

**Government of Pakistan**  
**Ministry of National Health Services, Regulation & Coordination**  
**Drug Regulatory Authority of Pakistan**  
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**DECISION OF THE 32<sup>ND</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 20-04-2021**

**Item No. I. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.**

S.No	Name of Establishment	Director/Proprietor /partners	Cold Chain (Yes/No)	Decision
1.	M/s Sublime Solutions, 391-B, Block Sher Shah Colony, Lahore.  <b>Godown:</b> Same as above.	Qurat-UI-Ain	No	<b>Approved</b> for storage of no-cold chain medical devices.
2.	M/s Lab Chem, 240A-5 Block G, Commercial Market, Sabzazar Scheme, Multan Road, Lahore.  <b>Godown:</b> Same as Above	Muhammad Hanif	No.	<b>Approved</b> for storage of room temperature medical devices.
3.	M/s Brothers Distributor, Gulzar-e-Madina Road, Zeb Super Market, Gujrat.  <b>Godown:</b> Same as Above	Mr. Zahid Mukhtar	No	<b>Approved</b> for storage of no-cold chain medical devices.
4.	M/s Fastline (Pvt) Ltd. 49-Km Multan Road, Phool Nagar, Tehsil Pattoki, Kasur.  <b>Godown:</b> Same as Above.	Syed Savail Meekal Hussain  Pirzada Zahid Hassan	No	<b>Approved</b> for storage of no-cold chain medical devices.

5.	M/s Imperial Dental Supply Co., 14 Sharif Plaza, 26 Shahrah-e-Quaid-e-Azam, Lahore.	Muhammad Iftikhar	No	<b>Approved</b> for storage of room temperature medical devices.
6.	M/s Medi Systems International, 5-A Mezzanine Floor, Sardar Begum Plaza, 109 west blue area, Islamabad	Pervaiz Zulfiqar	No	<b>Approved</b> for storage of room temperature medical devices.
7.	M/s Rigel Health (Pvt) Ltd, Office No. 911, 9 <sup>th</sup> floor, Portway Trade Centre, S.M.C.H.S., Main Shahrah-e-Faisal, Karachi.  <b>Godown:</b> House No.21, Muslim Colony, Near SMCHS, Block-B, Shahrah-e-Faisal, Karachi.	Raza Hasnain  Shahid Akhtar Shaikh	No.	<b>Approved</b> for storage of room temperature medical devices.
8.	M/s Sohail Corporation, Plot No.7, SR-5, Seraj Quarters Technocity, Karachi.  <b>Godown:</b> WH-42 , Ware House No.42, Karachi.	Mr. Sohail Kadvavi	No	<b>Approved</b> for storage of room temperature medical devices.
9.	M/s Samzco Trading Company, Office No. 501, Imperial Optical Center, Masjid Street, Ghari Khata, M.A. Jinnah Road, Karachi  <b>Godown:</b> Same as above.	Shaikh Zulqadar Masood	No	<b>Approved</b> for storage of room temperature medical devices.
10.	M/s. Hussainy Surgical  Shop No 18 Jabbar Plaza Syeddna Mohammad Burhanuddin Road, Saddar Karachi  <b>Godown:</b> Office No. 12-C, 5 <sup>th</sup> Floor, Nimco	Abbas Asgharbhair Bandukwala	No	<b>Rejected</b> due to the storage area being not sufficient for storage of warm range medical devices. It was advised by panel to firm to improve storage facility as current storage facility consists of small room

	Center Cambell Street, Karachi			on 5 <sup>th</sup> floor of building having no cargo lift.
11.	M/s M. S Agencies, Shoop No.3 & 4, Kutchi Gali No. 1, Marriot Road, Karachi.  <b>Godown:</b> Same as Above	Humayun Mansoor	No.	<b>Rejected</b> due to storage area not being as per GDPMD checklist and revise documents as per standard protocol of SOPs. Current storage facility is comprised of an open shop with no proper system for storage of medical devices.
12.	M/s Adeel Haroon Trading Co, Office No. 502, 5 <sup>th</sup> Floor, Plot No. RB-6, Aram Bagh Quarters Masjid Street, M.A Jinnah Road, Karachi.  <b>Godown:</b> Same as Above	Adeel Haroon	No	<b>Approved</b> for storage of room temperature medical devices.
13.	M/s Y.K International, F-22 1 <sup>st</sup> Floor Glass Tower, Near Tin Talwar, Main Clifton Road, Karachi.	Mr. Ghulam Shabbir	No	<b>Rejected.</b> Firm intend to import IOL, IOL injectors and lens solution for which storage area is not sufficient. The firm shows single cabinet for storage of medical devices at the time of inspection which was placed in office and there is no dedicated place for storage of medical devices. Documents as per checklist were also not prepared. Firm was advised to rectify the observations.
14.	M/s. Genesis International, Plot No. 32-C, Shop No.4	Mr. Jawaid Jumani	No	<b>Approved</b> for storage of room temperature

