

**Government of Pakistan**  
**Ministry of National Health Services, Regulation & Coordination**  
**Drug Regulatory Authority of Pakistan**  
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**DECISIONS OF THE 31<sup>ST</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 16-03-2021**

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

<b>S.No</b>	<b>Name of Establishment</b>	<b>Director/Proprietor /partners</b>	<b>Cold Chain (Yes/No)</b>	<b>Decision</b>
1.	M/s Geevet International, Office No. 11, Naaz Medicine Market, 1 <sup>st</sup> floor, Medicine Market, NamakMandi, Peshawar.  <b>Godown:</b> Office No. 12, Naaz Medicine Market, 1 <sup>st</sup> floor, Medicine Market, NamakMandi, Peshawar.	Syed Bashir	No	<b>Approved</b> for storage of non-cold chain medical devices.
2.	M/s Medco, 19-Khyber Bazar, Peshawar.  <b>Godown:</b> Gulbahar No.4, Safdar Town, Street No.03, House NO.1, Peshawar.	Mr. Muhammad Anwar	No	<b>Approved</b> for storage of non-coldchain medical devices subject to provision of Drug Sale License ( <b>DSL</b> ).
3.	M/s Biotech Scientific International, Flat No. 2, 4 <sup>th</sup> floor Khyber plaza 2, G-15 Markaz,	Mr. Atta Ullah, CEO	Yes	<b>Approved</b> for storage of non-cold chain medical devices subject to provision of Drug Sale License ( <b>DSL</b> ).

	Islamabad. <b>Godown Address:</b> Office No.8 & 9, 4 <sup>th</sup> Floor, Khyber Plaza, G-15 Markaz, Islamabad.			
4.	M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.  <b>Godown:</b> Same as Above	Syed Faisal Zaman  Syed Fahad Zaman	Yes	<b>Approved</b> for storage of room temperature along with cold chain medical devices.
5.	M/s Biodent Care Services, 82/C, Ferozepur Road, Near Shama Stop, Lahore.  <b>Godown:</b> Same as Above	Mr. HamoodurRehman	No	<b>Approved</b> for storage of non-cold chain medical devices.
6.	M/s Bio Med Vision, Plot NO. S 71-R20/A, 16 Edward Road, Near AG Office, Lahore.  <b>Godown:</b> Same as Above.	Mohsin Naeem  Ahsan Naeem	No	<b>Approved</b> for storage of non-cold chain medical devices.
7.	M/s Fatir Pharma, H/480, Block-C, OPF, Raiwind Road, Lahore.  <b>Godown:</b> Same as Above.	Syed Anjum Raza Zaidi  SyedaTasneem Zahra	No.	<b>Rejected</b> as the facility was developed inside a small room inside a house. One rack and one wooden pallet were placed inside the room. A large window was also present in the room which could be opened into the outside environment. A kitchen refrigerator was also present in the room. No device was installed to monitor the room temperature, neither was any device installed inside the refrigerator to monitor the temperature and humidity. There were no arrangements for maintaining the cold chain inside the premises.

				Moreover,there were no satisfactory arrangements for maintaining cold chain from the distributor to the customer. The documentation and record keeping was poor. Training of employees also needed improvement. Firm was not satisfactorily adhering to good storage and distribution practices for medical devices at the time of inspection.
8.	M/s Capra-Med (Pvt) Ltd, First Floor 81, Broadway Commercial, Paragon City BarkiRoad, Lahore.  <b>Godown:</b> Same as Above	Muhammad SaqibTasleem  SumairaIshaq	No	<b>Approved</b> for storage of non-cold chain medical devices.
9.	M/s Dodhys Healthcare (Pvt) Ltd., Office No.2, Plot No.320, STreet No.1, I-9 Industrial Area, Islamabad.  <b>Godown:</b> Same as Above	Salman-Ul-HaqDodhy (CEO)  Mahwish Salman-Ul-HaqDodhy (Director)	No	<b>Approved</b> for storage of room temperature medical devices.
10.	M/s Amson Vaccines & Pharma (Pvt) Ltd, Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.  <b>Godown:</b> Same as Above.	Mr.Shamim Ahmed Khan  Mr. Abbas Khan  Mr. Syed Saleem Asghar	Yes	<b>Approved</b> for storage of room temperature along with cold chain medical devices.
11.	M/s Aliz Healthtech Innovations (Pvt) Limited, Plot No.48-D, Mezzanine Floor, 21 <sup>st</sup> Commercial Street, DHA Phase-II Ext. Karachi.	Aftab Ahmed (CEO)	No	<b>Approved</b> for storage of room temperature medical devices.

	<b>Godown:</b> Same as Above.			
12.	M/s Atta Ullah Enterprises (AUE-Life Technologies), 384-M Block, Model Town, Lahore.	Hashim Mansoor (CEO) Hassan Mansoor (Dir)	No	<b>Approved</b> for storage of non-cold chain medical devices.
13.	M/s Medzntech (Pvt) Ltd, D-21, Sector 16-A, Govt. Teachers Co-Operative Housing Society, KDA Scheme 33, Karachi	KhaildMehmood Khan Fatima Khalid	No	<b>Approved</b> for storage of non-cold chain medical devices.
14.	M/s Atta Ullah Enterprises (AUE-Life Technologies), 384-M Block, Model Town, Lahore.	Hashim Mansoor (CEO) Hassan Mansoor (Dir)	No	<b>Approved</b> for storage of non-cold chain medical devices.
15.	M/s Medzntech (Pvt) Ltd, D-21, Sector 16-A, Govt. Teachers Co-Operative Housing Society, KDA Scheme 33, Karachi	KhaildMehmood Khan Fatima Khalid	No	<b>Approved</b> for storage of non-cold chain medical devices.

## II. POST LICENSE VARIATIONS.

### Case No.1.

M/s Eastern Medical Care (Pvt) Ltd, 7A, Block-N, Model Town Extension, Lahore has requested for approval of change of qualified/technical person in their ELI-00130 issued on 17-10-2018 as per detail given below: -

<b>Existing Technical Person</b>	<b>Proposed Technical Person</b>
Ms. AfshanFazal,R/O 532-A, Faisal Town, Lahore. CNIC # 35202-7977038-8	Ms. Sarwat Razzaq, D/o Abdul Razzaq, 6-E, Extension Lane No.07, Education Town, Wahdat Road, Lahore. CNIC # 341016505337-4

	(Pharm-D)
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**Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person as mentioned below :-**

Previous Technical Person	New Approved Technical Person
<b>Ms. AfshanFazal,R/O 532-A, Faisal Town, Lahore.</b>  <b>CNIC # 35202-7977038-8</b>	<b>Ms. Sarwat Razzaq, D/o Abdul Razzaq, 6-E, Extension Lane No.07, Education Town, Wahdat Road, Lahore.</b>  <b>CNIC # 341016505337-4</b> <b>(Pharm-D)</b>

**Case No.2:**

M/s Novo Nordisk Pharma (Pvt) Ltd, 113, Shahrah-e-Iran, Clifton, Karachi has requested for approval of change of qualified/technical person in their ELI-00264 issued on 31-10-2018 as per detail given below: -

Existing Technical Person	Proposed Technical Person
<b>Mr Syed Abdul Azeem, House No.R-703, Block 14, Federal B Area, Karachi.</b>  <b>CNIC # 42101-1556396-3</b>	<b>Mr. Muhammad Imran Iqbal, House No.207, Sector 31-D, Mohallah Block-B, P&amp;T Society, Korangi, Karachi East.</b>  <b>CNIC # 42201-5161847-1</b>  <b>(Pharm-D)</b>

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

Previous Technical Person	New Approved Technical Person
<b>Mr Syed Abdul Azeem, House No.R-703, Block 14, Federal B Area, Karachi.</b>  <b>CNIC # 42101-1556396-3</b>	<b>Mr. Muhammad Imran Iqbal, House No.207, Sector 31-D, Mohallah Block-B, P&amp;T Society, Korangi, Karachi East.</b>  <b>CNIC # 42201-5161847-1</b>  <b>(Pharm-D)</b>

**III. INSPECTION OF M/S ELILILLY PAKISTAN (PVT) LIMITED, KARACHI-STOCK ORDERED NOT TO DISPOSE OF ON FORM-1 UNDER SECTION 18 (1) OF THE DRUG ACT, 1976 .**

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

- i) Approved the expanded storage facility for medical devices having approximate area of warehouse is 16.5 x 13 feet which seems appropriate as per their products.
- ii) "Not to dispose of" of stock of above mentioned medical device is revoked in larger public interest.
- iii) Further, firm shall be issued strict warning to be careful in future from such activities.

**IV. CANCELLATION OF SOLE AGENCY AGREEMENT.**

**Decision:** The MDB discussed the matter at length and considering that the Company, namely, M/s Tech Zone, Lahore did not avail the opportunity of personal hearing decided to cancel the registration of the medical device, namely, I.CO Safety Syringe Auto-Disable (0.5, 3, 5 and 10ml) (Reg.No. MDIR-0001938) manufactured by M/s International Company for Medical Necessities, Industrial Zone, Block No.19 & 67, El-Zarby, Abu-Tig, Assiut, Egypt registered on 11<sup>th</sup> November, 2020, from the name of M/s Tech Zone, Lahore as the manufacturer had cancelled their Agency Agreement / contract/ Authorization for the said product.

**V. CANCELLATION OF REGISTRATION OF MEDICAL DEVICES TO BE IMPORTED FROM TAIWAN.**

**Decision:** Mr.Rizwan Hasan, Manager Regulatory Affairs bearing CNIC No. 37405-5613628-1 availed the opportunity of personal hearing on behalf of M/s Cardiac Care, Lahore and pleaded as follow:

The products should not be cancelled:

- i) They are good quality products already in use in GCC, ASEAN, UK, China, Malaysia and Finland;
- ii) The company has been importing these products for the last 10 years;
- iii) They have inventories of these products and if supplies / tender commitments are not fulfilled, the company is likely to be black-listed;
- iv) Cancellation of these products will deprive the people of Pakistan of good quality products.

The Board after the hearing decided to cancel the products as per clarification given on Policy Guidelines on Taiwan by Ministry of Foreign Affairs; that there is

no change in Pakistan's policy towards Taiwan. Pakistan does not recognize Taiwan as a State but as an integral part of the People's Republic of China. Accordingly, Pakistan does not have any diplomatic/consular relations with Taiwan. Similarly, no official contact, of any type, is maintained with Taiwan. According to Policy Guidelines on Taiwan, there are no restrictions on trade with Taiwan subject to following conditions: -

- Trade is conducted strictly on un-official basis and through private sector only.
- No direct contacts to be made with the Taiwan authority agencies.
- No Pakistan government functionary can visit Taiwan.
- No Taiwan authority functionary can visit Pakistan.
- Government/ official investment from Taiwan is not allowed into Pakistan.
- Exchange of delegations(s) is not allowed.
- Holding of trade exhibitions, establishment of display is not allowed.
- No publicity is given to Pakistan's trade or commercial contacts with Taiwan.
- Private businessmen can, technically, interact with Taiwan parties.

#### **VI. CANCELLATION OF SOLE AGENCY AGREEMENT.**

**Decision:** The Board discussed the matter at length and decided to issue show cause notice and giving an opportunity of hearing to M/s Dora Enterprises, 54-B, Model Town Lahore as to why not their above mentioned products manufactured by M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China registered on 7<sup>th</sup> August, 2019 be cancelled as the manufacturer had cancelled their Agency Agreement / contract/Authorization for the aforesaid products.

