provision following documents:- Original & valid agency agreement. Registration status or free sale certificate of any SRA. Provide technical details of QC along with CoA of respective product(s,  Provide the justifiable stability study data and protocols that suffice the claim of shelf life.

					Provide complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
7.	-do-	Legal Manufacturer:  M/s Jiangsu weikang Jiejing Medical Apparatus Co., Ltd 18 # Wenzhou Rd. Economical Development District, Shuyang 223600, China  FSC: China Valid Till: 2023.03.22	WERACON  (Foley Catheter) Claimed Shelf life: 03-years. Class: B	Foley catheter.	for provision following documents:- Original & valid agency agreement. Registration status or free sale certificate of any SRA. Provide technical details of QC along with CoA of respective product(s, Provide the justifiable stability study data and protocols that suffice

8.	M/s Nipro	Manufacturer:	Shunmei	These kits	the claim of shelf life.  Provide complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).  Approved.
	Medical Private Limited,	M/s Shunmei Medical Co. Ltd,	Hemodialysis Catheter Kit	provide temporary	Firm shall
	Building No. 24 Central	R401 of Building B, No. 8 of 1st	(Double lumen)	vascular access for	submit original and
	Commercial	Jinlong Road,	Codes & Sizes:	hemodialysis	Embassy
	Area, DHA		As per FSC UK	until a	attested FSC
	Phase 8, Ex-Park	Zone, Longgang	MHRA dated	permanent .	of MHRA.
	View, Lahore.	District, Shenzhen city, Guangdong,	15-01-2021	access is available or	
	ELI-00530	518116, China	Class B	until another	
	ELI 00330	STOTTO, CIMIL	Class B	type of	
		FSC China valid	Shelf Life: 3	dialysis	
		till: 02.03.2022	years	therapy is	
		FSC UK MHRA		substituted. Sterile,	
		valid till 26-05-		single use	
		2025		_	
9.	M/s Digital	Legal	Amplatzer <sup>TM</sup>	A	Approved.
	Imaging Systems, 121	Manufacturer: M/s Abbott	Amulet <sup>TM</sup> Left Atrial	percutaneous transcatheter	Firm shall
	Habitat	Medical, 5050	Appendage	device	submit
	Apartments,	Nathan Lane	Occluder	intended to	revised
	Shadman II,	North, Plymouth,		prevent	Letter of
	Ghaus-Ul-Azam	MN 55442, USA	Codes as per	thrombus	Autorization
	Road, Lahore	Manufacturing	FSC Belgium dated 14-09-	embolization from the left	with product name, MRP
	ELI-00094	Site:	2020	atrial	and valid
		St. Jude Medical,	2020	appendage	ISO13485.

		Costa Rica Ltda. Edificio # 44, Calle 0, Avenida 2, Zona Franca Coyol, EI Coyol, Alajuela, Costa Rica  FSC Belgium issued on 14.09.2020  FSC US FDA not available	Class D Shelf Life: 5 years	(LAA) in patients who have nonvalvular atrial fibrillation. Sterile, single use	
10.	-do-	Legal Manufacturer: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA  Manufacturing Site: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA  FSC Belgium issued on 17.09.2020  FSC US FDA not available	Amplatzer <sup>TM</sup> Trevisio <sup>TM</sup> Intravascular Delivery System  Codes as per FSC Belgium dated 17-09- 2020  Class D  Shelf Life: 3 years	Intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer TM Occluder devices. Sterile, single use	Approved.  Firm shall submit revised Letter of Autorization with product name, MRP and valid ISO13485.
11.	M/s Iqbal and Company Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector, E-11/4, Islamabad, Pakistan.  ELI-00117	Legal Manufacturer: Medical Components, Inc. dba Medcomp 1499 Delp Drive Harleysville PA 19438 USA  Manufacturing site: MARTECH MEDICAL	Medcomp® Single lumen Vascu-PICC® set (peripherally inserted central catheter) Class D Codes: MR17011101 MR17011121	Peripherally inserted central vein access catheter are indicated for short or long term access to the central venous system via peripheral	Approved.  Firm shall submit valid Free Sale Certificate.

12.	M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera, KPK ELI-00120	PRODUCTS Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali, Baja California MEXICO 21210  FSC US FDA valid till 22-01- 2021  Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112  FSC US FDA valid till 28-8-	VP1.9S20-NS VP1.9S50-NS Shelf Life: 3 years  EASYTRAK 2 IS-1 Lead (Implantable cardiac pacing lead)  Class D  Codes: 4542 4543 4544  Shelf Life: 2 years	insertion in neonates, infants and children. It may be used for administratio n of fluids, medication and nutritional therapy. Sterile, single use It is a coronary venous, steroid-eluting, dual electrode pacing/sensin g lead intended for chronic implantation as an integral part of a cardiac pulse generator. Sterile, single use	Approved.  Firm shall submit valid Free Sale Certificate.
12	1	2020	ENDOTAK	т. :	A 7
13.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site:	ENDOTAK RELIANCE 4- SITE implantable Defibrillator Lead Class D Codes: 0265 0266	It is a bipolar, transvenous, endocardial, steroid-eluting lead intended for chronic implantation as an integral part of an automatic	Approved.  Firm shall submit separate application for other types.

14.	-do-	M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112  FSC US FDA valid till 29-8- 2021  Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112  FSC US FDA valid till 28-8-	O275 O276  Shelf Life: 2 years  SUPPORTRAK Finishing Wire IS-1  Class D  Codes: 6667 6668 6669  Shelf Life: 2 years	implantable cardioverter/ defibrillator (AICD) or cardiac Resynchroni zation Therapy with Defibrillation (CRT-D) lead system. Sterile, single use Intended to aid in the placement of a Boston Scientific implantable coronary venous lead in the coronary venous vasculature. Sterile, single use	Approved.  Firm shall submit valid Free Sale Certificate.
15.	-do-	2020 Legal Manufacturer:	Stingray <sup>TM</sup> Guidewire with	Intended to facilitate	Approved.
		M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: M/s Lake Region Medical, 340 Lake	hydrophilic coating  Class D  Sizes and Codes as per US FDA FSC No. 1325- 11-2019  Shelf Life: 2	placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty	

		Hazeltine Dr, Chaska, MN USA 55318 FSC US FDA valid till 3-11- 2021	years	(PTCA) and percutaneous transluminal angioplasty (PTA). Not to be used in cerebral blood vessels. Sterile, single use	
16.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 301 Parkway, Global Park, La Aurora, Heredia Costa Rica FSC US FDA valid till 7-3-2021	ACUITY Whisper View <sup>TM</sup> Guidewire Class D Codes: 4640 4641 4642 4643 4647 4648 Shelf Life: 2 years	Intended to facilitate placement of Boston Scientific or Guidant Left Ventricular leads within the coronary venous vasculature Sterile, single use	Approved.  Firm shall submit valid Design Examinatio n Certificate, Free Sale Certificate and ISO13485.
17.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Limited, Business and Technology Park. Model Farm Road,	CRE Pro Wireguided Esophageal/Pylo ric/Colonic/Bilia ry Balloon Dilatation Catheter Class D Sizes and Codes as per FSC US FDA No. 8332- 4-2019	Indicated for use in adult and adolescent populations to endoscopical ly dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of	Approved.  Firm shall submit valid Free Sale Certificate and ISO13485.