	<p>Bukhari Commercial Lane No. 6, Phase-VI, D.H.A Karachi South Saddar Town , Karachi.</p> <p><b>Godown:</b> The Plaza Office No. 108 1<sup>st</sup> Floor Near Do Talwar Main Clifton Road Karachi.</p>	<p>Mr.Khalil Mamon Ms. Azra Jumani</p>		<p>medical devices.</p>
15.	<p>M/s Royal Medical, Office No. 26<sup>th</sup> 3<sup>rd</sup> Floor United Trader Center Plot No. 5, Block-6, Gulshan-e- iqbal, Karachi.</p> <p><b>Godown:</b> Same as Above</p>	Anum Ahmed	No.	<p><b>Approved</b> for storage of room temperature medical devices.</p>
16.	<p>M/s. Seamac (Pvt) Ltd, 301, 3<sup>rd</sup> Floor, Plot No. 186-C, AL-Murtaza Commercial Lane 5, DHA Phase-VIII, Karachi</p> <p><b>Godown:</b> Shop NO. 79, Ground floor, Old block, (Telephone office) Karachi.</p>	Mr. Razi Zaidi	No.	<p><b>Approved</b> for storage of warn range medical devices.</p>
17.	<p>M/s Advance Medical System, Office No. 8, Rehman Plaza 90/A-1, Depot Line Coast Guard Avenue, Karachi.</p> <p><b>Godown Address:</b> Shop No.4, 14 Behind HQ Coast Guard, Dholi Khatta, Karachi.</p>	Syed Riaz Hussain	No.	<p><b>Approved</b> for storage of room temperature medical devices.</p> <p>DSL Applied.</p>
18.	<p>M/s Fujifilm Pakistan, 37-D, Block-6, P.E.C.H.S., Karachi.</p> <p><b>Godown Address:</b> Plot No.54, Timber</p>	Syed Jameel Hussain (MD)	No.	<p><b>Approved</b> for storage of room temperature medical devices.</p>

	Pond Road, Karachi.			
19.	M/s Baqai Enterprises, Suit No. 25, 2 <sup>nd</sup> Floor, Barkat Lodge Building, Aram Bagh Road, Karachi.  <b>Godown: Same as above.</b>	Mr. Zaeem Baqai	No.	<b>Rejected.</b> Area is not sufficient for storage of medical devices as per provided intended list. Area consists of small room of 60 sq.ft. with no proper storage facility as per GDOMD checklist. Documents were also not prepared as described in the checklist.
20.	M/s Mirza Traders, Basement -13, Asim Centre, Opposite RGH Murree Road, Rawalpindi.	Ghafoor Ellahi	No.	<b>Approved</b> for storage of room temperature medical devices.
21.	M/s Hamza Enterprises, 3217, Ground Floor, Cantonment Hospital road, Rawalpindi.  <b>Godown: Same as Above</b>	Iftikhar Ahmed Satti	No.	<b>Rejected.</b> The panel did not recommend the grant of establishment license to import medical devices due to reasons that the firm is dealing in lab chemicals and glasswares but does not intend to import any medical device nor it has any storage facility available for the storage of the medical devices.
22.	M/s Science Centre, No. 3287, Adamjee Road, Saddar, Rawalpindi.  <b>Godown: Same as Above</b>	Mr. Najam Iqbal	Yes.	<b>Approved</b> for storage of medical devices with cold chain facility.
23.	M/s Lab Medikal	Mr. Usman javed	Yes	<b>Approved</b> for storage

	Solutions, Office No. 142, 1 <sup>st</sup> Floor, city center Bank road Saddar Rawalpindi Cantt.  <b>Godown:</b> Same as Above	Mr. Muhammad Amir Javed  Mr. Sohaib ul Hassan Mughal		of room temperature medical devices alongwith limited cold chain facility.
24.	M/s Mais Medical Products (Pvt) Limited, Office No.8, Second Floor, Qartaba Center, 7/8-Jail Road, Moazang Chungi, Lahore	Mr. Salman Rashid	No	<b>Approved</b> for storage of room temperature medical devices.
25.	M/s Impact International, 40/2, Abbott Road, Lahore	Mr. Javed Shoukat Bhatti	No	<b>Approved</b> for storage of room temperature medical devices
26.	M/s Hadi Health Care, J/114 Yasrab Street District Mianwali.	Syed Wajahat Ali	No	<b>Rejected.</b> As the panel did not recommend the grant of establishment license to import medical devices due to reasons that the firm was located on a narrow, broken street. The facility comprised of two rooms and an office which were located inside a house and had a common entrance/exit. The facility was unclean and had poor hygienic conditions. There was an open sewer right outside the entrance of the facility. The technical personnel lacked in basic training regarding Good Distribution Practices. Documentation was poor.

27.	M/s Ocusurg CO. Pharma and Surgical.  Shareef Centre, 68- Mozang road, Lahore  <b>Godown:</b> 6/1, Golding Road Lahore.	M.Zulfiqar Ali	No	<b>Approved</b> for storage of room temperature medical devices
28.	M/s Clifton Enterprises, Ground Floor, 166 Shadman 1, Tehsil and district Lahore	Mr. Muhammad Ammar	No	<b>Approved</b> for storage of room temperature medical devices
29.	M/s Appex Global Trading, 432, Plot No. 86 Street No. 10, I-9/2 Industrial Area, Islamaad  <b>Godown:</b> Same as Above	Mr. Muhammad Billal	No	<b>Approved</b> for warm range (above 30°C) medical devices without cold chain facility subject to provision of DSL.
30.	M/s Multilinkx Enterprises, Suit No. D1, 2 <sup>nd</sup> floor, Shah Plaza, Asghar Mall Road, Rawalpindi.  <b>Godown:</b> Same as Above	Shahbaz Ameer	No	<b>Approved</b> for warm range (above 30°C) medical devices without cold chain facility.
31.	M/s Delta Plus (Pvt) Ltd, Flat No. 2, First Floor, German Plaza, Mini Market No. 3, Khayaban-e-Kashmir, Sector G-15/4, Islamabad.	Shahid Nawaz Anjum  Raheel Sultan	No	<b>Rejected</b> as the firm does not exist at the given address.
32.	M/s. 3C International 1620, Main Doubel Road, Sector I-10/1, Islamabad.	Mr. Sharafat Ali  Muhammad Waqas	No.	<b>Deferred.</b> The MDB acceded to the request of the firm for grant of one week time for preparation and submission of documents. Firm does