#### **VII. SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.**

The case of the M/s Medica, Karachi for the below medical devices was considered by the MDB in its 17<sup>th</sup> and 25<sup>th</sup> meeting held 13-07-2020 and 02-12-202 respectively and approved subject to inspection of manufacturer abroad and provision of documents as mentioned against each: -

1.	M/s Medica, House No. 188- 1-B (First Floor) near Nursery	<b>Legal Manufacturer:</b> SaSanSaglikMazemeler IuretimvePazarlamaa.s. (DagyakaMah. 2004	Sasan Medical Disposable products. S.A.  Adult Tubing Set without	Extracorporeal tubing set is a medical device that is used	<b>Approved</b> subject to inspection of manufacturer
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	area, Block 2, PECHS Karachi.  (ELI-00237)	Cad. No: 6 Kahramankazan/ Ankara/ Turkiye.  (FSC Turkey issued on 09-03-2017)	filter.  Class B  Fee submitted.  RS 25000.  Shelf Life: 3 Years.  (Sizes & Codes as Per FSC)  Tubing Set Adult Ref: (SD920001/B)  Adult Tubing Set Without Filter (SD921001/A)  (SD921301/B)	with cardiopulmona ry pump and oxygenator for oxygenation of blood. In open heart surgeries and allows the blood to be sent to the oxygenator and then to the patient. It is disposable. The filter set used to hold particles and air bubbles in the set during circulation is an arterial filter set.	abroad or provision of CE mark documents and submission of below mentioned documents: -  Provide detail of manufacturing and quality control process.  provide shelf life supported  With stability data.  Proposed MRP of medical device.  Provide sole /exclusive original agency agreement from market authorization holder duly notarized from the country of origin.  Tubing Set Adult  Ref: (SD920001/B)  Not available in FSC.
2.	-do-	Legal Manufacturer:  SaSanSaglikMazemeler I uretimvePazarlamaa.s. (DagyakaMah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye.	Sasan Medical Disposable products.  S.A.Arterial Filter Loop Pediatric  Class B  Shelf Life: 3 Years.	Extracorporeal tubing set is a medical device that is used with Cardiopulmon ary pump and oxygenator for oxygenation of	<b>Approved</b> subject to inspection of manufacturer abroad.



		(FSC issuance 09-03-2017)	(Sizes & Codes as Per FSC)  Arterial Filter Loop Pediatric  Ref: SD9203CM/A	blood in open heart surgeries and allows the blood to be sent to the oxygenator and then to the patient.	
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**Decision:** The Board approved the above mentioned medical devices on the basis of CE marked documents.

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

**Decision:** The Board discussed and decided to refer the case to Drug Registration Board for cancellation of above mentioned medical device (registered as drug).

**IX. CANCELLATION OF REGISTRATION OF FARCOATH I.V. CANNULA REG. No. 073289.**

**Decision:** The Board discussed and decided to refer the case to Drug Registration Board for cancellation of above mentioned medical device (registered as drug).

**X. APPROVAL OF SITE FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.**

**Decision:** The Board approved the site of M/s Byonyks Private Limited, located at 18 KM, Multan Road, Behind Highnoon Laboratories (Pvt) Ltd, Lahore for establishment of manufacturing unit of medical devices.

**XI. CANCELLATION OF REGISTRATION OF ITRIX II RAPAMYCIN-ELUTING CORONARY STENT, REGN: NO.082105.**

**Decision:** The Board discussed the matter at length and decided to approve the product in the name of M/s Al-Farman Trading, Sargodha as fresh registration and further decided to refer the same product, registered earlier as drug in the name of M/s Cardiovascular Medical System, Lahore vide Regn.No.082105 dated 30-09-2016 to Drug Registration Board for its cancellation.

## **XII. REGISTRATION OF DISPOSABLE SYRINGES FOR IMPORT.**

The case of the K.M Enterprises, Lahore for the below medical device was considered by the MDB in its 14<sup>th</sup> meeting held 11-10-2019 and decided as mentioned against each:-

<b>M/s. K.M. Enterprises,</b>  605-D-Block, M.A. Johar Town, Lahore.	<b>Legal Manufacturer &amp; Manufacturing Site:</b>  M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShanQian Town, Changzhou Jiangsu China.  FSC China (Export Only)  Valid until 12-10-2019	<b>AMD Disposable Syringes</b>  <b>1ml, 2ml, 3ml, 5ml, 10ml, 20ml</b>  (Syringes for single use)  Class B  Shelf Life : 05 years  <b>Rs.40,000</b>	Disposable Syringes	<b>Approved</b> subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Full quality Assurance.
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**Decision:** The Board discussed and approved the renewal of AMD Disposable Syringes 2ml, 3ml and 5ml till 31<sup>st</sup> March, 2021.

## **XIII. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES ON PRIORITY BASIS).**

S. #	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description	Decision
1.	M/s Capra-Med (Pvt) Ltd. First Floor, 81 Broadway Commercial Paragon city, Barki Road, Lahore	<b>Legal Manufacturer:</b> International Company for Medical Necessities, 3 <sup>rd</sup> Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt  <b>Manufacturing site:</b>	I.CO Safety Syringe Auto disable  Class: B  Sizes: 0.5 ml, 1ml, 2ml 3 ml, 5 ml, 10ml	Syringe used to inject fluid into, or withdraw fluid from the body with a self-disabling safety feature to prevent re-use. Sterile, single-	<b>Approved.</b>

	ELI:	1. International Company for Medical Necessities, 3 <sup>rd</sup> Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt 2. International Company for Medical Necessities, Public Free Zone, Ismailia, Egypt  FSC Egypt valid till 26-05-2024 FSC Belgium issued on 04-02-2021	Shelf Life: 5 years  Fee submitted: 25,000/-	use	
2.	M/s SY'AH IMPEX,  1-6/15 Sector No. 5, Korangi Industrial Area Karachi Pakistan.  ELI: 00440	<b>Legal Manufacturer:</b>  M/s JiangyinNanquan Macromolecules Product Co., Ltd No. 618 Jingxian Road, Xiangang Street, Jiangyin city, China.  FSC: China  Valid till: 29-09-2021	SHIFA Auto Disable Syringes  (Auto -disable syringes)  Class -B  Shelf Life: 5 years  Sizes: 0.05ml, 0.1ml, 0.5ml, 1ml, 2ml	AD syringes include a reuse prevention feature i.e., feature that activates after intended use to prevent subsequent reuse of syringes. These syringes provide an opportunity to prevent reuse of injection equipment. The products are sterilized with EO Gas. The products are sterile, no toxicity, no pyrogen.	<b>Approved.</b>
3.	M/s Nipro Medical Private Limited, Building No. 24 Central Commercial	M/s JMI Syringes & Medical Devices Ltd. Manufacturer: Unique Heights, Level 11, 117, KaziNazrul Islam Avenue, Ramna,	JMI Auto Disable Syringe  Class B  Sizes: 0.1, 0.5, 3,	Sterile, single use auto-disable hypodermic syringe	<b>Approved.</b>  The firm shall submit original notarized Letter of

Area, DHA Phase 8, Ex-Park View, Lahore.  ELI-00530	Dhaka, 1217 Bangladesh Manufacturing site: M/s JMI Syringes & Medical Devices Ltd. Noapara, Chauddogram, Cumilla, Bangladesh  FSC Bangladesh issued on 27-2-2020.  FSC Germany issued on 23-09-2020.	5, 10ml  Shelf Life: 5 Years.  Fee submitted: Rs. 25,000/-		Authorization before issuance of registration certificate
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#### **XIV. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).**

<b>S.#</b>	<b>Name of Firm (s)</b>	<b>Name of Manufacturer</b>	<b>Name of Medical Devices.</b>	<b>Brief Description</b>	<b>Decision</b>
<b>1.</b>	M/s Capra-Med (Pvt) Ltd.First Floor, 81 Broadway Commercial Paragon city, Barki Road, Lahore  ELI:	<b>Legal Manufacturer:</b> International Company for Medical Necessities, 3 <sup>rd</sup> Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt  <b>Manufacturing site:</b> 1. International Company for Medical Necessities, 3 <sup>rd</sup> Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt 2. International Company for Medical Necessities, Public Free Zone, Ismailia, Egypt  FSC Egypt valid till 26- 05-2024 FSC Belgium issued on 04-02-2021	I.CO Hypodermic syringe 10ml  Class: B  Shelf Life: 5 years  Fee submitted: 25,000/-	Syringe used to inject fluid into, or withdraw fluid from the body Sterile, single-use	<b>Approved.</b>

<p>2.</p>	<p>M/s Johnson &amp; Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi  (ELI-00154)</p>	<p><b>Legal Manufacturer:</b> M/s Ethicon, LLC. 475 C Street, Los Frailes, Industrial Park, Suite 401, Guaynabo, PR 00969, USA</p> <p><b>Manufacturing Site:</b> M/s Johnson &amp; Johnson do Brasil Ind. Com. De Prod. p/ SaudeLtdaRodoviaPresidente Dutra KM 154, Sao Jose Dos Campos, Sao Paulo 12240-908, Brazil</p> <p>FSC USFDA valid till 12-03-2021</p>	<p>VicrylRapide™ (Polyglactin 910) Synthetic Absorbable Suture  Class D  Shelf life: 5 Years  Codes: VR2290, VR493, VR494, VR844, VR945, W9913, W9915, W9918, W9924, W9925, W9928, W9930, W9931, W9932, W9933, W9935, W9938, W9940, W9941, W9943, W9944, W9963, W9964, W9969, W9970  FSCs does not have codes. The manufacturer has given list of codes (notarized) that are manufactured by them.  Fee submitted: Rs. 50,000/-</p>	<p>Synthetic absorbable sterile surgical suture intended for use in soft tissue approximation where only short term wound support is required and where the rapid absorption of the suture would be beneficial. Sterile, single-use</p>	<p><b>Approved.</b></p>
<p>3.</p>	<p>M/s A.S. Enterprises, 3-Mozang, Lahore.  ELI: 00190</p>	<p><b>Manufacturer:</b> M/s SD Biosensor Inc. C-4<sup>th</sup>&amp;5<sup>th</sup>, 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si-Gyeonggi-do, 16690, Republic of Korea</p> <p><b>Manufacturing Site:</b> M/s SD Biosensor Inc. 74, Osongsaengmyeong 4-r0, Osong-eup,</p>	<p>Standard™ Q Malaria P.f/Pan Ag Test (kit)  Ref No: QMAL03G Code: 09MAL30D Size: 25 tests/kit  Class C</p>	<p>Rapid and membrane based immunochromatography for the qualitative detection of Plasmodium falciparum specific histidine rich protein 2 and plasmodium species specific</p>	<p><b>Approved.</b></p>

		Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea  FSC Germany valid till 08-06-2021	Shelf Life: 24 months  Fee submitted: Rs. 50,000/-	pLDH in human capillary and venous whole blood specimens of patients suspected of having malaria.	
4.	-do-	<b>Manufacturer:</b> M/s SD Biosensor Inc. C-4 <sup>th</sup> &5 <sup>th</sup> , 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon- si-Gyeonggi-do, 16690, Republic of Korea  <b>Manufacturing Site:</b> M/s SD Biosensor Inc. 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea  FSC Germany valid till 08-06-2021	Standard™ Q Malaria P.f/P.v Ag Test (kit)  Ref No: QMAL02G  Code: 09MAL20D Size: 25 tests/kit  Class C  Shelf Life: 24 months  Fee submitted: Rs. 50,000/-	Rapid and membrane based immunochromat ography for the qualitative detection of Plasmodium falciparum specific histidine rich protein 2 and plasmodium vivax specific pLDH in human whole blood specimens of patients suspected of having malaria.	<b>Approved.</b>
5.	M/s Nipro Medical Private Limited, Building No. 24 Central Commercial Area, DHA Phase 8, Ex-Park View, Lahore.  ELI-00530	Legal Manufacturer: Nipro Corporation 3-9- 3 Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan  Manufacturing site:  M/s Shibuya Corporation 2-232, Wakamiya, Kanazawa- shi, Ishikawa-ken, 920- 0054, Japan  FSC Belgium issued on 14-05-2020	Surdial X  (Single patient Dialysis Machine)  Class: C  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	It is a single patient hemodialysis system which provides dialysis fluid with a prescribed concentration and temperature to be used for hemodialysis treatment.	<b>Approved.</b>