		Cork, Ireland	Shelf Life: 36	the Sphincter	
			months	of Oddi with	
		ECC HC EDA	months		
		FSC US FDA		or without	
		valid till 21-4-		sphincteroto	
		2021		my.	
				Sterile,	
				single use	
18.	-do-	Legal Manufacturer:	Amplatz type renal sheath	Used to maintain the	Approved.
		M/s Boston		nephrostomy	Firm shall
		Scientific Corporation, 300	Class B	tract opening,	submit valid Free Sale
		Boston Scientific	Sizes and Codes	allowing	Certificate
				_	
		• '	-		ISO13485.
		USA 01752	2019	surgical	
		Manufacturing		on through	
		site:	Shelf Life: 4	the	
		M/s Boston	years	nephrostomy	
		Scientific		tract. Sterile,	
		Corporation, 780		single use	
		Brookside drive			
		spencer, IN USA			
		47460			
		FSC US FDA valid till 2-4-2021			
19.	-do-	Legal	ACUITY™ Pro	Intended to	Approved.
		Manufacturer:	Guide Catheter	access the	
		M/s Boston	Class D	coronary	Firm shall
		Scientific		venous	submit valid
		Corporation, 300	Sizes and Codes	system and	Free Sale
		Boston Scientific	as per FSC US	serves as a	Certificate
		Way,	FDA No.6175-3-	conduit for	and
		Marlborough, MA	2019	the delivery	ISO13485.
		USA 01752		of contrast	
			Shelf Life: 24	medium and	
		Manufacturing	months	devices,	
		site:		including	
		Boston Scientific		implantable	
		Corporation, Two		coronary	
		Scimed Place,		venous leads,	
		Maple Grove, MN		introduced	
		USA 55311		into the	
				coronary	
		FSC US FDA		venous	
		valid till 7-3-2021		system.	
19.	-do-	Way, Marlborough, MA USA 01752  Manufacturing site: M/s Boston Scientific Corporation, 780 Brookside drive spencer, IN USA 47460  FSC US FDA valid till 2-4-2021 Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN USA 55311  FSC US FDA	as per FSC US FDA No.3985-1- 2019  Shelf Life: 4 years  ACUITY <sup>TM</sup> Pro Guide Catheter Class D  Sizes and Codes as per FSC US FDA No.6175-3- 2019  Shelf Life: 24	smooth passage of surgical instrumentati on through the nephrostomy tract. Sterile, single use  Intended to access the coronary venous system and serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous	Approve Firm s submit v Free S Certificat and

				Sterile, single use	
20.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: M/s Boston Scientific Corporation, 2546 First Street Propark, EI Coyol Alajuela, COSTA RICA 20904  FSC US FDA valid till 7-2-2021	Percuflex <sup>TM</sup> Plus Ureteral Stent Sizes and Codes as per FSC US FDA No.3462-1- 2019 Class C Shelf Life: 36months	Intended to facilitate drainage from the kidney to the bladder via placement endoscopical ly or fluoroscopica lly by a trained physician. Sterile, single use	Approved.  Firm shall submit valid Free Sale Certificate and ISO13485.
21.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing site: M/s Boston Scientific Corporation, 780 Brookside drive spencer, IN USA 47460  FSC US FDA valid till 27-01- 2022	SpyScope™ DS II Access and Delivery Catheter  Class B  Codes: M00546610  Shelf Life: 24 months	Intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobi liary system including hepatic ducts. For use with the	Approved.  Firm shall submit original and Embassy attested Free Sale Certificate and valid ISO13485.

	1	T		l a ::	
				Spyglass DS	
				Digital	
				Controller.	
				Sterile,	
				single use	
22.	-do-	Legal	Hydra Jagwire	The Hydra	Approved.
		Manufacturer:	Single-Use High	Jagwire	
		M/s. Boston	Performance	Guidewire is	Firm shall
		Scientific	Guidewire	indicated for	submit valid
		Corporation 300,		use in	Free Sale
		Boston Scientific	Class: B	selective	Certificate
		Way,		cannulation	and
		Marlborough, MA	Shelf Life: 3	of the biliary	ISO:13485.
		01752 USA	years	ducts	
		<b>Manufacturing</b>		including the	
		Site:	Codes as per	common	
		Boston Scientific	FSC	bile,	
		Corporation 2546		pancreatic,	
		First Street,		cystic, right	
		Propark El Coyol,		and left	
		Alajuela COSTA		hepatic ducts	
		RICA 20904		and to aid in	
				the	
		FSC US FDA		placement of	
				diagnostic	
		Valid till 15-04-		and	
		2021		therapeutic	
				devices	
				during	
				bronchoscop	
				y procedures	
23.	-do-	<u>Legal</u>	AngioJet <sup>TM</sup>	The device is	Approved.
		<b>Manufacturer:</b>	Solent <sup>TM</sup> Omni	intended for	
		Boston Scientific	OVER-THE-	use with	Firm shall
		Corporation	WIRE	AngioJet	submit valid
		300, Boston	Thrombectomy	Ultra console	ISO:13485.
		Scientific Way,	Set	to break	
		Marlborough, MA		apart and	
		01752 USA	Class-C	remove	
		<b>Manufacturing</b>		thrombus	
		Site:	Shelf life: 2	from:	
		Boston Scientific	years	Upper and	
		Corporation Two		lower	
		Scimed Place,	Codes as per	extremity	
		Maple Grove MN	FSC	peripheral	
		55311 USA		arteries,	
		TO C. I. I		Upper	
		FSC Ireland		extremity	

		Valid till: 05-03- 2023		peripheral veins, Iliofemoral and other lower extremity veins, A-V access conduits, For use with AngioJet power plus techniques for control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.	
24.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing Site: M/s Boston Scientific Corporation, 2546 First Street Propark, EI Coyol Alajuela, COSTA RICA 20904	Jagwire™ High Performance Guidewire  Sizes and Codes: as per FSC US FDA dated 8156-4-2019  Class B  Shelf Life: 3 years	Indicated for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. Designed to be used during endoscopic biliary procedures for catheter	Approved.  Firm shall submit valid Free Sale Certificate and ISO13485.

		FSC US FDA		introduction	
		valid till 15-04-		and	
		2021		exchanges.	
		2021		_	
				Sterile,	
25	do	Lagal	Carre and TM DC	single use Intended to	Ammanad
25.	-do-	Legal	SpyScope <sup>TM</sup> DS		Approved.
		Manufacturer:	Access and	provide	E:111
		M/s Boston	Delivery	direct	Firm shall
		Scientific	Catheter	visualization	submit valid
		Corporation, 300	Class D	and to guide	Free Sale
		Boston Scientific	Class B	both optical	Certificate
		Way,	C- 1	and	and
		Marlborough, MA	Codes:	accessory	ISO13485.
		USA 01752	M00546600	devices for	
		Manufaataaia	Chalf I :C O4	diagnostic	
		Manufacturing	Shelf Life: 24	and	
		site:	months	therapeutic	
		M/s Boston		applications	
		Scientific		during	
		Corporation, 780		endoscopic	
		Brookside drive		procedures in	
		spencer, IN USA		the	
		47460		pancreaticobi	
				liary system	
		Edd Ha ED Y		including	
		FSC US FDA		hepatic	
		valid till 25-06-		ducts. For	
		2020		use with the	
				Spyglass DS	
				Digital	
				Controller. It	
				is part of	
				SpyGlass DS	
				Direct	
				Visualization	
				System	
				Sterile,	
	2.57			single use	
26.	M/s Krestacorp,	Legal	Klimax XXL	Klimax XXL	Deferred
	76-C, 3rd Floor,	Manufacturer/	Condoms	Condoms.	for
	Suit No.2,	Manufacturing	Class: C.	Natural	provision of
	Khayaban-e-	Site:	Claimed Shelf	Rubber Latex	original
	Jami, Street	M/s Karex	Life: 05 Years.	Male	FSC of
	No.9, DHA	Industries SDN		Condoms	country or
	Phase 7, Karachi	BHD PTD. 7906		with 8.5%	origin and
	(ELI-00258)	& 7907 Taman		benzocaine	FSC of any
		Pontian Jaya, Bt.		gel.	reference
		34, Jalan Johor,			country or