				not have DSL.
33.	M/s HA Shah & Sons, Office No. 3, 3 <sup>rd</sup> Floor, Saddar Begumk plaza, 109-W, Jinnah Avenue Blue Area, Islamabad.	Syed Waqar Ali Bukhari  Syed Mushraf Hussain Bukhari  Syed Zulfiqar Ali Bukhari	No	<b>Deferred.</b> The MDB acceded to the request of the firm for grant of 10 days time to fulfill the requirements. Firm does not have DSL.
34.	M/s Aspin Pharma (Pvt) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.	1.Tariq Moinuddin Khan  2.Nusrat Munshi  3.Adeela Tariq Khan  4.Muhammad Arslan Batla	No,	<b>Deferred.</b> The MDB acceded to the request of the firm for postponement of inspection till September, 2021.
35.	M/s Mediwise Pharma, Office No. 30, 1 <sup>st</sup> Floor, Mian Plaza, Chandni Chowk, Murree Road, Rawalpindi.  <b>Godown:</b> Same as Above	Muhammad Tufail Nasir	No	<b>Approved</b> for storage of room temperature medical devices.
36.	M/s Medco Medical & Dental Company, Office No. 15, 1 <sup>st</sup> Floor, Ciro's Building, 42 Haider Road, Saddar, Rawalpindi.  <b>Godown:</b> Same as Above	Sajid Saeed	Yes.	<b>Approved</b> for storage of room temperature alongwith cold chain medical devices.
37.	M/s Excel Medical Technology, House No. 616-C, Lane No. 5, Peshawar Road Rawalpindi.	Muhammad Asif Sohail	No	<b>Deferred.</b> The premises was locked and no person available at the time of inspection.
38.	M/s Zodiac International, Suite No. 482, Street 98, Sector	Mr. Attiq Ahmed	No	<b>Deferred.</b> The MDB acceded to the request of the firm for postponement of



	G-9/4, Islamabad		inspection.
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**Item No.II. APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES - CHANGE OF ADDRESSES.**

S.No.	Name and address of firms on inspection letter/ Application Form.	New/Changed address of the firm
1.	M/s Surgiquips, St.No.147-A, Aman Park, Baghban Pura, Lahore.	Ground Floor, Ruqiya Terrace, 51/A-2, Near Drug Courts, Lawrence Road, Lahore. <b>Godown Address:</b> 1 <sup>st</sup> Floor, 18 Syed Mauj Darya Road, Near PSO Office, Lahore.
2.	M/s Royal International, Office No. 225, A-II, Johar Town, Lahore.	House No.28-B Block BOR Society, Johar Town, Lahore.
3.	M/s Pakistan Oxygen Limited, Adjacent to HMC No.2, Taxila, <u>Rawalpindi</u>	Dockyard Road, West Wharf, Karachi.

**Decision:** The MDB discussed the matter at length and decided to constitute panel for inspection for above firms at new addresses for inspection of storage facilities. The Board also decided to reject in future the applications for grant of establishment licence to import medical devices if the constituted panel visits at the given address but the firm has changed their address and directed such firms to apply afresh for grant of establishment license to import medical devices with new addresses.

**Item No.III. EXEMPTION/WAIVER OF DRUG SALE LICENSE (DSL) FOR THE IMPORTERS IN THE APPLICATION FORM FOR THE GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES**

**Decision:**

The Board decided to recommend the exclusion of conditions of "Drug Sale License" from Form-2 for grant of Establishment License To Import Medical Devices for the approval of the Authority.

**Item No.IV. APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES**

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1	M/s Pharmatec Pakistan (Pvt) Limited.	D-86/A, S.I.T.E, Karachi.	Mr. Faizan Masood (Production Incharge)  Pharm-B	Miss Shaheen Jahan (QC Incharge)  Pharm-D

**Decision:** The Board discussed and approved the grant of Establishment License to M/s M/s Pharmatec Pakistan (Pvt) Limited, D-86/A, S.I.T.E, Karachi for manufacturing of medical devices and allowed the firm to utilize QC facility of licensed Pharmaceutical Unit for testing of their enlisted/registered medical devices for a period of three years or a final decision of the Authority on subject matter.

**Item No.V. APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.**

M/s 5M Solutions, Ground Floor, 66-Habibullah Road, Davis Road, Lahore, has applied for grant of Establishment License to manufacture medical devices under MDR, 2017. It is submitted that the manufacturing unit is located in commercial area/residential area.

**Decision:** The MDB discussed the matter at length and decided to reject the application of M/s 5M Solutions for grant of establishment license to manufacture medical devices due to the reason that the firm is located in commercial/residential area.

**Item No.VI. APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES**

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Essity Pakistan Limited  ELM-0008  <b>(Period 07-01-21 to 06-01-26)</b>	A/69 S.I.T.E, Manghopir Road, Karachi.	Mr. Iftikhar- ul-Hassan Niazi  (Production Incharge)  Pharm-B	Muhammad Sadiq Mallick  QC Incharge  Pharm-B
2.	M/s Karim Industries  ELM 0014  <b>period from 08-12-2020 to 07-12-2025</b>	1/2 Km Lahore Raiwind Road, Onside Roohi Nala Petrol Pump, Raiwind, District Lahore.	Mr. M. Hayat Hussain  (Production Incharge)  Pharm-D	Mr. Amar Mureed  QC Incharge  Pharm-D

**Item No.VII. APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES (DML-000788).**

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Lasani Health Care,	Plot No.29-A/R-1, Industrial Estate, Gadoon Amazai, KPK.	Mr. Inayat Ullah (Production Incharge)  Pharm-D	Mr. Sana Ullah  QC Incharge  Pharm-D

**Decision:** The MDB discussed and decided to approve the renewal of establishment license of M/s Lasani Health Care, Gadoon Amazai, KPK to manufacture medical devices for the period from 02-02-2019 to 01-02-2024.