6.	-do-	<p><b>Manufacturer:</b></p> <p>Nipro Medical (Hefei) Co. Ltd. No. 350, Yungu Road, Economic &amp; Technology Development Zone Hefei City, Anhui Province, 230601, P.R. China.</p> <p>FSC Belgium issued on 09-07-2019</p>	<p>NiproElisioHemodialyzer</p> <p>(Synthetic hemodialyzer)</p> <p><b>Code:</b></p> <p>Elisio-M (13M, 15M, 17M, 19M, 21M)</p> <p>Elisio-H (13H, 15H, 17H, 19H, 21H)</p> <p>Elisio-L (13H, 15H, 17H, 19H, 21H)</p> <p><b>Class: C</b></p> <p><b>Shelf Life: 3 years</b></p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Hemodialyzer used in hemodialysis indicated for patients having acute or chronic renal failure. Sterile, single-use</p>	<b>Approved.</b>
7.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Nipro Corporation 3-9-3 Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan</p> <p><b>Manufacturing site:</b></p> <p>M/s Shibuya Corporation 2-232, Wakamiya, Kanazawa-shi, Ishikawa-ken, 920-0054, Japan</p> <p>FSC Japan issued on 21<sup>st</sup> December, 2016</p>	<p><b>Surdial 55 plus</b> (Single Patient Dialysis Machine)</p> <p>Class: C</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Single patient hemodialysis machine for patients with acute or chronic renal failure</p>	<b>Approved.</b>
8.	-do-	<p><b>Manufacturer:</b></p> <p>Nipro Renal Solutions Spain S.L.U Poligono. Industrial Tumsa, Nave 31Mollerussa, (Leida),</p>	<p>NiproCart A2F</p> <p>(Powder Sodium Bicarbonate Cartridge for Hemodialysis)</p>	<p>Indicated for use in a bicarbonate hemodialysis for acute and chronic renal failure. Single-</p>	<b>Approved.</b>

		Spain  FSC Spain Issued on 20-07-2020	Codes:  NiproCart A2F 650 NiproCart A2F 760 NiproCart A2F 1100 Class: C  Shelf Life: 2 years  Fee submitted: Rs. 50,000/-	use	
9.	-do-	<b>Manufacturer:</b> Nipro Pure Water GmbH Werner-von-Siemens- Str. 2-6 D-76646 Bruchsal, Germany  FSC Germany issued on 26-06-2019	Nipro RO Medical (Water Treatment System for Dialysis)  Service life: 10 years  Class C  Fee submitted: Rs. 50,000/-	Used for the central water production in dialysis	<b>Approved.</b>
10.	M/s. Cardiac Care, 848-C, Shadman-I Lahore.  ELI-00070	Manufacturer: A&E Medical Corporation 5206 Asbury Road Farmingdale NJ USA 07727  FSC US FDA valid till 13 <sup>th</sup> August, 2021	A&E Medical® Rotating Surgical Punch  <b>Code:</b> 080-273, 080-353, 080-403, 080-453, 080-483, 080-503, 080-271, 080-351, 080-401, 080-451 080-481 080-501 Class: B Shelf Life: 5 years  Fee submitted: Rs. 25,000/-	Intended to create circular cuts in soft tissue or openings in soft vessel walls during surgical procedures. Sterile, single- use	<b>Approved.</b>
11.	M/s Rafi Sultan Enterprises  Plot No. 19-1-A, Office No M-5, Mezzanine	<b>Legal Manufacturer:</b> i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul	A1 Care™ Analyzer (HbA1c analyzer)  Class C	For point-of- care testing to measure quantitatively the glycated	<b>Approved.</b>  Firm shall submit valid FSCof Germany before



	floor, Business Center, Block 6, PECHS Main Shahrah-e-Faisal, Karachi.  (ELI-00232)	06646, Republic of Korea  <b>Manufacturing site:</b> i-SENS, Inc. 12, Harmony-ro, 275beongil, Yeonsu-gu, Incheon 22014, Republic of Korea. FSC Korea issued on 03-07-2019  FSC Germany valid till 30-09-2020	Code: 801800  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	hemoglobin (HbA1c) in whole blood and to report the test results as a ratio of HbA1c to total hemoglobin (% or mmol/mol)	issuance of registration certificate.
12.	-do-	<b>Legal Manufacturer:</b>  i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea  <b>Manufacturing site:</b>  i-SENS, Inc. 94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea.  (FSC Korea issued on 28-01-2019)  FSC Germany valid till 30-09-2020	CareSens® N Eco Blood Glucose Monitoring System  Class C  Code: GM01WAA  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	Used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management at home or clinical settings.	<b>Approved.</b>  Firm shall submit valid FSC of Germany before issuance of registration certificate.
13.	-do-	<b>Legal Manufacturer:</b>  i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea  <b>Manufacturing site:</b>  i-SENS, Inc. 12, Harmony-ro, 275beongil, Yeonsu-gu,	A1Care™ (HbA1c Cartridge)  Class C  Shelf Life: 20 months (if refrigerated)  12 months (if stored at room temperature)	Reagent Cartridge for use with A1 Care Analyzer, a point of care POC in vitro diagnostic (IVD) device to measure quantitatively the glycated hemoglobin	<b>Approved.</b>  Firm shall submit valid FSC of Germany before issuance of registration certificate.

		Incheon 22014, Republic of Korea.  FSC Korea issued on 03-07-2019  FSC Germany valid till 30-09-2020	Code: 801013  Fee submitted: Rs. 50,000/-	(HbA1c) and report the result as a ratio (% or mmol/mol) of HbA1c to total hemoglobin.	
14.	-do-	<b>Legal Manufacturer:</b>  i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea  <b>Manufacturing site:</b>  i-SENS, Inc. 94-1, Donghwagongdan-ro, Munmak-eup, Wonju- si, Gangwon-do, 26365, Republic of Korea.  (FSC Korea issued on 29-11-2017)  FSC Germany valid till 30-09-2020	CareSens® N Blood Glucose Test Strip  Class C  Shelf life: 24 Months  Fee submitted: Rs. 50,000/-	These test strips work with the Caresens N Brand of Blood glucose meters to quantitatively measures glucose in whole blood.	<b>Approved.</b>  Firm shall submit valid FSC of Germany before issuance of registration certificate.
15.	-do-	<b>Legal Manufacturer:</b>  i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea  <b>Manufacturing site:</b>  i-SENS, Inc. 94-1, Donghwagongdan-ro, Munmak-eup, Wonju- si, Gangwon-do, 26365, Republic of Korea.  (FSC Korea issued on 28-1-2019)	CareSens® N Blood Glucose Monitoring System  Class C  Code: GM505PAD  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	Used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management at home or clinical settings.	<b>Approved.</b>  Firm shall submit valid FSC of Germany before issuance of registration certificate.

		FSC Germany valid till 30-09-2020			
16.	-do-	<p><b>Legal Manufacturer:</b></p> <p>i-Sens, Inc. 94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do 26365, Korea.</p> <p>(FSC Korea issue 29-11-2017)</p> <p>FSC US FDA 26-09-2019 to 25-09-2021</p>	<p>CareSenS™II Blood Glucose Monitoring System.</p> <p>Blood Glucose Monitoring System, Self-testing, in vitro</p> <p>Class C</p> <p>Code:</p> <p>CareSens II (GM505C)</p>	<p>CareSens II Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management effectively at home or clinical settings.</p> <p>CareSens N Eco Blood Glucose Monitoring System should be used only for self-testing outside the body.</p>	<b>Approved.</b>
17.	M/S Verizon. 60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore. (ELI-00087)	<p><b>Manufacturer:</b></p> <p>Cook Ireland Limited, O'Halloran Road, National Technology Park, Limerick, Ireland</p> <p>FSC Ireland valid till August 13, 2023</p>	<p>Zimmon® Pancreatic Stent (SPSOF)</p> <p>Codes: Codes as per FSC Ireland CFS009441 dated 13-08-2018</p> <p>Class C</p> <p>Shelf Life: 03 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>This device is used to drain obstructed pancreatic ducts. Sterile, single-use</p>	<p><b>Approved.</b></p> <p>Firm shall submit valid LOA before issuance of registration certificate.</p>
18.	-do-	<p><b>Manufacturer:</b></p> <p>Cook Ireland Limited,</p>	<p>Cotton-Huibregtse®</p>	<p>This device is used to drain</p>	<p><b>Approved.</b></p> <p>Firm shall submit</p>

		<p>O'Halloran Road, National Technology Park, Limerick, Ireland</p> <p>FSC Ireland valid till 15-02-2024</p>	<p>Biliary Stent Set</p> <p>Codes:</p> <p>CHBS-10-3, CHBS-10-10, CHBS-10-11, CHBS-10-12, CHBS-10-15, CHBS-10-5 CHBS-10-7, CHBS-10-9, CHBS-11.5-10, CHBS-11.5-12 CHBS-11.5-15, CHBS-11.5-5 CHBS-11.5-7, CHBS-11.5-9 CHBS-7-10, CHBS-7-12 CHBS-7-15, CHBS-7-3, CHBS-7-5, CHBS- 7-6, CHBS-7-7 CHBS-7-9, CHBS- 8.5-12 CHBS-8.5-15, CHBS-8.5-5 CHBS-8.5-7, CHBS-8.5-9</p> <p>Class C</p> <p>Shelf Life: 03 years</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>obstructed biliary ducts.</p> <p>Sterile, single use</p>	<p>valid LOA before issuance of registration certificate.</p>
19.	-do-	<p><b>Manufacturer:</b></p> <p>Cook Ireland Limited, O'Halloran Road, National Technology Park, Limerick, Ireland</p> <p>FSC Ireland valid till 15-02-2024</p>	<p>Nasal Biliary Drainage Set</p> <p><b>Code:</b></p> <p>ENBD-10, ENBD- 5, ENBD-6, ENBD-7, ENBD-</p>	<p>Intended for temporary endoscopic drainage of the biliary duct through the nasal passage by use of an indwelling</p>	<p><b>Approved.</b></p> <p>Firm shall submit valid LOA before issuance of registration certificate.</p>

			8.5 Class B Shelf Life: 03 years Fee submitted: Rs. 50,000/-	catheter. Sterile, single-use	
20.	-do-	<b>Manufacturer:</b> Cook Ireland Limited, O'Halloran Road, National Technology Park, Limerick, Ireland  FSC Ireland valid till August 13, 2023	Cotton-Leung® Biliary Stent  Code:  CLSO-5-12, CLSO-5-15, CLSO-5-3, CLSO- 5-5, CLSO-5-7, CLSO-5-9, CLSO- 7-10, CLSO-7-11, CLSO-7-12, CLSO-7-13, CLSO-7-14, CLSO-7-15, CLSO-7-2, CLSO- 7-3, CLSO-7-4, CLSO-7-5, CLSO- 7-6, CLSO-7-7, CLSO-7-8, CLSO- 7-9, CLSO-7-16, CLSO-7-17, CLSO-7-18, CLSO-7-19, CLSO-7-20, CLSO-7-21, CLSO-8.5-10, CLSO-8.5-11, CLSO-8.5-12, CLSO-8.5-13, CLSO-8.5-14, CLSO-8.5-15, CLSO-8.5-16, CLSO-8.5-17, CLSO-8.5-18, CLSO-8.5-3, CLSO-8.5-5, CLSO-8.5-6,	This device is used to drain obstructed biliary ducts.  Sterile, single use	<b>Approved.</b>  Firm shall submit valid LOA before issuance of registration certificate