27.	M/s Anwar & Sons; Apartment-10, Safari Villas-2, Commercial complex, Bahria Town, Phase07, Rawalpindi ELI-00017.	82000, Pontian Johor Darul Takzim, Malaysia. (FSC Malaysia) Legal Manufacturer:  M/s SMI AG, Steinerberg 8 4780 St. Vith Belgium.  FSC of Belgium.	SURGICAL STEEL (Monofilament Stainless steel Sutures). Claimed Shelf life: 05-years. Class: C	Stainless steel sutures are intended to be mainly used for suturing and ligation of human bone tissues.	Approved.  Firm shall submit original Agency Agreement.
28.	Tramax Health, A-337, Block-D, North Nazimabad, Karachi (ELI-00026)	Legal Manufacturer: M/s Jeil Medical Corporation, 702- 703-704-705-706- 805-807-812-ho, 55, Digital-ro-gil, Guro-gu, Seoul, Korea. FSC Korea Issuance Date11- 05-2017 FSC Netherland valid till Sep, 2024	Leforte Neuro System (Bone Plate and Bone Screw)  Class-C Shelf life:  Codes as per FSC	Craniofacial bone fixation, non- bioabsorbabl e.	Approved.
29.	-do-	Legal Manufacturer: M/s Jeil Medical Corporation, 702- 703-704-705-706- 805-807-812-ho, 55, Digital-ro-gil, Guro-gu, Seoul, Korea.  FSC Korea Issuance Date11- 05-2017  FSC Netherland valid till Sep, 2024	Leforte System (Bone Plate and Bone Screw)  Class-C  Shelf life:  Codes as per FSC	Craniofacial bone fixation, non- bioabsorbabl e.	Approved.
30.	M/s Hakimsos (Pvt) Ltd.,	Legal Manufacturer:	Alsavin One Injection 2%	Each Product consists of	Approved.

31.	Hakimsons House, A-58/B SITE, Manghopir Road, Karachi (ELI-00396)  Life Cares, M- 20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	Alsanza Medizintechnik und Pharma GmbH Hermann- Burkhardt-Strabe 3 72793 Pfullingen Germany Manufacturing site: M/s VSY biotechnology Istanbul Tuzla organize sanayi Bolgesi 3. Cadde 3. Cadde No. Tepeoren  (FSC Germany issuance 02-06- 2021)  Legal Manufacturer: M/s URO Technology SDN BHD Lot 2491, Batu 39 1/2, Pontain Besar, 82000 Pontaian Johor, Malaysia.  FSC Malaysia Valid Till (15-05- 2020)	511XXYY/512X	2.4 ml of viscoelastic solution in a single use glass syringe for intraarticular use.	Deferred for provision of FSC of any reference country or CE mark documents.
		2020)	XYY 311XXYY/312X XYY 221XXYY 217XXYY		
32.	M/s. Freesia Enterprises House No. First Floor, 104, Dawn Plaza, bank Road, saddar, Rawalpindi. ELI-00201	Legal Manufacturer:  M/s. Ningbo Luke Medical Devices Co., Ltd Gujiayan Yangming Road 315400 Yuyao City, Zhejiang province China	Canack Single Kit Anesthesia Kit Class: B Shelf Life :05 years	The device is intended for general anesthesia surgeries.	Approved.  Firm shall submit valid ISO:13485.

33.	M/s Medequips SMC (Pvt) Ltd 30, -Shahrah-E- Quaid-E-Azam, Lahore  ELI- 00362  M/s A.S Enterprises, 03 Mozang Road, Lahore House No. 29-A Lytton Road, Lahore  ELI. 00190	FSC Germany Date of Issue: 23.06.2019  Legal Manufacturer CANON MEDICAL Systems Corporation, 1385 SHIMOISHIGAM I, OTWARA SHI TOCHIHI 324- 8550 JAPAN  FSC: Japan Date of Issue: 7 <sup>th</sup> August,2018  Legal Manufacturer: SuZhou Laishi Transfusion Equipment Co., Ltd Changsheng Road, Tongli Town Wujiang	Codes: AMP01 AMP02 AMP03  Viamo system  Diagnostic ultrasound system  Class: B  Service life: 4 years  Models: TUS-VC100  Laishi Triple Blood Bag  Class-D  Shelf life 3 years Codes/ sizes:	Viamo is diagnostic ultrasound system /echocardiog raphy equipment used for the diagnosis of general abdomen, obstetrics, and vascular superficial parts.  Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). with 16/17 G needle for	Approved.  Firm shall submit valid Letter of Authorizatio n.  Approved.  Firm shall submit valid FSC, ISO 13485 & Design examination
35.	-do-	District Suzhou City Jiangsu Province China  FSC: China Valid till: 2020.10.09 FSC Germany issuance: 26-06-2017  Legal Manufacturer:  SuZhou Laishi Transfusion Equipment Co., Ltd Changsheng Road, Tongli Town Wujiang District Suzhou	350/300*2 450/400*2 500/300*2  Laishi Disposable double Blood Bag  Class-D  Shelf life 3 years  Codes/ sizes:	Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). with 16/17 G needle for Single Use.	Approved.  Firm shall submit valid FSC, ISO 13485 & Design examination certificates.

	T	1	1	1	1
		City Jiangsu	350/300		
		Province China	450/400		
			500/300		
		FSC: China			
		Valid till:			
		2020.10.09			
		FSC Germany			
		issuance:			
		26-06-2017			
36.	M/s Global	Legal	Tro-Microcut	TRO-	Approved.
	Health Care	Manufacturer:		MICROCUT	rr -
	Midway	Troge Medical	(Surgical Blades)	Surgical	
	Commercial Plaz	<u> </u>	(Surgicul Bludes)	Blades are	
	No. 20, Back	20148 Hamburg	Class: B	used during	
	Side of Prism	Germany	Class. D	surgical	
	Arcade 2, Phase	Germany	Shelf Life: 5	procedures.	
		FSC: Germany			
	7, Bahria Town,	"	years		
	Rawalpindi.		C- 1- MD0106	pyrogenic	
	EL I. 00006	September, 2018	Code: MD0106	and a toxin.	
	ELI: 00086				
27	Vantach Madical	Taral	Easter	Hana for	Deferred
37.	Kantech Medical	<u>Legal</u>	Egemen	Uses for	Deferred
	System, Office	Manufacturer:	International	regional	for
	No. R-820	M/s TMT Tibbi	Spinal Needle	anesthesia for	provision of
	Ground Floor,	Medikal	(Quincke)	collection of	valid FSC
	Block-01,	Malzemeleri San.	~. ~	CSF from	of country
	Federal B Area,	/	Class-D	spinal fluid	of origin
	Karachi	Faith Mahallesi		without any	and FSC of
	(ELL00460)	1188 Sokak No. 14	Shelf life: 5	loss with	any
	(ELI-00460)	Sarnic-Gaziemir	years	safety.	reference
		Izmir, Turkey			country or
		FSC Turkey Valid	Codes & Sizes as		CE mark
		Till (31-10-2020)	per FSC		documents.
38.	-do-	Legal	Egemen	Bone	Deferred
		Manufacturer:	International	Marrow	for
		M/s TMT Tibbi	Bone Marrow	Biopsy	provision of
		Medikal	Biopsy Needle	Needle uses	valid FSC
		Malzemeleri San.		for	of country
		VE. TIC. Ltd. Sti,	Class-B	Diagnosis	of origin
		Faith Mahallesi		blood disease	and FSC of
		1188 Sokak No. 14	Shelf life: 5	Diagnosis,	any
		Sarnic-Gaziemir	years	staging and	reference
		Izmir, Turkey	June	therapeutic	country or
		iziiii, i dike y	Codes & Sizes as	monitoring	CE mark
		FSC Turkey Valid	per FSC	for lymph	documents.
		Till (31-10-2020)	perrise	proliferative	documents.
		1111 (31-10-2020)		disorders.	