**Item No.VIII. APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES (DML-000695).**

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Injection Systems (Pvt) Limited.	Plot No.271, main road, Industrial Estate, Gadoon Amazai, District Swabi, KPK.	Mr. Shah Khalid (Production Incharge)  Pharm-D	Mr. Adeel Ahmad  QC Incharge  Pharm-D

**Decision:** The MDB discussed and decided to approve the renewal of establishment license of M/s Injection Systems (Pvt) Limited, Gadoon Amazai, Swabi, KPK to manufacture medical devices for the period from 09-09-2020 to 08-09-2025

**Item No.IX. POST REGISTRATION VARIATIONS.**

**Case No.1.**

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

S.No	Registration Number	Name of Medical Device (s)
1.	MDIR-0001996	BD Ultra Fine Insulin Syringe (1ml)

It is submitted that the MDB in its 26<sup>th</sup> meeting held on 6<sup>th</sup> January, 2021 approved the change of name and address of Establishment from **M/s Premier Agencies, 60, Muslimabad, Jamshed Quarters, M.A. Jinnah Road Extension, Karachi** to **M/s Premier Sales (Private) Limited, Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi.**

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

**Case No.2.**

M/s Premier Sales (Private) Limited, Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi has requested for approval of change of manufacturing site of their following enlisted/registered medical devices for import as per detail mentioned below: -

S.No	Registration Number	Name of Medical Device (s)	Existing Manufacturing Site	Proposed Manufacturing Site
1.	MDIR-0000489	BD Micro-Fine™ + Pen Needle (5MM).	1. M/s Becton Dickinson and Company, Pottery Road, Dun Laoghaire County Dublin, Ireland.  2. M/s Becton Dickinson Medical (S) PTE, 30 Tuas Avenue 2,	M/s Becton Dickinson Medical Devices Co., Ltd, Suzhou No.1 Liangpu Street, Suzhou Industrial Park, Jiangsu, P.R. China.

			Singapore.	
2.	MDIR-0000487	BD Micro-Fine™ + Pen Needle (8MM).	-do-	-do-

It is submitted that the MDB in its 26<sup>th</sup> meeting held on 6<sup>th</sup> January, 2021 approved the change of name and address of Establishment from **M/s Premier Agencies , 60, Muslimabad , Jamshed Quarters, M.A. Jinnah Road Extension, Karachi** to **M/s Premier Sales (Private) Limited, Plot No.1-A/15, Sector 15, Korangi Industrial Area, Karachi.**

**Decision: The Board discussed and deferred the case for provision of Free Sale Certificate of country of origin as well as reference country having the address of new manufacturing site.**

**Case No.3.**

M/s Johnson & Johnson Pakistan (Pvt) Limited, Office No.806, 8<sup>th</sup> Floor Horizon Towers, Block 3, Scheme No.5, Clifton, Karachi has requested for grant of approval of additional sizes of their following registered imported medical device as per detail mentioned below: -

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0001428	Pinnacle Hip System	121720044 PINNACLE BANTAM ACET CUP 44MM 10 years  121720046PINNACLE BANTAM ACET CUP 46MM 10 years  121720048PINNACLE MULTIHOLE II CUP 48MM 10 years  121720050PINNACLE MULTIHOLE II CUP 50MM 10 years  121720052 PINNACLE MULTIHOLE II CUP 52MM 10 years  121720054 PINNACLE	121720044 PINNACLE BANTAM ACET CUP 44MM, 10 years  121720046 PINNACLE BANTAM ACET CUP 46MM, 10 years  121720048 PINNACLE MULTIHOLE II CUP 48MM, 10 years  121720050 PINNACLE MULTIHOLE II CUP 50MM, 10 years  121720052 PINNACLE MULTIHOLE II CUP 52MM, 10 years  121720054 PINNACLE MULTIHOLE II CUP 54MM, 10