			<p>CLSO-8.5-7,  CLSO-8.5-8,  CLSO-8.5-9,  CLSO-8.5-20,  CLSO-10-10,  CLSO-10-11,  CLSO-10-12,  CLSO-10-13,  CLSO-10-14,  CLSO-10-15  CLSO-10-16  CLSO-10-17  CLSO-10-18  CLSO-10-19  CLSO-10-20  CLSO-10-21  CLSO-10-2  CLSO-10-3  CLSO-10-4  CLSO-10-5  CLSO-10-6  CLSO-10-7  CLSO-10-8  CLSO-10-9  CLSO-11.5-8  CLSO-11.5-10  CLSO-11.5-11  CLSO-11.5-12  CLSO-11.5-13  CLSO-11.5-14  CLSO-11.5-15  CLSO-11.5-16  CLSO-11.5-17</p> <p>CLSO-11.5-18  CLSO-11.5-3  CLSO-11.5-5  CLSO-11.5-6  CLSO-11.5-7  CLSO-11.5-9  CLSO-11.5-20  Class C</p> <p>Shelf Life: 03 years</p> <p>Fee submitted: Rs.  50,000/-</p>		
21.	-do-	<p><b>Manufacturer:</b>  Cook Ireland Limited,  O'Halloran Road,</p>	<p>Universa® Soft  Multi-Length Stent  Set (ureteral stent</p>	<p>Used for  temporary  internal drainage</p>	<p><b>Approved.</b>  Firm shall submit</p>

		National Technology Park, Limerick, Ireland  FSC Ireland valid till January 28, 2024	set)  Code:  USI-500, USI-600, USI-700  Class C  Shelf Life: 03 years  Fee submitted: Rs. 50,000/-	from ureteropelvic junction to the bladder. Ureteral stents have been employed to relieve obstruction in a variety of benign, malignant and post-traumatic conditions. Sterile, single-use	valid LOA before issuance of registration certificate.  Firm shall apply separately for stent only registration.
22.	-do-	<b>Manufacturer:</b>  Cook Ireland Limited, O'Halloran Road, National Technology Park, Limerick, Ireland  FSC Ireland valid till August 13, 2023	Zimmon® Biliary Stent (ZSO)  <b>Code:</b>  ZSO-7-7, ZSO-7-10, ZSO-10-8,  ZSO-10-15, ZSO-10-10, ZSO-10-12,  ZSO-10-2, ZSO-10-3, ZSO-10-4,  ZSO-10-5, ZSO-10-6, ZSO-10-7,  ZSO-10-9, ZSO-5-3, ZSO-5-5,  ZSO-5-9, ZSO-5-12, ZSO-5-15,  ZSO-5-10, ZSO-5-4, ZSO-5-7, ZSO-6-10, ZSO-6-4, ZSO-6-7, ZSO-6-9, ZSO-7-3, ZSO-7-16, ZSO-7-18, ZSO-7-12, ZSO-7-15, ZSO-7-4, ZSO-7-5, ZSO-7-6, ZSO-7-9, ZSO-8-	This device is used to drain obstructed biliary ducts. Sterile, single-use	<b>Approved.</b>  Firm shall submit valid LOA before issuance of registration certificate.

			12, ZSO-8-15, ZSO-8-10, ZSO-8-4, ZSO-8-5, ZSO-8-7, ZSO-8-9  Class C  Shelf Life: 03 years  Fee submitted: Rs. 50,000/-		
23.	M/s 4A International Plot 7, Street 11, Lawyers Society Chaklala, Rawalpindi.  (ELI-00099)	<b>Legal manufacturer:</b>  Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.  FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018	<b>Detro Sept AF</b>  (Ethanol 10%, 2- Propanol 20%, DidecyI, dimethyl oxyethyl ammonium propionate 0.1- 05%)  Class- B  Shelf Life: 2 years  Sizes:1L, 5L	Alcohol Based surface Disinfectant.	<b>Approved.</b>
24.	-do-	<b>Legal manufacturer:</b>  Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.  FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018	<b>DETRO MULTI CARE</b>  (Phosphoric Acid, AlkyIPolyglycozide , Sodiumdodecylsulf ate)  Code/ sizes:  5L,1L  Class- B  Shelf Life: 3 years	Concentrated Solution for Rust Resolving and Maintenance`.	<b>Approved.</b>
25.	-do-	<b>Legal manufacturer:</b>  Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7,	<b>DETRO Cid Enzyme</b>  (Enzyme (amylase,Lipase, Protease)	Enzymatic Cleaning and disinfectant solution for instrument and	<b>Approved.</b>



		<p>Esenyurt, Istanbul, Turkey.</p> <p>FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018</p>	<p>Didecylmethylamm onium chloride, Benzalkonium Chloride, BIS (3-aminopropyl) dodecylamine)</p> <p>Class- C</p> <p>Shelf Life: 2 years</p> <p>Sizes: 1L, 2L, 5L</p>	Endoscopes`.	
26.	-do-	<p><b>Legal manufacturer:</b></p> <p>Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.</p> <p>FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018</p>	<p><b>DETRO ACTIV</b> (Peracetic Acid Powder, with enzyme amylase, Lipase, protease)</p> <p>Class- C</p> <p>Shelf Life: 2 years</p> <p>Sizes: 1L, 2L, 2.5L</p>	Disinfectant for instrument and Endoscope`.	<b>Approved.</b>
27.	-do-	<p><b>Legal manufacturer:</b></p> <p>Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.</p> <p>FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018</p>	<p><b>DETRO San Floor</b> Didecylmethylamm onium chloride, Benzalkonium Chloride, BIS (3 – aminopropyl) dodecylamine</p> <p>Class- C</p> <p>Shelf Life: 2 years</p> <p>Sizes: 1L, 2L, 5L</p>	Concentrated Surface disinfectant`.	<b>Approved.</b>

28.	-do-	<p><b>Legal manufacturer:</b></p> <p>Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.</p> <p>FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018</p>	<p><b>DETRO San Ait</b></p> <p>Hydrogen Per oxide 6% Silver Nitrate Solution 30ppm</p> <p>Class- B</p> <p>Shelf Life: 2 years</p> <p>Sizes:  1L, 5L</p>	<p>Hydrogen Per oxide 6% Silver Nitrate Solution 30ppm</p>	<b>Approved.</b>
29.	-do-	<p><b>Legal manufacturer:</b></p> <p>Detro Healthcare KimyaSanayi A.S Ataturk mah. Adnan Menderes cd. No. 7, Esenyurt, Istanbul, Turkey.</p> <p>FSC: Turkey Date of issue:08.05.2018 (valid for 36 months) FSC France issuance 14-11-2018</p>	<p><b>DETRO OPA</b></p> <p>Orthophytalaldehyd e 0.55%</p> <p>Class- C</p> <p>Shelf Life: 2 years</p> <p>Sizes:  5L</p>	<p><b>Orthophytalald ehyde 0.55%</b></p>	<b>Approved.</b>
30.	M/s Medisurg Innovatives Health Care, 1/6-N, Block 6, PECHS, Main Nursery, Shahrah- e-Faisal, Karachi (ELI-00242)	<p><b>Legal Manufacturer:</b> M/s ALN Route de la Gare 20240 Ghisonaccia France</p> <p><b>Manufacturing Site:</b> M/s ALN 589 Chemin du Niel 83230 Bormes les Mimosas, France</p> <p>FSC France Issuance Date(08-07-2019)</p>	<p>ALN Optional Vena Cava Filter</p> <p>Class-D</p> <p>Shelf life: 5 Years</p> <p>Codes &amp; Sizes as per FSC</p>	<p>ALN Optional Vena Cava Filter acts mechanically on the inferior vena cava. It opens and closes with each breath (16/min) thus allowing to fracture the formation of a large thrombus and thus avoid any risk of pulmonary embolism. It</p>	<b>Approved.</b>

				provides effective protection against PE. It is intended to be implanted in adult patients whose vena cava diameter is less than or equal to 32mm, from Juglar, Brachial, Femoral and Popliteal route placement.	
31.	M/S AMEER SONS 305-A, Upper Mall, Lahore (ELI-0058)	<b><u>Legal Manufacturer:</u></b> Oculus Private Limited  10 KAKI BUKIT AVENUE 1 # 06-08 SINGAPORE 417942  FSC Singapore issuance:08-01-2019  FSC: BELGIUM  Date of issue 11-03-2019	Flexcon® Prosthetic Contact Lens  Class B  Shelf Life 05 years	Flexcon Prosthetic Contact lens is indicated for concealing unsightly scarring or abnormalities of the iris. The lens may or may not have optical correction of refractive ametropia and shall follow a wearing schedule as recommended by an eye care practitioner.	<b>Approved.</b>
32.	-do-	<b><u>Legal Manufacturer:</u></b> Oculus Private Limited  10 KAKI BUKIT AVENUE 1 # 06-08 SINGAPORE 417942  FSC Singapore issuance:08-01-2019  FSC: BELGIUM  Date of issue 11-03-	(Freshkon 55)  (Soft Contact Lens)  Class B  Shelf Life 06 years	Freshkon 55 is applied directly to the cornea and is designed for daily wear for the correction of refractive ametropia in aphakic or non-aphakic persons, with non-diseased eyes	<b>Approved.</b>

		2019		that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.	
33.	-do-	<p><b><u>Legal Manufacturer:</u></b></p> <p>Oculus Private Limited</p> <p>10 KAKI BUKIT AVENUE 1 # 06-08 SINGAPORE 417942</p> <p>FSC Singapore issuance:08-01-2019</p> <p>FSC: BELGIUM</p> <p>Date of issue 11-03-2019</p>	<p>Flexcon® Super Thin Contact Lens</p> <p>Contact lens</p> <p>Class B</p> <p>Shelf Life 05 years</p>	<p>Flexcon Super Thin Contact Lens is indicated for daily wear optical correction of refractive ametropia in aphakic or non-aphakic persons, with non-diseased eyes. The lens may be prescribed in spherical powers ranging from -20.00D to +20.00D.</p>	<b>Approved.</b>
34.	<p>M/s Sure Bio-Diagnostics &amp; Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi.</p> <p>(ELI-00084)</p>	<p><b><u>Legal Manufacturer:</u></b></p> <p>Diagnostic Automation /Cortex Diagnostics Inc. 21250 Califa St, Suite 102 and 116 Woodland hills, CA USA 91367</p> <p>(FSC USA Validity 01-02-2021 to 31-01-2023)</p>	<p>Alcohol Urine RaipDip</p> <p>Insta Test</p> <p>Alcohol Saliva Insta Test</p> <p>Amphetamine Urine RapidDip</p> <p>Barbiturate Urine RapiDip™Insta Test</p> <p>Benzodiazepine Urine RapiDip™InstaTest</p> <p>Methamphetamine Urine RapiDip™InstaTest</p>	N/A	<b>Approved.</b>