39.	-do-	Legal	Egemen	Hernia	Deferred
37.	do	Manufacturer:	International	repairs.	for
		M/s TMT Tibbi	Epidural Set	Genitourinar	provision of
		Medikal	Epidurui Set	y procedures.	valid FSC
		Malzemeleri San.	Class-D	Lower	of country
		VE. TIC. Ltd. Sti,	Class-D	extremity	of origin
		Faith Mahallesi	Shelf life: 5	orthopedic	and FSC of
		1188 Sokak No. 14		procedures.	
			years	procedures.	any
		Sarnic-Gaziemir	Cadas & Ciassas		reference
		Izmir, Turkey	Codes & Sizes as		country or
		ECC Total Valid	per FSC		CE mark
		FSC Turkey Valid			documents.
40	1	Till (31-10-2020)	Г	TT C	D. C 1
40.	-do-	Legal	Egemen	Uses for	<b>Deferred</b>
		Manufacturer:	International	regional	for
		M/s TMT Tibbi	Semi-Automatic	anesthesia for	provision of
		Medikal	Biopsy	collection of	valid FSC
		Malzemeleri San.	14G, 16G, 18G,	CSF from	of country
		VE. TIC. Ltd. Sti,	20G	spinal fluid	of origin
		Faith Mahallesi	CI D	without any	and FSC of
		1188 Sokak No. 14	Class-D	loss with	any
		Sarnic-Gaziemir		safety.	reference
		Izmir, Turkey	Shelf life: 5		country or
			years		CE mark
		FSC Turkey Valid			documents.
		Till (31-10-2020)	Codes & Sizes as		
			per FSC		
41.	M/s Health Care	Legal	Vesocclude	intended for	Approved.
	Internatinal, 1 <sup>st</sup>	Manufacturer:	Ligating Clip	marking and	
	Floor 210/J-2,	M/s Teleflex		ligating of	Firm shall
	Johar Town	medical 3015	Hemostatic Clip,	any linear	submit
	Lahore	Carrington Mill	Ligating Clip	tissue	Embassy
		Blvd Morrisville,		structure or	attested
	ELI00141	NC USA 27560	Class C	vessels	FSC.
		<b>Manufacturing</b>		during an	
		site:	Shelf Life: 3	operation for	
		Symmetry surgical	years	homeostasis	
		Vesocculaude,		or marking	
		LLC 7429 ACC	Codes as per	purpose	
		Blvd. Suite 101	FSC	where use of	
		Raleigh North		non-	
		Carolina 27617		absorbable	
		USA.		clips is	
				required	
1			1	ı	
		FSC US FDA			
		FSC US FDA valid till 20-05-			

42.	M/s Global	Legal	CAPII	LLAR	YS 3	For the	Approved.
	Marketing	Manufacturer:	G!	_		separation of	
	Services, 111, Hali Road	SEBIA 27 rue Leonard de Vinci,	Class-B			the normal hemoglobin'	
	Westridge1,	Parc Parc	Na	ide	Sh	s (A, A2 and	
	Rawalpindi,	Technologique	me	nti	elf	F) in human	
	Pakistan	Léonard de Vinci,	as	fie	life	blood	
	ELI-00109	CP 8010 LISSES, 91008 EVRY	per lab	r		samples, and for the	
		Cedex, France	el			detection of	
			CA	25	3	the major	
		FSC France	PI 3	07	ye	hemoglobin	
		issuance: 13-02-2019	HE MO		ars	variants (S, C, E and D)	
		13 02 2019	GL			by capillary	
			OB			electrophores	
			IN(			is in alkaline	
			E) Hb	47	4	buffer (pH 9.4) with the	
			AF	77	ye	SEBIA	
			CO		ars	CAPILLAR	
			NT			YS	
			RO L			<u>3</u> <u>instruments.</u>	
			NO	47	4	mstruments.	
			RM	78	ye		
			AL		ars		
			Hb A2				
			CO				
			NT				
			RO				
			L				
			(5) PA	47	4		
			TH	79	ye		
			OL		ars		
			OG IC				
			AL				
			Hb				
			A2				
			CO NT				
			RO				
			L				
			Hb	47	4		
			AF	92	ye		

			CC.	I	0#0		
			SC		ars		
			CO				
			NT				
			RO L				
42	1.	T 1		TAD	N/C	The CADI 2	A
43.	-do-	Legal	CAPII			The CAPI 3 CDT kit is	Approved.
		Manufacturer: SEBIA 27 rue	3 – CD	ı Kı	ι:		
		Leonard de Vinci,	Class-I	)		designed for	
		Parc	Class-1	)		the separation of the	
		Technologique	Na	ide	Sh	transferrin	
		Léonard de Vinci,	me	nti	elf	isoforms in	
		CP 8010 LISSES,	as	fie	life	human serum	
		91008 EVRY		r	me	and the	
		Cedex, France	per label	1		quantification	
		Coden, France	CAP		2	of the CDT	
		FSC France	13	25	ye	(carbohydrate	
		issuance:	CDT	09	ars	deficient	
		13-02-2019	CDT		an S	transferrin)	
			SA			by capillary	
			MP			electrophores	
			LES			is in alkaline	
			TRE		2	buffer (pH	
			AT	20	ye	8.8) with the	
			ME	54	ars	CAPILLAR	
			NT			YS 3	
			SOL			instrument	
			UTI				
			ON				
			TET			1	
			RA				
			VA	20	3		
			LEN	20	ye		
			T	57	ars		
			CDT				
			/ IS				
			CDT				
			CAP				
			ILL				
			AR				
			YS		5		
			CAL	47			
			IBR	60	ye ars		
			AT		ars		
			ORS				
			(2				
			level				
			s)				

			HIG H CDT CO NTR OL INT ER ME DIA TE CDT	47 72 47 73	3 ye ars		
			CO NTR OL NO RM AL CDT CO NTR OL	47 95	3 ye ars		
44.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France	CAPILL - Hb Al Class-B Nam e as per medi cal devic	lc Kit		The CAPI 3 Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human	Approved.
		FSC France issuance: 13-02-2019	e label CAPI 3 Hb A1c CAPI LLA RYS 3 & MC SWI TCH RAC	2 5 1 5	3 ye ars	blood, by capillary electrophores is in alkaline buffer (pH 9.4) with the CAPILLAR YS 3 instrument.	

			K FOR HbA 1c (1) Hb A1c CAPI LLA RY CALI BRA TOR S (2) MUL TI- SYS TEM Hb A1c CAPI LLA RY CON TRO LS (2)	4 7 5 5 5	5 ye ars		
45.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France  FSC France issuance: 13-02-2019	CAPI 3 IMMUN NG Kit Class-B  Na me as per med ical devi ce label CAP I 3 IM MU NO TYP ING	TON	Shelf life e	The CAPI 3 IMMUNOT YPING kit is designed for the detection and the characterizati on of monoclonal proteins (immunotypi ng) in human urine and serum with the CAPILLAR YS 3 instrument, SEBIA, for capillary electrophores is	Approved.

			IT / IF 478 ye ar s		
46.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France  FSC France issuance: 13-02-2019	CAPI 3 PROTEIN(E) Kit Class-B Shelf life: 3 years Code: 2503	The CAPI 3 PROTEIN(E) 6 kit is designed for the separation of human serum proteins by capillary electrophores is in alkaline buffer (pH 9.9) with the CAPILLAR YS 3 instrument.	Approved.
47.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France  FSC France issuance: 13-02-2019	CAPI 3 URINE Kit  Class-B  Shelf life: 3 years  Code: 2513	The CAPI 3 URINE kit is designed for the preparation of human urine samples for analysis with the CAPI 3 URINE procedure with the CAPI 3 PROTEIN(E ) 6 kit. The CAPI 3 URINE procedure on the CAPILLAR YS 3 automated instrument is intended for	Approved.

				the qualitative analysis of urinary protein profile to detect abnormalities .	
48.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France  FSC France issuance: 13-02-2019	Capillarys 3 OCTA Instrument Class-A Shelf life: N/A Code: 1245	The CAPILLAR YS 3 OCTA instrument provides fully automated electrophores is sequencing, from the primary sample tube, with cap for hemoglobin analyses and without cap for other analyses, right through to the final electrophoret ic pattern: sample identification , sample dilution, capillary washing, sample injection into the capillaries, migration, detection, results processing and transfer	Approved.

				over a computer network.	
49.	-do-	Legal Manufacturer: SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France  FSC France issuance: 13-02-2019	CAPILLARYS 3 TERA Instrument and Accessories  Class-A Shelf life: N/A  Codes: 1246, 1248	The CAPILLAR YS 3 instrument provides fully automated electrophores is sequencing, from the primary sample tube, with cap for hemoglobin analyses and without cap for other analyses, right through to the final electrophoret ic pattern: sample identification , sample dilution, capillary washing, sample injection into the capillaries, migration, detection, results processing and transfer over a computer network.	Approved.