			<p>MULTIHOLE II CUP 54MM 10 years</p> <p>121720056 PINNACLE MULTIHOLE II CUP 56MM 10 years</p> <p>121720058 PINNACLE MULTIHOLE II CUP 58MM 10 years</p> <p>121720060 PINNACLE MULTIHOLE II CUP 60MM 10 years</p> <p>121722048 PINNACLE SECTOR II CUP 48MM 10 years</p> <p>121722050 PINNACLE SECTOR II CUP 50MM 10 years</p> <p>121722052 PINNACLE SECTOR II CUP 52MM 10 years</p> <p>121722054 PINNACLE SECTOR II CUP 54MM 10 years</p> <p>121722056 PINNACLE SECTOR II CUP 56MM 10 years</p> <p>121722058 PINNACLE SECTOR II CUP 58MM 10 years</p> <p>121722060 PINNACLE SECTOR II CUP 60MM 10 years</p> <p>121828748 PINN LNR CON +4 10D 28IDX48OD 5 years</p> <p>121828750 PINN LNR CON +4 10D 28IDX50OD 5 years</p> <p>121832752 PINN LNR CON +4 10D 32IDX52OD 5 years</p> <p>121832754 PINN LNR CON +4</p>	<p>years</p> <p>121720056 PINNACLE MULTIHOLE II CUP 56MM, 10 years</p> <p>121720058 PINNACLE MULTIHOLE II CUP 58MM, 10 years</p> <p>121720060 PINNACLE MULTIHOLE II CUP 60MM, 10 years</p> <p>121722048 PINNACLE SECTOR II CUP 48MM, 10 years</p> <p>121722050 PINNACLE SECTOR II CUP 50MM, 10 years</p> <p>121722052 PINNACLE SECTOR II CUP 52MM,, 10 years</p> <p>121722054 PINNACLE SECTOR II CUP 54MM, 10 years</p> <p>121722056 PINNACLE SECTOR II CUP 56MM, 10 years</p> <p>121722058 PINNACLE SECTOR II CUP 58MM, 10 years</p> <p>121722060 PINNACLE SECTOR II CUP 60MM, 10 years</p> <p>121828748 PINN LNR CON +4 10D 28IDX48OD,, 5 years</p> <p>121828750 PINN LNR CON +4 10D 28IDX50OD, 5 years</p> <p>121832752PINN LNR CON +4 10D 32IDX52OD, 5 years</p> <p>121832754PINN LNR CON +4 10D 32IDX54OD, 5 years</p> <p>121832756 PINN LNR CON +4 10D 32IDX56OD, 5 years</p> <p>121832758 PINN LNR CON +4 10D</p>
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			<p>10D 32IDX54OD 5 years</p> <p>121832756 PINN LNR CON +4 10D 32IDX56OD 5 years</p> <p>121832758 PINN LNR CON +4 10D 32IDX58OD 5 years</p> <p>121832760 PINN LNR CON +4 10D 32IDX60OD 5 years</p> <p>121836756 PINN LNR CON +4 10D 36IDX56OD 5 years</p> <p>121836758 PINN LNR CON +4 10D 36IDX58OD 5 years</p> <p>121836760 PINN LNR CON +4 10D 36IDX60OD 5 years</p> <p>121881752 PINN DELTA CER INSRT 52ODX36ID 5 years</p> <p>121881754 PINN DELTA CER INSRT 54ODX36ID 5 years</p> <p>121881756 PINN DELTA CER INSRT 56ODX36ID 5 years</p> <p>121881758 PINN DELTA CER INSRT 58ODX36ID 5 years</p> <p>121881760 PINN DELTA CER INSRT 60ODX36ID 5 years</p> <p>121882748 DELTA CER INSERT 32ID X 48OD 5 years</p> <p>121882750 DELTA CER INSERT 32ID X 50OD 5 years</p> <p>121882752 PINN DELTA CER INSRT 52ODX32ID 5 years</p> <p>121883744 PINN DELTA CER INSRT 44ODX28ID 5 years</p> <p>121883746 PINN DELTA CER INSRT 46ODX28ID 5 years</p> <p>121883748 PINN DELTA CER INSRT 48ODX28ID 5 years</p> <p>121883750 PINN DELTA CER</p>	<p>32IDX58OD, 5 years</p> <p>121832760 PINN LNR CON +4 10D 32IDX60OD, 5 years</p> <p>121836756 PINN LNR CON +4 10D 36IDX56OD, 5 years</p> <p>121836758 PINN LNR CON +4 10D 36IDX58OD, 5 years</p> <p>121836760 PINN LNR CON +4 10D 36IDX60OD, 5 years</p> <p>121881752 PINN DELTA CER INSRT 52ODX36ID, 5 years</p> <p>121881754 PINN DELTA CER INSRT 54ODX36ID, 5 years</p> <p>121881756 PINN DELTA CER INSRT 56ODX36ID, 5 years</p> <p>121881758 PINN DELTA CER INSRT 58ODX36ID, 5 years</p> <p>121881760 PINN DELTA CER INSRT 60ODX36ID, 5 years</p> <p>121882748 DELTA CER INSERT 32ID X 48OD, 5 years</p> <p>121882750 DELTA CER INSERT 32ID X 50OD, 5 years</p> <p>121882752 PINN DELTA CER INSRT 52ODX32ID, 5 years</p> <p>121883744 PINN DELTA CER INSRT 44ODX28ID, 5 years</p> <p>121883746 PINN DELTA CER INSRT 46ODX28ID, 5 years</p> <p>121883748 PINN DELTA CER INSRT 48ODX28ID, 5 years</p> <p>121883750 PINN DELTA CER INSRT 50ODX28ID, 5 years</p> <p>121883752 PINN DELTA CER</p>
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		<p>INSRT 50ODX28ID 5 years</p> <p>121883752 PINN DELTA CER INSRT 52ODX28ID 5 years</p> <p>121883754 PINN DELTA CER INSRT 54ODX28ID 5 years</p> <p>121883756 PINN DELTA CER INSRT 56ODX28ID 5 years</p> <p>121883758 PINN DELTA CER INSRT 58ODX28ID 5 years</p> <p>121883760 PINN DELTA CER INSRT 60ODX28ID 5 years</p> <p>121928144 PINN MAR +4 10D 28IDX44OD 5 years</p> <p>121928146 PINN MAR +4 10D 28IDX46OD 5 years</p> <p>121928148 PINN MAR +4 10D 28IDX48OD 5 years</p> <p>121928150 PINN MAR +4 10D 28IDX50OD 5 years</p> <p>121928152 PINN MAR +4 10D 28IDX52OD 5 years</p> <p>121928154 PINN MAR +4 10D 28IDX54OD 5 years</p> <p>121928156 PINN MAR +4 10D 28IDX56OD 5 years</p> <p>121928158 PINN MAR +4 10D 28IDX58OD 5 years</p> <p>121928160 PINN MAR +4 10D 28IDX60OD 5 years</p> <p>121932148 PINN MAR +4 10D 32IDX48OD 5 years</p> <p>121932150 PINN MAR +4 10D 32IDX50OD 5 years</p> <p>121932152 PINN MAR +4 10D 32IDX52OD 5 years</p> <p>121932154 PINN MAR +4 10D</p>	<p>INSRT 52ODX28ID, 5 years</p> <p>121883754 PINN DELTA CER INSRT 54ODX28ID, 5 years</p> <p>121883756 PINN DELTA CER INSRT 56ODX28ID, 5 years</p> <p>121883758 PINN DELTA CER INSRT 58ODX28ID, 5 years</p> <p>121883760 PINN DELTA CER INSRT 60ODX28ID, 5 years</p> <p>121928144 PINN MAR +4 10D 28IDX44OD, 5 years</p> <p>121928146 PINN MAR +4 10D 28IDX46OD, 5 years</p> <p>121928148 PINN MAR +4 10D 28IDX48OD, 5 years</p> <p>121928150 PINN MAR +4 10D 28IDX50OD, 5 years</p> <p>121928152 PINN MAR +4 10D 28IDX52OD, 5 years</p> <p>121928154 PINN MAR +4 10D 28IDX54OD, 5 years</p> <p>121928156 PINN MAR +4 10D 28IDX56OD, 5 years</p> <p>121928158 PINN MAR +4 10D 28IDX58OD, 5 years</p> <p>121928160 PINN MAR +4 10D 28IDX60OD, 5 years</p> <p>121932148 PINN MAR +4 10D 32IDX48OD, 5 years</p> <p>121932150 PINN MAR +4 10D 32IDX50OD, 5 years</p> <p>121932152 PINN MAR +4 10D 32IDX52OD, 5 years</p> <p>121932154 PINN MAR +4 10D</p>
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		<p>32IDX54OD 5 years</p> <p>121932156 PINN MAR +4 10D 32IDX56OD 5 years</p> <p>121932158 PINN MAR +4 10D 32IDX58OD 5 years</p> <p>121932160 PINN MAR +4 10D 32IDX60OD 5 years</p> <p>121936152 PINN MAR +4 10D 36IDX52OD 5 years</p> <p>121936154 PINN MAR +4 10D 36IDX54OD 5 years</p> <p>121936156 PINN MAR +4 10D 36IDX56OD 5 years</p> <p>121936158 PINN MAR +4 10D 36IDX58OD 5 years</p> <p>121936160 PINN MAR +4 10D 36IDX60OD 5 years</p> <p>136528310 ARTIC DELTA CERAMIC 28MM +1.5 5 years</p> <p>136528320 ARTIC DELTA CERAMIC 28MM +5.0 5 years</p> <p>136528330 ARTIC DELTA CERAMIC 28MM +8.5 5 years</p> <p>136529000 ARTICUL/EZE BALL 22.225+4 NK 5 years</p> <p>136530000 ARTICUL/EZE BALL 22.225+7 NK 5 years</p> <p>136532310 ARTIC DELTA CERAMIC 12/14 32MM +1 5 years</p> <p>136532320 ARTIC DELTA CERAMIC 12/14 32MM +5 5 years</p> <p>136532330 ARTIC DELTA CERAMIC 12/14 32MM +9 5 years</p> <p>136536310 ARTIC DELTA</p>	<p>32IDX54OD, 5 years</p> <p>121932156 PINN MAR +4 10D 32IDX56OD, 5 years</p> <p>121932158 PINN MAR +4 10D 32IDX58OD, 5 years</p> <p>121932160 PINN MAR +4 10D 32IDX60OD, 5 years</p> <p>121936152 PINN MAR +4 10D 36IDX52OD, 5 years</p> <p>121936154 PINN MAR +4 10D 36IDX54OD, 5 years</p> <p>121936156 PINN MAR +4 10D 36IDX56OD, 5 years</p> <p>121936158 PINN MAR +4 10D 36IDX58OD, 5 years</p> <p>121936160 PINN MAR +4 10D 36IDX60OD, 5 years</p> <p>136528310 ARTIC DELTA CERAMIC 28MM +1.5, 5 years</p> <p>136528320 ARTIC DELTA CERAMIC 28MM +5.0, 5 years</p> <p>136528330 ARTIC DELTA CERAMIC 28MM +8.5, 5 years</p> <p>136529000, ARTICUL/EZE BALL 22.225+4 NK, 5 years</p> <p>136530000, ARTICUL/EZE BALL 22.225+7 NK, 5 years</p> <p>136532310 ARTIC DELTA CERAMIC 12/14 32MM +1, 5 years</p> <p>136532320 ARTIC DELTA CERAMIC 12/14 32MM +5, 5 years</p> <p>136532330 ARTIC DELTA CERAMIC 12/14 32MM +9, 5 years</p> <p>136536310 ARTIC DELTA</p>
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			CERAMIC 36MM +1.5 5 years 136536320 ARTIC DELTA CERAMIC 36MM +5.0 5 years 136536330 ARTIC DELTA CERAMIC 36MM +8.5 5 years 136536340 ARTIC DELTA CERAMIC 36MM +12.0 5 years	CERAMIC 36MM +1.5, 5 years 136536320 ARTIC DELTA CERAMIC 36MM +5.0, 5 years 136536330 ARTIC DELTA CERAMIC 36MM +8.5, 5 years 136536340 ARTIC DELT A CERAMIC 36MM +12.0, 5 years
2.	MDIR-0001432	Ethibond Excel polyester suture	X893G, X4843G, X4B37G, X4B77G, X6977M, X582H, X905G, X884G, X894G, X6757G, X6761G, X31059H, X32071H, X31083H, W6191, W10B52, W10B54, W10B55, W10B72, W10B77, W4843, W4846, W6552, W6767, W6935, W6936, W6937, W6977, W893, X523H, X937H, 10X42N, 10X82N, PXX41N, PXX43N, PXX76N, PXX80N, 10X86N	869G, W6597, W6759, W6760, W6890, W6891, W6934, W6952, W6987, W6997, X522H, X558H.