			<p>Marijuana Urine RapiDip™Insta Test</p> <p>Opiates/Heroin/Mo rphine Urine RapiDip™Insta Test</p> <p>Class B</p> <p>Shelf life: 2 years</p> <p>Sizes &amp; Codes as Per FSC</p>		
35.	<p>M /s Alliance Medical 12-B, 1<sup>st</sup> Floor, Agro Flats, Shadman, Lahore.</p> <p>ELI-00147</p>	<p><b>Legal Manufacturer:</b> Genoss Co. Ltd. 1F, Gyeonggi R&amp;DB Center, 226, 2F, GSBC, 105, Gwanggyo-ro, Yeongtong-gu, Suwon- si, Gyeonggi-do, Korea.</p> <p>FSC Korea Date of issue 2.08.2017 FSC Netherland validity 03-10-2023</p>	<p><b>GENOSS EXTRACTOR Aspiration Catheter</b> (Embolectomy Catheter)</p> <p>Class: D</p> <p>Shelf life: 3 years</p> <p>Codes: GAC-6-110, GAC- 7-130, GAC-8-150</p>	<p>The EXTRACTOR Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.</p>	<b>Approved.</b>
36.	-do-	<p><b>Legal Manufacturer:</b> Genoss Co. Ltd. 1F, Gyeonggi R&amp;DB Center, 226, 2F, GSBC, 105, Gwanggyo-ro, Yeongtong-gu, Suwon- si, Gyeonggi-do, Korea.</p> <p>FSC Korea Date of issue 2.08.2017 FSC Netherland validity 03-10-2023</p>	<p><b>(GENOSS PTCA Balloon Catheter)</b> PTCA (Percutaneous Transluminal Coronary Angioplasty) Catheter</p> <p>Class: D</p> <p>Shelf Life: 3 years</p> <p>Codes as per FSC</p>	<p>The rapid exchange PTCA Balloon Catheter is intended for use during percutaneous transluminal coronary angioplasty for the purpose of improving myocardial blood flow in a localized stenotic lesion</p>	<b>Approved.</b>

				of the coronary arteries	
37.	-do-	<p><b>Legal Manufacturer:</b> Genoss Co. Ltd. 1F, Gyeonggi R&amp;DB Center, 226, 2F, GSBC, 105, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea. FSC Korea Date of issue 2.08.2017 FSC Netherland validity03-10-2023.</p>	<p><b>GENOSS NC PTCA Balloon Catheter</b>  (PTCA Percutaneous Transluminal Coronary Angioplasty_ Catheter  Class D  Shelf Life 3 years  CODES AS PER FSC:</p>	<p>The Non-compliant PTCA Balloon Catheter is intended for the balloon dilatation of the stenotic part of a coronary artery or bypass graft stenosis in patients indicating coronary ischemia for the purpose of improving myocardial perfusion.  Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction in-stent restenosis.  Post-delivery expansion of balloon expandable coronary stents.</p>	<b>Approved.</b>
38.	<p>M/s Asto Life Science Pvt Ltd, 44/1, Block-K, Model Town Lahore  ELI-00103</p>	<p><b>Legal Manufacturer:</b> Becton, Dickinson and Company (BD) 7 Loveton Circle sparks, MD 21152  FSC: FDA U.S FDA  Valid till 21</p>	<p>BD BACTEC BLOOD CULTURE SYSTEM  (Bacterial growth detection system)  Class- B</p>	Bacterial growth detection system	<b>Approved.</b>

		March,2021	Codes as per FSC		
39.	M/s AL-HAMD Enterprises, FL-11/1/1, Block06, Gulshan-e-Iqbal, Karachi  ELI: 00285	<b><u>Legal Manufacturer</u></b> FARMOMAKE FOR ADVANCE MEDICAL INDUSTRIES (S.A.E) Borg AL-Arab, 4 <sup>th</sup> Industrial Zone, Block-2, Part 7/16, Alexandria Egypt  FSC: Egypt  Date of Issue8th November,2016  FSC Germany issuance 08-04-2020	FARCOCATHE I.V CANNULA (Safety Type)  Class-B  Shelf Life: 5 years  Sizes: 14G,16G,18G,20G, 22G, 24G,26G	I.V Cannula to be introduced into a peripheral vein for administering infusion & IV Drugs	<b>Deferred</b> till cancellation of Farcocath I.V. Cannula (registered as drug) by the Registration Board.
40.	-do-	<b><u>Legal Manufacturer:</u></b> FARMOMAKE FOR ADVANCE MEDICAL INDUSTRIES (S.A.E) Borg AL-Arab, 4 <sup>th</sup> Industrial Zone, Block-2, Part 7/16, Alexandria Egypt  FSC: Egypt  Date of Issue: 8th November,2016  FSC Germany issuance 08-04-2020	FARCOCATHE I.V CANNULA (With Stopper Type))  Class-B  Shelf Life: 5 years  Sizes: 14G,16G,18G,20G, 22G, 24G,26G	I.V Cannula to be introduced into a peripheral vein for administering infusion & IV Drugs	<b>Deferred</b> till cancellation of Farcocath I.V. Cannula (registered as drug) by the Registration Board.
41.	-do-	<b><u>Legal Manufacturer:</u></b> FARMOMAKE FOR ADVANCE MEDICAL INDUSTRIES (S.A.E) Borg AL-Arab, 4 <sup>th</sup> Industrial Zone, Block-2, Part 7/16, Alexandria Egypt  FSC: Egypt	FARCOCATHE I.V CANNULA (Injection Fort Type)  Class-B  Shelf Life: 5 years  Sizes:	I.V Cannula to be introduced into a peripheral vein for administering infusion & IV Drugs	<b>Deferred</b> till cancellation of Farcocath I.V. Cannula (registered as drug) by the Registration Board.

		Date of Issue: 8th November,2016  FSC Germany issuance 08-04-2020.	14G,16G,18G,20G, 22G, 24G,26G		
42.	M/s. Digital Imaging Systems, 121- Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore.  ELI-00094	<b><u>Legal Manufacturer:</u></b> Abbott Medical. 4 Robbins Road, Westford, MA 01886 USA <b><u>Manufacturing Site</u></b> St. Jude MedicalCosta Rica Ltda. Edificio #44Calle 0, Ave. 2, Zona FrancaCoyol, El Coyol, Alajuela, Costa Rica 1897-4050  FSC US FDA valid till 17 <sup>th</sup> September, 2020	DragonFly™ OPTIST™ Kit Imaging Catheter  Codes: C408646  Class: D  Shelf Life: 2 years  Fee submitted: Rs. 50,000/-	Intended for visualization and imaging of coronary arteries during an interventional procedure. Sterile, single use	<b>Approved.</b>  Firm shall submit valid FSC and MRP before issuance of registration certificate.
43.	M/s Mehran International 498/C  Feroz Shah Mehta Road, Karachi.  ELI-00351	<b><u>Legal Manufacturer:</u></b> Changzhou Kenno Medical Instruments Co., Ltd. No. 2188, Longcheng Road, Xinzha Street, Zhonglou District Changzhou 213012 Jiangsu China.  FSC MHRA issuance 09-11-2017	M.I Cannula with Heparin cap and stopper  Class-B  Shelf life: 5 years  Sizes as per FSC	IV Catheters	<b>Approved.</b>
44.	-do-	<b><u>Legal Manufacturer:</u></b> Changzhou Kenno Medical Instruments Co., Ltd. No. 2188, Longcheng Road, Xinzha Street, Zhonglou District Changzhou 213012 Jiangsu China.  FSC MHRA issuance 09-11-2017	M.I Cannula pen type with stopper  Class-B  Shelf life: 5 years  Sizes as per FSC	IV Catheters	<b>Approved.</b>



45.	-do-	<p><b><u>Legal Manufacturer:</u></b> Changzhou Kenno Medical Instruments Co., Ltd. No. 2188, Longcheng Road, Xinzha Street, Zhonglou District Changzhou 213012 Jiangsu China.</p> <p>FSC MHRA issuance 09-11-2017</p>	<p>M.I Cannula pen type with cover</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes as per FSC</p>	IV Catheters	<b>Approved.</b>
46.	-do-	<p><b><u>Legal Manufacturer:</u></b> Changzhou Kenno Medical Instruments Co., Ltd. No. 2188, Longcheng Road, Xinzha Street, Zhonglou District Changzhou 213012 Jiangsu China.</p> <p>FSC MHRA issuance 09-11-2017</p>	<p>M.I Cannula wing type with stopper</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes as per FSC</p>	IV Catheters	<b>Approved.</b>
47.	-do-	<p><b><u>Legal Manufacturer:</u></b> Changzhou Kenno Medical Instruments Co., Ltd. No. 2188, Longcheng Road, Xinzha Street, Zhonglou District Changzhou 213012 Jiangsu China.</p> <p>FSC MHRA issuance 09-11-2017</p>	<p>M.I Cannula wing type with injection port</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Sizes as per FSC</p>	IV Catheters	<b>Approved.</b>
48.	M/s. Mezan International 59 BR II, Opp.DCO, House Haji Meherban Road, Jhelum ELI-00096.	<p><b><u>Legal Manufacturer:</u></b> M/s ACTO Pharma SANAYI TIC. A.S (located at AkcaburgazMahallesi, 3038 SoK No 11 34522 Esenyurt Istanbul) Turkey</p>	<p>ACTODERM (62,8 g2=Propanol (active substance 70% v/v) and auxiliary substance (Butyldiglycol,</p>	Skin disinfectant	<b>Deferred for</b> provision of valid FSC of country of origin and provision of FSC of reference country or CE marked

		FSC Turkey valid till 13-03-2021	Lanolin)  Class B  Shelf Lie: 3 years  Codes:  06.2501.50 06.2501.100 06.2501.250 06.2501.500 06.2501.1 06.2501.5		documents.
49.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi.  ELI-00020	<b>Legal Manufacturer</b>  M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom.  FSC U.K  Issued on 01.03.2016	Clearlite, Anesthetic Face Mask  Class B  Shelf Life: 05 years  Code: 7291000, 7292000, 7293000, 7295000, 7290000, 7294000, 7296000	To deliver anesthetic gas and oxygen to a patient	<b>Approved.</b>
50.	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 27-05-2025	ARCHITECT SARS-CoV-2 IgG II Quant Kit  Class C  1. SARS-CoV-2 IgG II Quant Reagent Kit Shelf life: 6 months Code: 6S6022 Tests: 100 tests 2. SARS-CoV-2	Chemiluminescent microparticle immunoassay (CMIA) used for qualitative and quantitative determination of IgG antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i system. To be	<b>Approved.</b>  The firm shall submit original FSC and MRP before issuance of registration letter.