50.	-do-	Legal	EIAgen HBsAg	The EIAgen	Approved.
50.	-40-	Manufacturer:	Kit	Detect HIV 4	Approved.
		M/s. Adaltis S.r.l.	EIAgen Detect	Total	
		Via Durini, 27 –	HIV 4 total	Screening	
		20122 Milano –	Screening Kit	assay is a 4th	
		Italy	Screening Kit	_	
		•	Class-D	generation	
		Manufacturing	Class-D	solid phase	
		Site:	C1 1CT 'C 15	Enzyme-	
		M/s. Adaltis S.r.l.	Shelf Life: 15	linked	
		Via Luigi Einaudi,	months	immunosorb	
		7 - 00012	G 1	ent assay	
		Guidonia	Codes:	using a	
		Montecelio	071011 (Kit of	mixture of a	
		(Roma) – Italy	96 tests)	antigens and	
		TO C. I.	071012 (Kit of	antibodies	
		FSC Italy	192 tests)	for the in	
		Issued on 13th	071015 (Kit of	vitro	
		March, 2018	480 tests)	diagnostic	
				screening in	
				human serum	
				or plasma	
				(EDTA,	
				Heparin and	
				Citrate) of	
				antibodies to	
				HIV-1, HIV-	
				2 and HIV-1	
				p24 antigen.	
				This kit is a	
				combined	
				Ag/Ab assay	
				and is not to	
				be used for	
				the detection	
				of HIV-1 p24	
				antigen	
				alone.	
51.	M/s OPTISURG	Legal	ONE USE PLUS	The OUP	Approved.
	17/c-1, Valancia	Manufacturer:	SBK HEAD	LASIK	F F = 5 . 552.
	Town, Lahore	MORIA SA	(One Use plus	microkerato	Firm shall
	Pakistan	(Private limited)	SBK Head	me system is	submit
		15 Rue George	Microkeratome)	intended for	notarized
	(ELI-00305)	Besse	T.Herokeratollie)	use in the	LOA, ISO
	(LLI 00303)	92160Antony-	Class: B	making of a	13485 & EC
		France	Class. D	corneal flap	certificate.
		1 Tance	Shelf Life: 59	in patients	certificate.
		FSC: France	months	•	
			monuis	undergoing	
		Date of Issue: 9th		Lasik surgery	

		M1 0010	C- 1-	1	1
		November, 2018	Code:	or other	
			19393/90	treatment	
			19393/130	requiring	
				initial	
				lamellar	
				resection of	
			OTTO THEE DITTE	the cornea	
52.	-do-	<u>Legal</u>	OUP USE PLUS	The OUP	Approved.
		<b>Manufacturer:</b>	MOTOR	LASIK	
		MORIA SA		microkerato	
		(Private limited)	Class: B	me system is	
		15 Rue George		intended for	
		Besse	Shelf Life: 5	use in the	
		92160Antony-	years	making of a	
		France	~ 1 10015	corneal flap	
			Code: 19345	in patients	
		FSC: France		undergoing	
		Date of Issue: 9th		Lasik surgery	
		November, 2018		or other	
		,		treatment	
				requiring	
				initial	
				lamellar	
				resection of	
				the cornea	
53.	-do-	Legal	M2SU HEAD	The LASIK	Approved.
		<b>Manufacturer:</b>		M2-M2SU	
		MORIA SA	(M2SU Head of	microkerato	
		(Private limited)	Microkeratome	me system is	
		15 Rue George	System)	intended for	
		Besse	bystem)		
			CI D		
		92160Antony-	Class: B	making of a	
		France		corneal flap	
			Shelf Life: 59	in patients	
		FSC: France	months	undergoing	
	•	l			
1		Date of Issue: 9th		Lasik surgery	
			Code:	Lasik surgery or other	
		Date of Issue: 9th November, 2018	Code: 19334/90	or other	
			19334/90	or other treatment	
				or other treatment requiring	
			19334/90	or other treatment requiring initial	
			19334/90	or other treatment requiring initial lamellar	
			19334/90	or other treatment requiring initial lamellar resection of	
			19334/90	or other treatment requiring initial lamellar	
		November, 2018	19334/90 19334/130	or other treatment requiring initial lamellar resection of the cornea.	
54.	-do-	November, 2018  Legal	19334/90 19334/130	or other treatment requiring initial lamellar resection of the cornea.	Approved.
54.	-do-	November, 2018  Legal Manufacturer:	19334/90 19334/130	or other treatment requiring initial lamellar resection of the cornea.	Approved.
54.	-do-	November, 2018  Legal	19334/90 19334/130	or other treatment requiring initial lamellar resection of the cornea.	Approved.
54.	-do-	November, 2018  Legal Manufacturer:	19334/90 19334/130 OUP REUSABLE	or other treatment requiring initial lamellar resection of the cornea.  The OUP LASIK	Approved.

		15 Rue George Besse 92160Antony- France FSC: France	(Oup reusable Suction ring of microkeratome system)	intended for use in the making of a corneal flap in patients undergoing	
		Date of Issue: 9th November, 2018	Class: B  Shelf Life: 59 months  Code: 19391/-1 19391/0 19391/1 19391/2	Lasik surgery or other treatment requiring initial lamellar resection of the cornea	
			19391/2 19391/3		
55.	-do-	Legal Manufacturer: MORIA SA (Private limited) 15 Rue George Besse 92160Antony- France FSC: France Date of Issue: 9th November, 2018	ONE-BUSIN GLIDES  Class: B  Shelf Life: 59 months  Code: ONE-BUSIN GLIDES 17300×5	The OUP LASIK microkerato me system is intended for use in the making of a corneal flap in patients undergoing Lasik surgery or other treatment requiring initial lamellar resection of the cornea	Approved.
56.	M/s Meher Traders, Office A21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi  (ELI-00128)	Manufacture: M/s Huaian Pingan Medical Instrument Co.	PASILK Silk Braided Sutures  Class-D  Shelf life: 5 years  Codes as per FSC	Silk sutures are widely used as ligature and are also used for other applications like skin, ophthalmic, GI tract, etc	Approved.

	FSC Spain			
	issuance			
	10-05-2021			
57do-	Legal Manufacture: M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China.  FSC China Valid Till 10-04-2021  FSC Spain issuance 10-05-2021	PACRYL Polyglactin 910 Sutures  Class-D  Shelf life: 3 years  Codes as per FSC	Polyglactin 910 Surgical Sutures are indicated for use in general soft tissue approximatio n and/or ligation, including use in ophthalmic procedures; but not for use in cardiovascul ar or neurological	Approved.
58do-	Legal Manufacture: M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China.  FSC China Valid Till 10-04-2021  FSC Spain issuance 10-05-2021	PASORB Polyglycolic Acid Sutures  Class-D  Shelf life: 5 years  Codes as per FSC	tissues.  The Polyglycolic Acid surgical suture is indicated for use in general surgery, plastic surgery, ophthalmic surgery, gynecology and obstetrics, episiotomy, urology, orthopedics, gastroenterol ogy, general closure, ligatures, pediatrics and cuticular.	Approved.