**Decision: The Board approved the additional size of above mentioned medical devices as mentioned against each.**

**Case No.4.**

M/s Abbott Laboratories (Pakistan) Ltd Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi has requested for approval of change of manufacturer for their already registered medical devices for import as per detail given below. They have further stated that product name and catalogue will remain same: -

S.No.	Product Name	Regn. No.	Existing Name and Address of Manufacturer	Proposed Name and Address of Manufacturer
1.	m-Pima HIV-1/2 Detect	MDIR-0001560	M/s Alere Technologies GmbH Loebstedter Starrse 103-105, 07749 Jena, Germany.	M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.

2.	Pima CD4	MDIR-0001907	M/s Alere Technologies GmbH Loebstedter Strasse 103-105 07749 Jena, Germany.	M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.
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**Decision:** The Board approved the change of manufacturing site of M/s Abbott Laboratories (Pakistan) Ltd Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi for their following mentioned medical devices as mentioned below:-

S.No.	Product Name	Regn. No.	Previous Name and Address of Manufacturer	New Approved Name and Address of Manufacturer
1.	m-Pima HIV-1/2 Detect	MDIR-0001560	M/s Alere Technologies GmbH Loebstedter Starrse 103-105, 07749 Jena, Germany.	M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.
2.	Pima CD4	MDIR-0001907	M/s Alere Technologies GmbH Loebstedter Strasse 103-105 07749 Jena, Germany.	M/s Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, 07743 Jena, Germany.