			<p>IgG II Quant Reagent Kit Shelf life: 6 months Code: 6S6032 Tests: 500 tests 3. SARS-CoV-2 IgG II Quant Calibrator Kit Shelf life: 5 months Code: 6S6002 4. SARS-CoV-2 IgG II Quant Control Kit Shelf life: 5 months Code: 6S6012</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Also to be used as an aid in evaluating immune status of individuals with quantitative measurement of IgG antibodies against the spike receptor-binding domain (RBD) of SARS-CoV-2. Results should not be used as the sole basis of diagnosis</p>	
51.	-do-	<p>Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland</p> <p>FSC Ireland valid till 27-05-2025</p>	<p>Alinity SARS-CoV-2 IgG II Quant Kit</p> <p>Class C</p> <p>1. SARS-CoV-2 IgG II Quant Reagent Kit Shelf life: 6 months Code: 6S6122 Tests: 100 tests 2. SARS-CoV-2 IgG II Quant Reagent Kit Shelf life: 6 months Code: 6S6132 Tests: 500 tests 3. SARS-CoV-2</p>	<p>Chemiluminescent microparticle immunoassay (CMIA) used for qualitative and quantitative determination of IgG antibodies to SARS-CoV-2 in human serum and plasma on the Alinity system. To be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and</p>	<p><b>Approved.</b></p> <p>The firm shall submit original FSC and MRP before issuance of registration letter</p>

			<p>IgG II Quant Calibrator Kit Shelf life: 5 months Code: 6S6102</p> <p>4. SARS-CoV-2 IgG II Quant Control Kit Shelf life: 5 months Code: 6S6112</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>other laboratory tests. Also to be used as an aid in evaluating immune status of individuals with quantitative measurement of IgG antibodies against the spike receptor-binding domain (RBD) of SARS-CoV-2. Results should not be used as the sole basis of diagnosis</p>	
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**XV. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).**

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	<p><b>Legal Manufacturer:</b> M/s Abbott GmbH &amp; Co KG Max-Planck Ring 2, 65205 Wiesbaden, Germany.</p> <p><b>Manufacturing site:</b> M/s Sanmina-SCL Systems Singapore Pte Ltd 2 Chai Chee Drive Singapore 469044 Singapore.</p> <p>FSC Germany Issuance Date(19-07-2019)</p>	<p>Alinity I Processing Module</p> <p>Class A</p> <p>Shelf Life: N/A</p> <p>Code: 03R6501</p>	Alinity I Processing Module	<b>Approved.</b>
2.	-do-	<p><b>Legal Manufacturer:</b> M/s Abbott Molecular Inc., 1300 East Avenue Des Plaines Illinois, USA.</p>	<p>m2000rt Instrument &amp; Accessories</p> <p>Class A</p> <p>Shelf Life:</p>	The m2000rt system provides for real-time measurement of the stages of the PCR. Real-time	<p><b>Approved.</b></p> <p>The firm shall submit valid FSC and ISO 13485 before issuance of registration</p>

		FSC USFDA Valid Till (30-01-2021)	N/A  Codes & Sizes as per FSC	PCR measures PCR amplification as it occurs, cycle-by-cycle, allowing quantitative measurements to be made during the highly-reproducible exponential phase of the PCR.	certificate.
3.	-do-	<b>Legal Manufacturer:</b> M/s Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park, IL 60064, USA.  FSC USFDA Valid Till (21-01-2021)	Architect c8000 Processing Module Architect c Systems ICT Module  Class A  Shelf Life: N/A  Codes & Sizes as per FSC	Architect c8000 Processing Module Architect c Systems ICT Module uses both photometric and potentiometric detection technology to measure the concentration of analytes in samples.	<b>Approved.</b>  The firm shall submit valid FSC before issuance of registration certificate.
4.	M/s Alliance Medical 12-B, 1 <sup>st</sup> Floor, Agro Flats, Sherman, Lahore.  ELI-00147	<b>Legal Manufacturer:</b> Genoss Co. Ltd. 1F, Gyeonggi R&DB Center, 226, 2F, GSBC, 105, Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea.  FSC Korea Date of issue 2.08.2017 FSC Netherland validity 03-10-2023	(GENOSS Inflator Set.) (Catherter Balloon)  Class A  Shelf Life: 3 years  CODES AS PER FSC: GI30V-BA1, GI30V-BA2, GI30V-BB1, GI30V-BB2, GI30-BA1, GI30-BA2, GI30-BB1, GI30-BB2, GI30V-SA1, GI30V-SA2,	The Genoss Inflators are designed to be used to inflate/deflate balloon catheters during angioplasty procedures as well as to monitor pressure within the balloon. Note: applied on F-7(A)	<b>Approved.</b>

			GI30V-SB1, GI30V-SB2, GI30V-S, GI30-SA1, GI30-SA2, GI30-SB1, GI30-SB2, GI40V-BA1, GI40V-BA2, GI40V-BB1, GI40V-BB2, GI40-BA1, GI40-BA2, GI40-BB1, GI40-BB2, GI40V-SA1, GI40V-SA2, GI40V-SB1, GI40-SA1, GI40-SA2, GI40-SB1, GI40-SB2, GBI-B30, GBI-B30S, GBI-B30V, GBI-B30VS, GBI-B40, GBI-B40S, GBI-B40V, GBI-B40VS.		
5.	-do-	<p><b>Legal Manufacturer:</b> Aries Srl, Via XXV Luglio 43 – 41037, Mirandola, Modena, Italy</p> <p><b>Manufacturer Site:</b> Millennium Utility Srl, via GheorgeDoiia 68, 43550 SighetuMarmatiei Romania.</p> <p>FSC: Italy Date of issue 7.6.2017</p>	<p><b>ARIES Three Stop Extension Line</b> (Pressure Extension Line). (Extension Line)</p> <p>Class A</p> <p>Shelf Life 5 years</p> <p>Codes: IN022155, IN022160, IN022162, IN022165, IN022170, IN022155, IN026004, IN026005, IN026010, IN026012, IN026022, IN026025, IN026030, IN026035.</p>	The pressure monitoring line is intended to be used in fluid management and pressure monitoring applications.	<b>Approved.</b>
6.	M/s. Hashir Surgical Services,	<p><b>Legal Manufacturer:</b> M/s. ShengGuang</p>	<b>FFP2 Particulate Respirator</b>	It works as a	<b>Approved.</b>

	Office No.5, 2nd Floor, Syed's Tower, University Road, Peshawar.  (ELI-00075)	Medical Instrument Co., Ltd, East of Longshan Road JiaxianPingdingshan city, Henan 467000 China.  FSC China 15/05/2020 Valid for two years	Class A  Shelf Life: 2 years.  Code: SG-201	barrier preventing pathogen, microbe, bacteria and particles from entering body through nasal and oral cavity.	
7.	M/s Asto Life Sciences Pvt Ltd, 44/1, K Block Model Town Lahore  ELI-00103	<b><u>Legal Manufacturer:</u></b>  Becton, Dickinson and Company BD Bio Sciences 2350, QUME DR. San Jose, CA USA  FSC HPRA  Validity till 08-05- 2023	BD FACSPresto CD4 System Flow Cytometer  Class-A  Shelf Life:  Code: 651000 655495 657681(24 months)	Flow Cytometer	<b>Approved.</b>  Firm shall submit valid QMS certificate before issuance of registration certificate.
8.	M/s ACP System, 13 & 23 Naval Fleet Club, Iqbal SJ (Shaheed) Road, Karachi  (ELI-00001)	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA.  (FSC Valid USFDA 14-01-2021)	DeBakey Forceps  Surgical Reusable (non Sterile) Instruments  Class A  Shelf Life: Made of Stainless Steel and Titanium. It is resuable Shelf Life depends on care.  Sizes & Codes as per FSC	Surgical Reusable (non Sterile) Instruments	<b>Approved.</b>  Firm shall submit valid FSC and QMS certificate before issuance of registration certificate.
9.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA.	Thoracoscopic Knot Tier/Pusher  Class A  Shelf Life: Depends upon care	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.

		(FSC Valid USFDA 14-01-2021)	Sizes & Codes as per FSC		
10.	-do-	<b>Legal Manufacturer:</b> M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA. (FSC Valid USFDA 14-01-2021)	MIS Clip Applier  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
11.	-do-	<b>Legal Manufacturer:</b> M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA. (FSC Valid USFDA 14-01-2021)	MIS Scissors  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
12.	-do-	<b>Legal Manufacturer:</b> M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA. (FSC Valid USFDA 14-01-2021)	Bard-Parker handle  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
13.	-do-	<b>Legal Manufacturer:</b> M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110- 120, Houston, TX 77035, USA. (FSC Valid USFDA 14-01-2021)	Multi-Purpose Clamps  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
14.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical	MIS Needle Holders	Surgical Instruments	<b>Approved.</b>  Firm shall submit



		Inc., 11333 Chimney Rock Rd Suite 110-120, Houston, TX 77035, USA.  (FSC Valid USFDA 14-01-2021)	Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC		valid FSC and FQA certificate before issuance of registration certificate.
15.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110-120, Houston, TX 77035, USA.  (FSC Valid USFDA 14-01-2021)	Yasargil-Type Applying Forceps  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
16.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110-120, Houston, TX 77035, USA.  (FSC Valid USFDA 14-01-2021)	VATS Forceps  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
17.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney Rock Rd Suite 110-120, Houston, TX 77035, USA.  (FSC Valid USFDA 14-01-2021)	Yasargil-Type Occlusion Clip  Class A  Shelf Life: Depends upon care  Sizes & Codes as per FSC	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and FQA certificate before issuance of registration certificate.
18.	-do-	<b>Legal Manufacturer:</b>  M/s Wexler Surgical Inc., 11333 Chimney	Metzenbaum Scissors	Surgical Instruments	<b>Approved.</b>  Firm shall submit valid FSC and

		Rock Rd Suite 110-120, Houston, TX 77035, USA. (FSC Valid USFDA 14-01-2021)	Class A Shelf Life: Depends upon care Sizes & Codes as per FSC		FQA certificate before issuance of registration certificate.
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**XVI. 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

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description
1.	M/s Eastern Medical Care (Pvt) Ltd, 7A Block N, Model Town Extension, Lahore  ELI-00130	Manufacturer: ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia  FSC Malaysia valid till 04-08-2025  FSC Ireland valid till 27-09-2024	ASAP Latex Powder Free Examination Gloves  Size: Small, Medium, Large  Class: A  Shelf life: 3 years  Fee submitted: Rs. 5,000/-	Non-sterile, single use, powder free, natural rubber latex examination glove
2.	-do-	Manufacturer: ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia  FSC Malaysia valid till 04-08-2025  FSC Ireland valid till 27-09-2024	ASAP Latex Powdered Examination Gloves  Size: Small, Medium, Large, Extra large, Extra Small, Extra extra large  Class: A  Shelf life: 3 years  Fee submitted: Rs.	Non-sterile, single use, powdered, natural rubber latex examination glove

			5,000/-	
3.	-do-	<p><b>Manufacturer:</b> ASAP International Sdn. Bhd No. 1, Jalan Sitar 33/6, Seksyen 33 Shah Alam, Selangor, 40400 Malaysia</p> <p>FSC Malaysia valid till 04-08- 2025</p> <p>FSC Ireland valid till 27-09- 2024</p>	<p>ASAP Lite Nitrile Powder Free Examination Gloves</p> <p>Size: Small, Medium, Large, Extra-large, Extra Small, Extra extra large</p> <p>Class: A</p> <p>Shelf life: 3 years</p> <p>Fee submitted: Rs. 5,000/-</p>	Non-sterile, single use, powdered, natural rubber latex examination glove

**Decision: The Board approved the above mentioned products at Sr. No.1-3.**

4.	<p>M/s Meher Traders,  Office No. A-21- 22 First Floor ZeenatMedecine Market North Nappier Road, Karachi.  (ELI-00128)</p>	<p><b>Manufacturer:</b>  Hunan LuzhouHuikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China.  FSC China valid till 13-10- 2021</p>	<p>Wellmed Infusion Set  Class-B  Shelf Life: 5 Years  Sizes &amp; Codes as per FSC  HB6-2, HB6-3, HB6-4, HB6-5, HB6-7, HB6-8.</p>	Sterile infusion set for single use: hypodermic needle intended for the aspiration of fluids or for the injection of fluids immediately after filling.
5.	-do-	<p><b>Legal Manufacturer:</b>  Nanchang Kaimed Medical Apprautus Co., Ltd.  Jinxian Medical Device Industrial Area, Nanchang City, Jiangxi Province, 331700 China.</p>	<p>WellMed  Endotracheal Tube  Class-B  Shelf Life: 5 Years  Sizes &amp; Codes as per FSC</p>	Tracheal tubes may also be used as a route for administration of certain medications such as salbutamol, atropine, epinephrine, ipratropium, and lidocaine. Tracheal Tubes are commonly used for airway management in the settings of general anesthesia, critical care, mechanical ventilation, and emergency medicine.