59.	-do-	Legal	PACHROM	Catgut	Deferred
		Manufacture:	Chromic Catgut	chrome	for
		M/s Huaian Pingan		sutures are	provision
		Medical	Class-D	intended for	FQA,
		Instrument Co.	G1 10 110 7	use in general	Design
		Ltd, No.128, West	Shelf life: 5	soft tissue	EXaminatio
		Meigao Road,	years	closing and/or	n and FSC of any
		Huaian, Jiangsu, China.	Codes as per FSC	ligation; in	of any reference
		Cillia.	Codes as per 13C	particular in	country or
		FSC China Valid		general	CE marked
		Till		surgery,	documents.
		10-04-2021		gastrointestin	
				al surgery,	
				gynecology,	
				obstetrics,	
				urology,	
				ophthalmic	
				surgery	
60.	-do-	Legal	PALENE	A	Approved.
	2, 2	Manufacture:	Polypropylene	polypropylen	пррионоск
		M/s Huaian Pingan	Sutures	e suture is	
		Medical		a synthetic	
		Instrument Co.	Class-D	monofilamen	
		Ltd, No.128, West	G1 10 110 7	t plastic	
		Meigao Road,	Shelf life: 5	thread used	
		Huaian, Jiangsu, China.	years	for wound closure in	
		Cillia.	Codes as per	many	
		FSC China Valid	FSC as per	surgical	
		Till		procedures.	
		10-04-2021			
		FSC Spain			
		issuance			
61.	M/s Bain	10-05-2021 Manufacturer:	Poin Dianaschia	Intended to	Annwayad
01.	Medical Private	M/s Bain Medical	Bain Disposable A.V. Fistula	be used as	Approved.
	Limited, Ground	Equipment	Needle Sets	vein puncture	Firm shall
	Floor with	(Guangzhou) Co.,		for the	submit valid
	Mezzanine, Plot	Ltd. No. 10,	Class B	hemodialysis	FSC of
	-58-C, Street	Juncheng Road,	Shelf Life: 3	treatment.	China.
	No.24, Touheed	Eastern Area,		Sterile,	
	Commerial Area,	Economic &	Years	singleuse	
	Phase-5, DHA,	Technological			
	Karachi	Development	Codes:		
		District,	BAIN-A.V.F-		

	(ELI-00614)	Guangzhou 510760, China (FSC China valid till 26-5-2021) (FSC Germany valid till 22-2- 2022)	001S BAIN-A.V.F- 002S BAIN-A.V.F- 003S BAIN-A.V.F- 004S BAIN-A.V.F- 005S BAIN-A.V.F- 006S BAIN-A.V.F- 007S BAIN-A.V.F- 008S		
62.	-do-	Manufacturer: M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China  (FSC China valid till 02-9-2021) (FSC Germany valid till 22-2- 2022)	Bain Tubing Sets for Hemodialysis  Class B Shelf Life: 3 Years  Codes: BAIN-BL-009 BAIN-BL-010 BAIN-BL-011 BAIN-BL-012	Intended to connect with the dialyzer to the patient in dialysis treatment. Sterile, single use	Approved.
63.	-do-	Manufacturer: M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou	Bain Hollow Fiber Dialyzer Class C Shelf Life: 3 Years	Used for the hemodialysis treatment of acute and chronic renal failure. Sterile, single use	Approved.  Firm shall submit valid FSC of China.

510760, China	B-16HF, B-	
(FSC China valid till 04-7-2021) (FSC Germany valid till 22-2- 2022)	18HF, B-20HF	

## Item No.IX. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

The following applications for grant of enlistment of medical devices for import on prescribed form 6-A Under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB:-

Decision: TheBoard discussed and decided as mentioned against each.

<b>S.</b> #	Name of Firm	Name of	Name of	Brief	Decision
	(s)	Manufacturer	Medical	Description	
			Devices.		
1.	M/s. Tech	M/s PIKDARE	SOFFIX MED	A post OP	Deferred.
	Zone,	Manufacturer	(PIC	dressing is an	
	Ground Floor		SOLUTION)	adhesive	The firm shall
	Weal House, 8	Via Saldarini	Post-Operation	dressing with	provide the
	Faiz Road,	Catelli 10,	Dressing.	sterile pad	following
	Lahore.	22070 Casnate	Claimed Shelf	applied to a	documents:-
	ELI-00040.	Con Bernate	life: 03-years.	wound to	
		COMO, Italy	Class: A	promote healing	
				and protect the	<ul> <li>Original</li> </ul>
		FSC: Italy		wound from	and valid
		(copy)		further harm	agency
					agreement
					<ul> <li>Valid</li> </ul>
					certificate
					of ISO-
					13485/
					Latest
					GMP.
					<ul> <li>Technical</li> </ul>
					details of
					mfg. details
					along with
					CoA of

					respective product.  Original registration status or free sale certificate in any SRA.  The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life.  Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
2.	-do-	M/s PIKDARE Manufacturer  Via Saldarini Catelli 10,	AQUA-BLOC (PIC Solution) Water Proof Post-Operation Dressing.	A WATER PROOF POST OP DRESSING IS AN ADHESIVE	The shall provide the following
		22070 Casnate Con Bernate COMO, Italy	Claimed Shelf life: 03-years. Class: A	DRESSING WITH STERILE PAD APPLIED TO	<ul><li>documents:-</li><li>Original</li></ul>

ECC. To 1		A WOLNED TO	1 1'1
FSC: Ital (copy)	у	A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM	and valid agency agreement  Valid certificate of ISO-13485/ Latest GMP.  Technical details of mfg. details along with CoA of respective product.  Original registration status or free sale certificate in any SRA.  The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life.  Complete EPSPs of subject products and label duly approved in
			of origin or

					and protocols that suffice the claim of shelf life.  • Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
4.	-do-	M/s PIKDARE Manufacturer  Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO, Italy  FSC: Italy (copy)	SECURFIX PLUS (Transparent dressing for cannula) Claimed Shelf life: 03-years. Class: A	A Cannulla Dressing is an Adhesive Dressing used to Control Intravenous (IV) Catheter Insertion Sites.	The shall provide the following documents:-  • Original and valid agency agreement  • Valid certificate of ISO-13485/ Latest GMP.  • Technical details of mfg. details along with CoA of respective product.  • Original registration status or free sale

					certificate in any SRA.  The data provided for claimed shelf life is
					not Satisfactory , provide the justifiable stability study data and protocols that suffice the claim of shelf life.  Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
5.	-do-	Legal Manufacturer:  M/s Pikdare S.p.A Via Saldarini Cateli 10, 22070 Casnate con Bernate Como, Italy  Manufacturing Site:  Zhejiang	MIRAGE (Scalp Vein Set) Claimed Shelf life: 03-years. Class: B	The Scalp vein set is used for blood Smapling and injection of small amounts of Infusion solutions.	Deferred.  The shall provide the following documents:-  • Original and valid agency agreement  • Valid certificate of ISO-

Kindly Medical Devices Co.,		13485/ Latest GMP.
Ltd no 758 5th Binhai Road Binhai Industrial Park, Longwan		<ul> <li>Technical details of mfg. details along with CoA of</li> </ul>
Province PRC		respective product.
FSC: China Date of Issue: 12.03.2018		<ul> <li>Original registration status or free sale certificate in any</li> </ul>
		SRA. • The data
		provided for claimed shelf life is not
		Satisfactory , provide the
		justifiable stability study data
		and protocols that suffice
		the claim of shelf life.
		• Complete EPSPs of subject
		products and label duly
		approved in the country of origin or
		any stringent
		regulatory authority
		(SRA).