### Case No.5.

M/s AGP Limited, B-23-C, SITE, Karachi has requested for correction in address of manufacturer of their following registered medical devices for import (typographical mistake) as per detail given below:

S.No.	Red No.	Name of Medical Device	Address of manufacturer mentioned on registration letter	Correction required in manufacturer address
1.	MDIR-0002117	oneject Auto Disable Syringe (0.05ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>Jl</b> Olympic Raya Kav, B9 KawasanIndustriSentul Bogor 16810-Indonesia.

2.	MDIR-0002118	oneject Auto Disable Syringe (0.5ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>JI</b> Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.
3.	MDIR-0002099	Oneject Auto Disable Syringe (RUP)  (1ml, 2ml, 3ml & 5ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>JI</b> Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.

**Decision: The MDB approved the correction of manufacturer address in already following registered medical device as mentioned below:-**

S.No.	Red No.	Name of Medical Device	Address of manufacturer mentioned on registration letter	Correct Address of manufacturer
1.	MDIR-0002117	oneject Auto Disable Syringe (0.05ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>JI</b> Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.
2.	MDIR-0002118	oneject Auto Disable Syringe (0.5ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>JI</b> Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.
3.	MDIR-0002099	Oneject Auto Disable Syringe (RUP)  (1ml, 2ml, 3ml & 5ml)	M/s PT Onject Indonesia, Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.	M/s PT Onject Indonesia, <b>JI</b> Olympic Raya Kav, B9 Kawasan Industri Sentul Bogor 16810-Indonesia.

**Case No.6.**

The case of M/s Essity Pakistan Limited, A-69,SITE, Manghopir Road, Karachi for approval of change of importer (company) name from **M/s BSN Medical (Pvt) Limited** to **M/s Essity Pakistan Limited** in their already registered/enlisted medical devices for import as per detail given below was placed before the MDB in its 28<sup>th</sup> meeting held on 28-1-2021 and MDB acceded to the request of the firm for change of importer (company) name from **M/s BSN Medical (Pvt) Limited** to **M/s Essity Pakistan Limited** on registration certificates of their below mentioned registered/enlisted medical devices for import:-

S.#	Regn. No.	Name of Medical Device	Existing Name of importer on Registration/ Enlistment letters	Proposed Name of Importer on Registration/ Enlistment letters
1.	MDIE-0000011	Leukomed (Absorbent Wound Dressing)	M/s BSN Medical (Pvt) Limited, A-69, SITE, Manghopir Road, Karachi	M/s Essity Pakistan Limited, A-69, SITE, Manghopir Road, Karachi.
2.	MDIE-0000012	Fixomull Stretch (Adhesive Tape)	-do-	-do-
3.	MDIE-0000013	Leukomed T Plus (Transparent Absorbent Wound Dressing)	-do-	-do-
4.	MDIE-0000029	Soffban Plus (Synthetic Orthopedic Padding)	-do-	-do-
5.	MDIR-0000348	Cutimed Gel	-do-	-do
6.	MDIR-0000349	Cutimed Cavity	-do-	-do
7.	MDIR-0000350	Cutimed Siltec	-do-	-do
8.	MDIR-0000715	Cutimed Sorbact Hydroactive	-do-	-do

**Decision:** The MDB ratified and approved the correction of Registration Number of the products mentioned at serial No.5,6 & 7 from MDIR-0000348, MDIR-0000349, MDIR-0000350 to MDIR-0000248, MDIR-0000249, MDIR-0000250.

**Case No.7.**

It is submitted that case of M/s Essity Pakistan Limited, A-69, S.I.T.E, Manghopir Road, Karachi for approval of additional sizes of their following already enlisted medical device for import as per detail mentioned below was placed before the MDB in its 28<sup>th</sup> meeting held on 28-01-2021 and decided as under :-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDIE-0000012	Fixomull Stretch (Adhesive Tape)	02036-00 10 m x 5cm 24 Boxes per Shipper  02037-00 10 m x 10cm 24 Boxes per Shipper	10cm x 1cm

**Decision:** The MDB ratified and approved the correction of size of above mentioned product i.e. from 10cm x 1cm to 10cm x 1m.

**Case No.8.**

M/s Roche Pakistan Limited, 37-C, BI-6, PECHS, Karachi has requested for grant of approval of additional pack size of their following registered imported medical device as per detail mentioned below:

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0001940	Cobas SARS-CoV-2 Kit	Cobas SARS-CoV-2 Code: 09175431190  Cobas SARS CoV-2 Control Kit	Cobas SARS-CoV-2 Code: 09343733190 Size: 480 Tests Shelf Life: 12 Months

			Code: 09175440190	
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**Decision: The Board approved the additional size/code of below mentioned medical devices as mentioned against each subject to submission of differential fee of Rs.20,000/-. The Board also directed the MDMC Division to clearly identify the post registration variations and change in particulars to avoid ambiguity**

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	New Approved Additional Sizes/ Codes.
1.	MDIR-0001940	Cobas SARS-CoV-2 Kit	Cobas SARS-CoV-2 Code: 09175431190  Cobas SARS CoV-2 Control Kit Code: 09175440190	Cobas SARS-CoV-2 Code: 09343733190 Size: 480 Tests Shelf Life: 12 Months

**Item No.X. APPLICATIONS FOR PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS.**

**Decision: The MDB approved and ratified the issuance of Import Permit (Form-10) to M/s Textile Testing International, 347-S, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore to import medical device namely 3 Ply Surgical Masks (Qty:1500+1500=3000 Pcs) from M/s Banyan USA, LLC, 24 Central Drive, Farmingdale, NY 11745 for testing purpose only.**