		(FSC valid till 01-06-2021)	Endotracheal Tube  Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	
6.	-do-	<b>Manufacturer:</b>  Hunan LuzhouHuikang Development Co., Ltd Located at Xiangshang Industrial Park, Guanxia County, Suining, Hunan Province, China.  FSC China valid till 13-10-2021	Wellmed  Disposable Syringe (with Needle) 1ml, 3ml, 5ml, 10ml  Class B  Shelf Life: 5 Years  Sizes & Codes as per FSC  1ml, 3ml, 5ml, 10ml	The Sterile syringe with hypodermic needle intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe will be rendered unusable after use.
<p><b>Decision: The Board approved the above mentioned products at Sr. No.4-5 and Sr.No.6 Wellmed Disposable Syringe (with Needle) only 1ml and 10ml Approved on the basis of CE marked documents provided by the firm.</b></p>				
7.	M/s Asto Life Sciences Pvt Ltd, Plaza No., Block Orchard 1, Paragon city, Barki Road, Lahore Cantt.  ELI-00103	<b>Legal Manufacturer</b> Becton, Medical (S) Pte Ltd 30 Tuas Avenue 2, Singapore 539461 Singapore.  FSC: Singapore issuance 20-11-2018	BD™ precision glide needles  Class-B  Shelf life: 5 years  Codes/ sizes as per FSC:	BD Hypodermic Needles are single use, sterile sharp bevel-edged, hollow tubular metal device intended to be used in conjunction with syringes, secondary medication sets or phlebotomy equipment's to prepare and administer fluids/ medications/ drugs to a

			18G-27G (BD Hypodermic Needles 18G to 27 G)	
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**Decision: The Board approved the above mentioned product at Sr. No.7 on the basis of CE marked documents provided by the firm.**

8.	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
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**Decision: The Board approved the above mentioned product at Sr. No.8 on the basis of CE marked documents provided by the firm.**

9.	M/s Anwar & Sons, Apartment No.10, Safari Villas-2, Commercial Complex, Bahria Town Phase 7, Rawalpindi  (ELI-00017)	Manufacturer: M/s. SUMI Spolka z ograniczona, odpowiedzialnosciaSp.k. ul. Drobiarska, 35, 05- 070 Sulejowek, Poland. FSC Poland issued on 05.07.2017	Tracheal Tubes Class B  Types: Tracheal tube with cuff, type magil Tracheal tube with cuff type magil, siliconised Tracheal tube with low pressure cuff, type murphy Tracheal tube with low pressure cuff, type murphy, siliconised Tracheal tube with low pressure cuff, type murphy, siliconised with stylet Tracheal tube with high volume cuff, type murphy, siliconised	Tracheal tubes
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			<p>Tracheal tube without cuff, type murphy</p> <p>Tracheal tube without cuff, type murphy, siliconised</p> <p>Tracheal tube without cuff, type murphy, siliconised with stylet</p> <p>Tracheal tube without cuff, type murphy, soft, siliconised with stylet</p> <p>Microlaryngeal tracheal tube, siliconised</p> <p>Microlaryngeal tracheal tube, siliconised, reinforced</p> <p>Tracheal tube with suction lumen, type murphy, siliconised</p> <p>Reinforced tracheal tube with cuff, type murphy</p> <p>Reinforced tracheal tube with cuff, type murphy, siliconised</p> <p>Reinforced tracheal tube with cuff, type murphy, siliconised with stylet</p> <p>Reinforced tracheal tube without cuff, type murphy</p> <p>Reinforced tracheal tube without cuff, type murphy, siliconised</p> <p>Reinforced tracheal tube without cuff,</p>	
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			<p>type murphy, siliconised, with stylet Preformed tracheal tube with cuff, oral, type murphy Preformed tracheal tube with cuff, oral, type murphy, siliconised Preformed tracheal tube with cuff, oral - forehead, type murphy, siliconised Preformed tracheal tube with cuff, oral -forehead, type murphy, siliconised Preformed tracheal tube without cuff, oral, type murphy, Preformed tracheal tube without cuff, oral, type murphy, siliconised Preformed tracheal tube without cuff, oralforehead, type murphy, siliconised Preformed tracheal tube without cuff, oralforehead, type murphy, siliconised Preformed tracheal tube with cuff, nasal, type murphy Preformed tracheal tube with cuff, nasal, type murphy, siliconised Preformed tracheal tube without cuff, nasal, type murphy Preformed tracheal tube without cuff, nasal, type murphy,</p>	
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			<p>siliconized</p> <p>Codes against each type as per FSC dated 05-07-2017</p> <p>Shelf Life: 05 years Fee submitted: Rs. 25,000/-</p>	
10.	-do-	<p>Manufacturer: M/s. SUMI Spolka z ograniczona, odpowiedzialnosciaSp.k. ul. Drobiarska, 35, 05- 070 Sulejowek, Poland.</p> <p>FSC Poland issued on 05.07.2017</p>	<p>Tracheostomy Tubes</p> <p>Class C</p> <p>Types:</p> <p>Tracheostomy tube with low pressure cuff Tracheostomy tube with low pressure cuff, siliconised Tracheostomy tube with cuff, siliconised Tracheostomy tube with double cuff, siliconized Tracheostomy tube without cuff Tracheostomy tube without cuff, siliconised Tracheostomy tube without cuff, without connector, siliconised Tracheostomy tube with suction lumen, siliconised Tracheostomy tube with cuff, with adjustable flange, siliconised Tracheostomy tube without cuff, with adjustable flange,</p>	Tracheostomy tubes



			<p>siliconised Reinforced tracheostomy tube with cuff, with adjustable flange, siliconised Reinforced tracheostomy tube without cuff, with adjustable flange, siliconised</p> <p>Codes against each type as per FSC dated 06-07-2017</p> <p>Shelf Life: 05 years Fee submitted: Rs. 50,000/-</p>	
<p><b>Decision: The Board discussed the case in length and in the light of recommendation of a Committee Member i.e. Dr. Muhammad Tahir Aziz approved the above mentioned medical devices at Sr. No.9-10.</b></p>				
11.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road Karachi</p> <p>ELI: 00351</p>	<p>Legal Manufacturer: M/s Shandong Qinkal Medical Industry Co., Ltd the Southern Tip of Quancheng Road in Industrial Pasrk) Medical Equipment Industrial Park, Chengwu, County, Heze City, Shandong Province P.R China.</p>	<p><b>RELATION</b> Burette Infusion Set 100 ML</p> <p>Class-B.</p> <p>Claimed Shelf Life: 5 years</p>	Relation Burette Infusion Set 100 ML
12.	-do-	<p>Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China. FSC: China</p>	<p>Suction Connecting Tube.</p> <p>Codes &amp; Sizes: As per FSC</p> <p>Class-B</p> <p>Claimed Shelf Life: 5 years</p>	Suction Connecting Tube

13.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China FSC: China.	Nasal Oxygen Cannula.  Codes & Sizes: As per FSC  Class-B  Claimed Shelf Life: 5 years	Nasal Oxygen Cannula
14.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China FSC: China	<b>RELATION</b> Oxygen Mask with Reservoir Bag  Codes & Sizes: As per FSC  Class-B.  Claimed Shelf Life: 5 years	Relation Oxygen Mask with Reservoir Bag
15.	-do-	Legal Manufacturer: M/s Hunan Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China FSC:China	<b>M.I</b> Sterile Hydrodermic Disposable Syringes.  (1 ml Insulin)  Codes & Sizes: As per FSC  Class-B.  Claimed Shelf Life: 5 years	M.I Sterile Hydrodermic Disposable Syringes 1 ml Insulin)
16.	-do-	Legal Manufacturer: Hunan Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China	<b>M.I.</b> Hydrodermic Disposable Syringes.  (1 ml)	M.I Hydrodermic Disposable Syringes 1 ml

		FSC: China.	Codes &Size: As per FSC Class-B Claimed Shelf Life: 5 years	
17.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China. FSC: China	Suction Catheter Cap Cone connector. Codes &Size: As per FSC Class-B. Claimed Shelf Life: 5 years	Suction Catheter Cap Cone connector
<p><b>Decision: The Board discussed and decided to approve the above mentioned medical devices at Sr. No.11-17.</b></p>				

**Item No.XVIII. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).**

Following applications for registration of Medical Devices for import (COVID related item):-

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi	TURKLAB TIBBI MALZEMELER SAN ve TIC A.S. ITOB 10017 Sokak No. 2 Tekeli - Menders - Izmir/TURKEY  FSC Turkey valid	TOYO® COVID-19 Ag Test (device)  Code: TCV03  Class C (applied as B)  Shelf life: 24 Months  Fee submitted: Rs.	Used for in-vitro qualitative detection of the antigen of novel corona virus in human throat swabs or nasal swabs	<b>Deferred</b> since the product is manufactured in Turkey which is not a reference country.

	(ELI-00084)	till 07-02-2024	25,000/-		
2.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah-e-Faisal Karachi  (ELI-00010)	<b>Manufacturer:</b> M/s DiaSorin S.p.A., Via Crescentino, snc 13040 Saluggia (VC) Italy  FSC Italy issued on 10-07-2020	Liaison® SARS CoV-2 IgM (Kit)  Class C  1. Liaison® SARS CoV-2 IgM Code: 311470 Shelf life:6 months  2. Liaison® Control SARS CoV-2 IgM Code: 311471 Shelf life: 6 months  Fee submitted: Rs.50,000/-	Uses chemiluminescence immunoassay (CLIA) technology for the qualitative determination of specific IgM antibodies to SARS-CoV-2 in human serum or plasma samples. Intended as an aid in the diagnosis of COVID-19 and to support the study of immune status of patients who may have been exposed to and infected by SARS-CoV-2. Results should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform about infection status	<b>Approved</b>  Firm shall provide the FSC embassy attested, Letter of Authorization copy provided and MRP not provided
3.	-do-	<b>Manufacturer:</b> M/s DiaSorin S.p.A., Via Crescentino, snc 13040 Saluggia (VC) Italy  FSC Italy issued on 19-05-2020	Liaison® SARS CoV-2 S1/S2 IgG (Kit)  Class C  1. Liaison® SARS-CoV-2 S1/S2 IgG Code: 311450 Shelf life:6 months  2. Liaison® Control SARS-CoV-2 S1/S2 IgG Code: 311451 Shelf life: 6 months  Fee submitted: Rs.50,000/-	Uses chemiluminescence immunoassay (CLIA) technology for the quantitative determination of anti-S1 and anti-S2 specific IgG antibodies to SARS-CoV-2 in human serum or plasma samples. Intended as an aid in the diagnosis of COVID-19 and to support the study of immune status of infected patient by providing an indication of the presence of neutralizing IgG antibodies against SARS-CoV-2. Results should not be used as the sole basis to	<b>Approved.</b>