6.	-do-	Legal	MIRAGE	The Scalp vein	Deferred.
		Manufacturer:	SMART-SAFE	set is used for	
			(Scalp Vein Set	blood Smapling	The shall
		BUCA 058	with safety)	and injection of	provide the
		MAH,	Claimed Shelf	small amounts	following
		DOGUS CAD.	life:	of Infusion	documents:-
		3/19 SOK. NO.	03-years.	solutions.	
		6, OSB 1,	Class: B		0
		BOLGE,			Original
		BUCA,			and valid
		IZMIR,			agency
		TURKEY			<ul><li>agreement</li><li>Valid</li></ul>
		FSC:			• vand certificate
		TURKEY			of ISO-
					13485/
		Date of issue:			Latest
		27.09.2019			GMP.
		_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			<ul> <li>Technical</li> </ul>
					details of
					mfg. details
					along with
					CoA of
					respective
					product.
					<ul> <li>Original</li> </ul>
					registration
					status or
					free sale
					certificate
					in any
					SRA.
					• The data provided
					for claimed
					shelf life is
					not
					Satisfactory
					, provide
					the
					justifiable
					stability
					study data
					and
					protocols
					that suffice
					the claim of
					shelf life.

					• Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
7.	-do-	Legal Manufacturer:  M/s Pikdare S.p.A  Viz Saldarini Catelli 10, 22070 Casnate con Bernate COMO , Italy  Manufacturin g Site: Zhejiang Kindly Medical Device Co., Ltd No. 758, 5th Binhai road, Binhai Industrial Park, Longwan District 325025 Wenshou, Zhejiang Province PRC  FSC: CHINA  Date of issue: 16-03-2018	GRUPA (Disposable Camera Cover) Claimed Shelf life: 03-years. Class: A	A sterile disposable Endoscopy Camera Cover is a Sheath that is used to protect the endoscopy camera.	Approved.  The shall provide the following documents:-  • Original and valid agency agreement •

8.	-do-	Legal	GRUPA		Disposab	le.	Approved.
		Manufacturer:	(Disposab	le	Surgical		11pp10 veu.
			Surgical		Sets	r	The shall
		JIANGSU	Sets)	1			provide the
		WEILKANG	Claimed	Shelf			following
		JIEJING	life:				documents:-
		MEDICAL	03-years.				
		APPARATUS	Class: A				<ul> <li>Original</li> </ul>
		CO., LTD 18#					and valid
		WENZHOU					agency
		RD					agreement
		ECONOMICA					<ul> <li>Valid</li> </ul>
		L					certificate
		DEVELOPME					of ISO-
		NT DISRICT					13485/
		SHURANT					Latest
		223600 CHINA					GMP.
		CHINA					<ul> <li>Technical details of</li> </ul>
		FSC: China					details of mfg. details
		1 SC. Cillia					along with
		valid till: 20					CoA of
		Sep.2021					respective
		2					product.
							<ul><li>Original</li></ul>
							registration
							status or
							free sale
							certificate
							in any
							SRA.
							• The data
							provided
							for claimed
							shelf life is
							not
							Satisfactory
							, provide
							the
							justifiable stability
							study data
							and
							protocols
							that suffice
							the claim of
							shelf life.
							• Complete
	1	1	1		l .		

					EPSPs of subject products and label duly approved in
					the country of origin or any stringent regulatory authority (SRA).
9.	M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera, KPK ELI-00120	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752  Manufacturing Site: ENERCON TECHNOLOG IES 25 NORTHBROO K DR. P.O. BOX 665 GRAY, ME USA 04039  FSC US FDA valid till 08- 09-2021	SpyGlass DS <sup>TM</sup> Digital Controller  Code: M00546650  Shelf Life: N/A  Class A  Rs. 5000/-	Endoscopic video imaging system that receives video signals from the Scope, processes the video signals and outputs video images to an attached monitor. It is part of SpyGlass DS Direct Visualization System	Approved.  Firm shall submit Embassy attested FSC and valid ISO13485.

# Item No.X. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

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

<b>S.</b> #	Name of Firm	Name of	Name of	Brief Descintion	Decision
1.	(s)/Importer  M/s Otsuka Pakistan Limited, 30-B, SMCHS, Karachi (ELI-00243)	Manufacturer  Manufacturer: Shanghai Microport EP MedTech Co., Ltd. Building 23 & 28, Lane 588, Tianxiong Road, Pudong New District 201318 Shanghai, China. (FSC China valid till 25-2- 2021) (FSC Netherlands valid till 17-09- 2023)	Fire Magic <sup>TM</sup> Cardiac RF Ablation Catheter  Class D  Shelf Life: 3 Years  Codes: As Per Netherlands FSC  Fee submitted: Rs. 50,000/- As drug on Form-5A (Product approved in 256 <sup>th</sup> meeting of Reg Board. Registration letter was not issued)	Indicated for use in cardiac electrophysiol ogical mapping, simulation and ablation to treat the arrhythmia when used in conjunction with a radiofrequenc y generator. Sterile, single-use	Approved.
2.	M/s. Moon enterprises, 5/6 Rabani Road Old Anarkali Lahore ELI-00356.	Legal Manufacturer & mfg. site: Antitoxin GmBH Industries 88 69245 Bammental Germany FSC: Germany Date of Issue 18.09.2018.	ImuMed (ABO- SYSTEM) Anti-A monoclonal IgM Anti-A monoclonal IgM Code 01.001- 01.003 Class- D. Shelf Life: 05-Years.	ABO- SYSTEM) Anti-A monoclonal IgM Anti-A monoclonal IgM	Approved.
3.	M/s. Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442	Legal Manufacturer  Wuxi Bio Hermes and Bio- medical technology Co. Ltd, No 136 Mashan	Bio HermesGLYCO HEMOGLOBIN ANALYZER Class: C	In vitro diagnostic test used for quantitative analysis of A1c Glycohemogl obin or A1c glycohemogli	Approved.  Firm shall submit valid FSC of China.

Meiliang Road	Service Life: 5	bin fraction in
Binhu wuxi	years	whole venous
Jiangsu 214092,		blood.
China	Model:	
	A1C-M21	
Manufacturing		
Sites:		
No. 88 Mashan		
Meiliang road,		
Binhu, Wuxi		
214092, Jiangsu,		
China		
No. 136 Mashan		
Meiliang road,		
Binhu, Wuxi		
214092, Jiangsu,		
China		
11 <sup>th</sup> Floor, 530		
Mansion, #18		
Qingyuan Road,		
Xinwu distict,		
Wuxi 214135,		
Jiangsu, China		
Jiangsa, Ciina		
FSC: China		
Valid till		
17.07.2021		

# Item No.XI. <u>REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE</u> (Form 7).

	Name & Address	Name of	Brief	Decision
Sr.	of Establishment	Medical	Description	
No.		<b>Devices With</b>		
		Size		
	M/s Crespak	Engel Plus Auto	It is a sterile	Approved.
	Medical	Discard Syringe	single-use plastic	
	Industries, 8Km	(2ml, 2.5ml,	syringe or	
1.	Manga raiwind	3ml, 5ml) (22G,	medical device	
1.	Road, Lahore	23G, 24G)	intended for	
	(ELM-0004)		immediate use	
		Class B	for the	
			administration of	

		Shelf Life: 03 Years	injectable preparation.	
	M/s Lahore	Injekt Auto	It is a sterile	Approved.
2.	Medical Instruments (Pvt) Ltd., 48Km Lahore-Kasur Road, Lahore (ELM- Not Issued)	Disable Syringe (3ml, 5ml)  Class B  Shelf Life: 02  Years	single-use plastic syringe or medical device intended for immediate use for the administration of injectable preparation.	72pp20/000
3.	M/s Smile Surgicals (Pvt) Ltd., HO: Plot No.06, Abbpara Housing Society Canal Road, Lahore 296-L, Street No.13, Industrial Estate, Gadoon Amazi, Dist Swabi (KPK)  (ELM-0022)	Smile Auto disable Syringes  Class B  Shelf Life: 05 Years  Sizes: 3ml & 5ml  Rs.20,000/-	Autodisable Syringes	Approved.  Firm shall provide stability data for claimed shelf life.
4.	M/s Unisa (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak, District Nowshera (ELM-0002)	UNILOCK Auto disable Sterile Single Use Plastic Syringes Class B Shelf Life: 05 Years SIZES: 1ml, 2.5ml, 3ml,5ml, 10ml & 20ml Rs. 20,000/-	Auto disable Sterile Single Use Plastic Syringes	Approved.  Firm shall provide stability data for claimed shelf life.

## Item No.XII. RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE (Form 7).

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Injection Systems (Pvt) Ltd., Plot No.271, Main Road, Industrial Estate, Gadoon Amazai. (ELM-0034)	BIOSAFE Disposable Syringe Propylene syringe with gasket as SS needle. (1ml, 3ml, 5ml, 10ml) Class B Shelf Life: 05 Years Previous Registration # 064426 29-09-2020 to 28- 09-2025	Biosafe Syringe is used in clinical medicine to administer drug subcutaneously, intramuscularly and intravenously.	Approved the renewal of 1ml and 10ml only.  Firm shall submit stability data of claimed shelf life.
2.	-do-	BIOSAFE Disposable Syringe Propylene syringe with gasket without needle. (2ml, 3ml, 5ml, 10ml) Class B Shelf Life: 05 Years Previous Registration # 064427 29-09-2020 to 28- 09-2025	Biosafe Syringe is used in clinical medicine to administer drug subcutaneously, intramuscularly and intravenously.	Approved the renewal of 10ml only.  Firm shall submit stability data of claimed shelf life.

## Item No.XV. <u>APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.</u>

The below mentioned firm has applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel was constituted for

inspection of their establishment. The information about the firm/company and recommendations of the panel are submitted for consideration of MDB please: -

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Samad Rubber Works (Pvt) Ltd., Apparel Division	Plot No. 02, Faizi street, 23-Km, Ferozepu r Road, Lahore	Ms. Rahat Kanwal Pharmacist (Productio n Incharge)	

Decision: The Board discussed and approved the grant of Establishment License to M/s Samad Rubber Works (Pvt) Ltd., Apparel Division, Plot No. 02, Faizi street, 23-Km, Ferozepur Road, Lahore for manufacturing of medical devices i.e. PPEs (Gowns, Coveralls and Shoe Cover).

## Item No.XVI. REQUEST FOR GRANT OF ADDITIONAL SIZES OF REGISTERED MEDICAL DEVICES FOR IMPORT

M/s Nisa Impex (Pvt) Ltd, Maxim Arcade, Plot No.13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA-II, G.T. Road, Islamabad, has requested for grant of approval of additional sizes of their following registered medical device for import as per detail mentioned below: -

S.No	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
2.	MDIR-0001282	Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle)	M/s Chengdu Xinjin Shifeng Medical Apoparatus & Instrument Co. Ltd, No.46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu- City, P.R. China.	Size: 0.4. 0.45,	

Decision: The Board discussed and approved the aditional sizes as per detail mentioned below:-

S.#	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/ Codes	New Approved Additional Sizes/ Codes.
1.	MDIR- 0001282	Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle)	Apoparatus & Instrument Co.	1ml, 2ml, 5ml, 10ml Needle Size: 0.4. 0.45, 0.5, 0.55. 0.6, 0.7, 0.8, 0.9.	0.05ml, 0.5ml, 2.5ml and 3ml.

## Item No. XVII. GUIDELINES TO MANUFACTURE MEDICAL DEVICES BY THE DRUG MANUFACTURING LICENCE HOLDERS.

Guidelines for manufacturing of medical devices by the Drug Manufacturing License (DML) holders has been drafted and placed at Annex-II for consideration of MDB please.

Decision: The Board after deliberations approved the folloing Guidelines (Annex-II) for the Drug Manufacturing License (DML) holders.

Annex-II

## GUIDELINES TO MANUFACTURE MEDICAL DEVICES BY THE DRUG MANUFACTURING LICENCE HOLDERS

#### INTRODUCTION

Drug Regulatory Authority of Pakistan Act, 2012 )DRAP Act, 2012 (was enacted on 13<sup>th</sup> November, 2012. The objective of DRAP Act is to regulate, manufacture, import, export, storage, distribution and sale of therapeutic goods including medical devices on ensure quality, safety and efficacy of these therapeutic goods in larger public interest.

Under the DRAP Act 2012,medical devices for human and animal usewere brought under the regulations. Under the said Act, Medical Devices Rules, 2015 were promulgated which were subsequently replaced by Medical Devices Rules 2017 notified on 16<sup>th</sup> Jan, 2018 for the regulation

of all types of medical devices. The said Act and rules can be downloaded from official website of the DRAP.

Before the promulgation of Medical Devices Rules, 2015, a number of medical devices were defined as drugs under the Drugs Act, 1976 and few others were declared as drugs through various SROs. Medical devices covered under the said Act were excluded from the definition of drug in Schedule-1 of DRAP Act, 2012 vide SRO.824(I)/2018 dated 26<sup>th</sup> June, 2018. Further, various SROs declaring medical devices as drugs were repealed vide SRO.167(I)/2017 dated 15<sup>th</sup> March, 2017 and were required to be registered as medical devices under Medical Devices Rules, 2015. These products which were with either defined as drugs or declared as drugs have now been made part of Schedule E of SRO 526(I)/2021 dated 30<sup>th</sup> April, 2021. The manufacturing of the abovementioned medical devices and dialysis solutions were carried out in the same premises as that of drugs under Drug Manufacturing License (DML).

Devices other than those defined as drugs or declared as drugs came into regulation for the first time upon promulgation of Medical Devices Rules, 2015 and subsequently Medical Devices Rules, 2017.

The DRAP Act 2012 and the rules framed thereunder do not restrict the manufacturing of medical devices and pharmaceuticals in the same plot. Furthermore, there is no specific requirement of plot size in the Medical Devices Rules, 2017. This is in line with international practices where vertical constructions/expansions are taking place. Moreover, internationally, ISO 13485 in EU, Medical Device Directives or In Vitro Devices Regulations in UK and 21 CFR part 820 Quality System Regulations in USA are followed. All these regulations describe similar manufacturing requirements for pharmaceutical and medical devices with more strict regulations for pharmaceuticals than medical devices.

The purpose of these guidelines is to facilitate the local manufacturing of medical devices, provideease in doing business, promote exports and outline steps which should be taken, as necessary and appropriate, by manufacturers of medical devices with the objective of ensuring that their products are of the intended quality and nature.

### **CHAPTER 1**

## Manufacture of Schedule E medical devices and Dialysis Solutions

The DML holders will be allowed to manufacture Schedule E medical devices and Dialysis Solution in the same building as that of pharmaceutical products by following the below mentioned procedure:-

### 1. Application of Building Layout Plan:

The applicant will apply to the Division of Licensing for the approval of building lay out. Triplicate copies with duly marked section of medical devices along with the HVAC drawings, personnel and material flow needs to be submitted along with prescribed fee. The building layout plan will be approved by the said Division as per its SOPs for the approval of building

layouts. Quality control lab of pharmaceuticals may also be utilized for the testing of medical devices

## 2. Application for the grant of Establishment License to Manufacture Medical Devices:

The applicant will apply to the Medical Devices& Medicated Cosmetics (MDMC) Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of Medical Devices including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)

## 3. Application for the grant of Medical DeviceEnlistment/Registration:

The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.

### **CHAPTER 2**

## Manufacture of Medical Devices other than Schedule E and Dialysis Solutions.

The DML holders intending to manufacture medical devices other than Schedule E and Dialysis Solution will be allowed to manufacture their said medical device on the same plot in separate building by following the below mentioned procedure:-

### 1. Application of Building Layout Plan:

The applicant will apply to the MDMC Division for the approval of building lay out. Application shall be submitted on cover letter along with prescribed fee and Triplicate copies of duly marked facilities along with the HVAC drawings (where applicable), personnel and material flow. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layout. Quality control lab of pharmaceuticals may also be utilized for the testing of medical devices

### 2. Application for the grant of Establishment License to Manufacture Medical Devices:

The applicant will apply to the MDMC Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of MDMC including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)

#### 3. Application for the grant of Medical DeviceEnlistment/Registration:

The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.