				diagnose or exclude SARS-CoV-2 infection or to inform about infection status	
4.	M/s Meditec Instruments Co., Suit No. 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi (ELI-00233)	Manufacturer: Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China FSC Belgium issued on 16-10-2020	Finecare™ SARS CoV-2 IgG/IgM Test (Device)  Class C Codes: W278  Shelf Life: 12 Months  Fee submitted: Rs. 50,000/-	Fluorescence immunoassay used along with Finecare™ FIA™ meters for qualitative detection of IgG and IgM antibodies of SARS-CoV-2 in human whole blood, serum and plasma specimen. Clinically the test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19) which is caused by SARS-CoV-2. The test provides preliminary test results. Negative results cannot exclude the possibility of SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision	<b>Approved.</b>
5.	M/s Hospicare Systems, Mezzanine Floor, RabbiyaGarden , Plot No. 3, MCHS, Shaheed-e-Millat road, Karachi (ELI-00274)	Manufacturer: M/s AESKU. Diagnostics GmbH & Co. KG, Mikroforum Ring 2, D-55234 Wendelsheim, Germany  FSC Germany issued on 29-07-2020	AESKULISA® SARS-CoV-2 NP IgG (Kit)  Class C Codes: 6122 Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Qualitative and quantitative immunoassays for the detection of human IgG antibodies in serum or plasma directed against the nucleocapsid protein of SARS-CoV-2. The test serves for confirmation of a contact with the pathogen and supports in immune status determination. Intended as an aid in the diagnosis of COVID-19. Results should not be used as the sole basis to	<b>Approved.</b>

				diagnose or exclude SARS-CoV-2 infection or to inform about infection status	
6.	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 27-05-2025	Alinity SARS-CoV-2 IgG Kit  Class C  1. SARS-CoV-2 IgG Reagent Kit Shelf life: 6 months Code: 06R90-32 Tests: 500 tests 2. SARS-CoV-2 IgG Reagent Kit Shelf life: 6 months Code: 06R90-22 Tests: 100 tests 3. SARS-CoV-2 IgG Calibrator Kit Shelf life: 6 months Code: 06R90-02 4. SARS-CoV-2 IgG Control Kit Shelf life: 6 months Code: 06R90-12  Fee submitted: Rs. 50,000/-	Chemiluminescent microparticle immunoassay (CMIA) used for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma on the Alinity system. To be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results should not be used as the sole basis of diagnosis	<b>Approved.</b>  Firm shall submit original FSC before issuance of registration certificate.
7.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland  FSC Ireland valid till 27-05-2025	Alinity SARS-CoV-2 IgM Kit  Class C  1. SARS-CoV-2 IgM Reagent Kit Shelf life: 6 months Code: 06R9132 Tests: 500 tests 2. SARS-CoV-2 IgM Reagent Kit Shelf life: 6 months Code: 06R9122 Tests: 100 tests 3. SARS-CoV-2	Chemiluminescent microparticle immunoassay (CMIA) used for qualitative detection of IgM antibodies to SARS-CoV-2 in human serum and plasma on the Alinity system. To be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results should not be used as the sole	<b>Approved.</b>  Firm shall submit original FSC before issuance of registration certificate.

			<p>IgM Calibrator Kit Shelf life: 6 months Code: 06R9102</p> <p>4. SARS-CoV-2 IgM Control Kit Shelf life: 6 months Code: 06R9112</p> <p>Fee submitted: Rs. 50,000/-</p>	basis of diagnosis	
8.	-do-	<p>Manufacturer:</p> <p>M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland</p> <p>FSC Ireland valid till 27-05-2025</p>	<p>ARCHITECT SARS-CoV-2 IgG Kit</p> <p>Class C</p> <p>1. SARS-CoV-2 IgG Reagent Kit Shelf life: 6 months Code: 06R86-32 Tests: 500 tests</p> <p>2. SARS-CoV-2 IgG Reagent Kit Shelf life: 6 months Code: 06R86-22 Tests: 100 tests</p> <p>3. SARS-CoV-2 IgG Calibrator Kit Shelf life: 6 months Code: 06R86-02</p> <p>4. SARS-CoV-2 IgG Control Kit Shelf life: 6 months Code: 06R86-12</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Chemiluminescent microparticle immunoassay (CMIA) used for qualitative detection of IgG antibodies to SARS- CoV-2 in human serum and plasma on the ARCHITECT i system. To be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results should not be used as the sole basis of diagnosis</p>	<p><b>Approved.</b></p> <p>Firm shall submit original FSC before issuance of registration certificate.</p>
9.	-do-	<p>Manufacturer:</p> <p>M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland</p>	<p>ARCHITECT SARS-CoV-2 IgM Kit</p> <p>Class C</p> <p>1. SARS-CoV-2 IgM Reagent Kit Shelf life: 6 months</p>	<p>Chemiluminescent microparticle immunoassay (CMIA) used for qualitative detection of IgM antibodies to SARS- CoV-2 in human serum and plasma on the ARCHITECT i system. To be used as</p>	<p><b>Approved.</b></p> <p>Firm shall submit original FSC before issuance of registration certificate.</p>

		FSC Ireland valid till 27-05-2025	<p>Code: 06R87-32 Tests: 500 tests 2. SARS-CoV-2 IgM Reagent Kit Shelf life: 6 months</p> <p>Code: 06R87-22 Tests: 100 tests 3. SARS-CoV-2 IgM Calibrator Kit Shelf life: 6 months</p> <p>Code: 06R87-02 4. SARS-CoV-2 IgM Control Kit Shelf life: 6 months</p> <p>Code: 06R87-12</p> <p>Fee submitted: Rs. 50,000/-</p>	an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results should not be used as the sole basis of diagnosis	
10.	-do-	<p>Manufacturer: Abbott Rapid Diagnostics Jena GmbH., Orlaweg 1, 07743 Jena, Germany</p> <p>FSC Germany issued on 15-04-2020</p>	<p>Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/Venous whole blood/serum/plasma)</p> <p>Class C</p> <p>Shelf life: 24 months</p> <p>Code: ICO-T402</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Immunochromatographic test for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma, venous, and fingerstick whole blood. For professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The test provides preliminary test results. Negative result don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision. The test is not intended to be used as a donor screening test for SARS-CoV-2.</p>	<p><b>Approved.</b></p> <p>Firm shall submit original FSC before issuance of registration certificate.</p>



11.	-do-	<p><b>Manufacturer:</b> M/s Abbott Rapid Diagnostics, Jena GmbH., Orlaweg 1, 07743 Jena, Germany.</p> <p>FSC Germany issued on 01-02- 2021</p>	<p><b>Panbio COVID-19 Ag Rapid Test Device (Nasal)</b></p> <p>Class C</p> <p>Ref.</p> <p>41FK11</p> <p>41FK21</p> <p>Shelf Life: 12 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Panbio COVID-19 Ag Rapid Test Device is an in vitro diagnostics rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria.</p> <p>Panbio COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.</p> <p>The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.</p>	<p><b>Approved.</b></p> <p>Firm shall submit original FSC before issuance of registration certificate.</p>
12.	Roche Pakistan Ltd., 1st Floor, 37- B, Block 6, PECHS, Karachi	<p><b>Manufacturer:</b> Roche Diagnostics GmbH</p>	<p>Elecsys Anti SARS-CoV-2 Test Kit</p>	<p>Immunoassay intended for the qualitative detection of antibodies to SARS-</p>	<p><b>Approved.</b></p>

(ELI-00009)	<p>Sandhofer Str.116 68305 Mannheim Germany</p> <p>FSC Germany issued on 04-05-2020</p> <p>FSC Germany issued on 28-05-2020</p>	<p>Class C</p> <p>Elecsys Anti SARS-CoV 2 Ref No: 09203079190</p> <p>Shelf life: 4 Months</p> <p>Pack size: 300 tests</p> <p>Elecsys Anti SARS-CoV 2 Ref No: 09203095190</p> <p>Shelf life: 4 Months</p> <p>Pack size: 200 tests</p> <p>PreciControl Anti-SARS-CoV-2 Ref No: 09216928190</p> <p>Shelf life: 4 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>CoV-2 in human serum and plasma. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-Cov-2 indicating recent or prior infection. It should not be used to diagnose acute SARS-CoV-2 infection</p>	
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**XVII. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7).**

<b>Sr. No.</b>	<b>Name &amp; Address of Establishment</b>	<b>Name of Medical Devices with Size</b>	<b>Brief Description</b>	<b>Decision</b>
<b>1.</b>	M/s SurgiPlast, Plot No.78, Road L-4, Industrial Estate, Gadon Amazai ELM-0030	<p>Clinic Auto Disable Syringes 2ml, 3ml, 5ml</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Rs. 20,000/-</p>	Auto Disable Syringe	<b>Approved.</b>

**XVIII. REGISTRATION OF RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)**

Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	Brief Description	Decision
1.	M/s SurgiPlast, Plot No.78, Road L-4, Industrial Estate GadoonAmazai (ELM-0030)	Clinic I.V Infusion Set (with 20G/21G/22G Needle)  Class: B Shelf Life: 05 Years  Reg No.070390  Fee submitted in Registration Division on 2016 (copy Submitted) Rs.10,000/-  Codes & Sizes as already registered.	I.V Infusion Set	<b>Approved</b> subject to provision of stability study data for claimed shelf life.
2.	-do-	Clinic Disposable Syringes (1ml, 10ml)  Class: B  Shelf Life: 05 Years  Reg No. 070391  Fee submitted in Registration Division on 2016 (copy Submitted) Rs.10,000/-  Codes & Sizes as already registered.	Disposable Syringes	<b>Approved</b> subject to provision of stability study data for claimed shelf life.
3.	M/s Cotton Craft (Pvt) Ltd., 12 KM, Multan Road, Canal View Society, Lahore  [ELM-0015]	PARAGAZ (Paraffin Gauze) Class: C Shelf Life: 03 Years  Reg. No. 016658 Fee submitted Rs.10,000/- 10cm x 10cm (36 Pieces) 10cm x 10cm (30 Pieces) 15cm x 15cm  Codes & Sizes as already registered	Paraffin Gauze BPC	<b>Approved</b> subject to provision of stability study data for claimed shelf life.

4.	-do-	<p>PolyGras Dressing Surgical Tulle Dressing (Polymyxin B. Sulphate + Bacitracin Zinc)</p> <p>Class: C Shelf Life: 03 Years</p> <p>Reg. No. 037140</p> <p>Fee submitted Rs.10,000/-</p> <p>15cm x 20cm 10cm x 10cm</p> <p>Codes &amp; Sizes as already registered.</p>	Dressing Surgical Tulle Dressing	<b>Deferred</b> for product specific inspection to verify the manufacturing facility for production of sterile product and provision of stability study data for claimed shelf life.
5.	-do-	<p>Gauze Swab / Sponges USP</p> <p>Class: C Shelf Life: 03 Years</p> <p>Reg. No. 016659</p> <p>Fee submitted Rs.10,000/-</p> <p>5cm x 5cm 7.5cm x 7.5cm 10cm x 10cm</p> <p>Codes &amp; Sizes as already registered</p>	Gauze Swab	<b>Approved</b> subject to provision of stability study data for claimed shelf life.

**XIX: ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (FORM 6).**

Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	Brief Description	Remarks	Decision
2.	M/s Uniferoz (Pvt) Ltd., Plot No.32/8 & 33/2, Sector 125, Korangi Industrial Area, Karachi	Sani swab Alcohol Pad (Alcohol pad saturated with 70% isopropyl Alcohol (IPA))	Topical antiseptic and disinfectant	Provide Stability Studies for claimed shelf life	<b>Approved.</b>

		Class A Shelf Life: 04 Years 100 Pads/Pack, 200 Pads/Pack			
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**XX: CANCELLATION OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES (ELI-00514).**

**Decision: The Board discussed the matter and acceded the request of the firm for cancellation of Establishment License to Import Medical Devices (ELI-No.00514) of M/s Health Care Solutions, Shop No.51-52, 2<sup>nd</sup> Floor, Ghakkar Hathyal, Main Simly Road, Barakahu, Islamabad.**

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