**Item No.XI. REQUEST FOR EXTENSION IN SHELF LIFE OF REGISTERED MEDICAL DEVICES FOR IMPORT.**

M/s Trans Angio System, Suit No.507, Progressive Square, Block-6, PECHS, Shahrah-e-Faisal, Karachi has requested for extension in shelf life of their already following registered medical devices for import:-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
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081287	Yukon Choice PC Sirolimus Eluting Stent System	<b>Manufacturer:</b> M/s Translumina GmbH, Neue Rottenhurger StraBe 50, 72379, Hechingen, Germany.	18 months	24 months
MDIR-0000544	Yukon Chrome PC Sirolimus Eluting CoCr Coronary Stent System	-do-	18 month	24 month

**Decision:** The Board approved the shelf life of the above products from 18 months to 24 months with the direction to submit the Sterility tests and microbiological studies along with any study done on impurities of Sirolimus.

**Item No.XII. REQUEST FOR GRANT OF ADDITIONAL SIZES OF REGISTERED MEDICAL DEVICES FOR LOCAL MANUFACTURE.**

**Case No.01.**

M/s Atco Laboratories Limited, B-18, S.I.T.E, Karachi has requested for grant of approval of additional sizes of their following registered medical device for local manufacture as per detail mentioned below: -

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
2.	MDMR-000063	Hiclean Advance Hard Surface disinfectant (Odorless, Lemon)	1 Liter Bottle, 5 Liter Can and 20 Liter Can.	50ml Bottle, 100ml Bottle, 250ml Bottle, 500ml Bottle, 750ml Bottle, 2 Liter Bottle, 10 Liter Can and 30 Liter Can.

**Decision:** The Board approved the additional sizes of following medical device as mentioned below.

S.No	Regn.No.	Name of Medical Device	Existing Approved Sizes/ Codes	New Approved Additional Sizes/ Codes.
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1.	MDMR-000063	Hiclean Advance Hard Surface disinfectant (Odorless, Lemon)	1 Liter Bottle, 5 Liter Can and 20 Liter Can.	50ml Bottle, 100ml Bottle, 250ml Bottle, 500ml Bottle, 750ml Bottle, 2 Liter Bottle, 10 Liter Can and 30 Liter Can.
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**Case No.02.**

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, 7 <sup>th</sup> Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu-City, P.R. China.	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.

**Decision: The MDB discussed and approved the case for verification/confirmation of FSC.**

**Item No.XIII. DUPLICATION OF SOLE /EXCLUSIVE AUTHORIZATION TO TWO IMPORTERS IN PAKISTAN.**

It is submitted that following two products were present before the Medical Device Board in its 27<sup>th</sup> and 29<sup>th</sup> meetings respectively: -

1.	M/s Roche PakistanLtd., 1st Floor, 37-B, Block 6, PECHS, Karachi	Legal Manufacturer: M/s SD Biosensor, Inc. C-4 <sup>th</sup> & 5 <sup>th</sup> ,16, Deogyong-daero 1556beon-gil, Yeongtong-gu,	SARS-COV-2 Rapid Antigen Test (Device Kit)	Rapid chromatographic immunoassay for the qualitative detection of specific antigens of	<b>Deferred</b> for clarification of Sole Agency Agreement of the applied product from manufacturer
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	(ELI-00009)	<p>Suwon-si Gyeonggi-do 16690, Republic of Korea</p> <p>Manufacturing site:</p> <p>74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk- do, 28161, Republic of Korea</p> <p>FSC Germany Issuance Date 19.11.2020</p> <p>Certificate of Korea issued on 28-10-2020</p>	<p>Class C</p> <p>Shelf Life: 24 Months (ongoing)</p> <p>Size: 25 tests</p> <p>Ref: 9901- NCOV-01G</p> <p>(Cat No: 09327592190)</p> <p>Fee submitted: Rs.50,000/-</p>	<p>SARS-CoV-2 present in human nasopharynx. Intended to detect antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19. This product is strictly intended for professional use in laboratory and point of care environments.</p>	abroad.
2.	<p>M/s A.S. Enterprises, 3- Mozang, Lahore.</p> <p>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> 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk- do, 28161, Republic of Korea</p> <p>FSC Korea issued on 12-11-2020</p>	<p>Standard™ Q COVID-19 Ag Test (Device)</p> <p>Ref No: Q- NCOV-01G</p> <p>Class-C</p> <p>Shelf Life: 24 months (Accelerated stability studies of 19 weeks provided)</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Rapid chromatographic immunoassay for the qualitative detection of specific antigen to SARS-CoV-2 present in human nasopharynx. It is for professional use only and is intended to be used as an aid in the early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms. The result on this test should not be the basis for the</p>	<b>Approved</b> subject to provision of original valid Embassy attested FSC of Germany

		FSC Germany copy (Not Embassy attested) valid till 31.12.2021		diagnosis.	
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**Decision:** The Board directed the MDMC Division to write email to the manufacturer abroad explaining the rule position related to Sole authorization/agreement from manufacturer abroad with importer in Pakistan and ask for clarification as to who is the authorized Sole/Exclusive distributor for this product in Pakistan.

**Item No.XIV. CORRECTION OF SHELF LIFE OF ALREADY APPROVED MEDICAL DEVICES (TYPOGRAPHICAL ERROR).**

The below mentioned application of M/s Eastern Medical Care (Pvt) Ltd, Lahore was placed before the MDB in its 31<sup>st</sup> meeting held on 16<sup>th</sup> March, 2021 and decided as under: -

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision of MDB
1.	M/s Eastern Medical Care (Pvt) Ltd, 7A Block N, Model Town Extension, Lahore  <b>Evaluator:</b> AD-IV [272-P]	<b>Manufacturer:</b> 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. 5,000/-	Non-sterile, single use, powdered, natural rubber latex examination glove.	<b>Approved.</b>

**Decision:** The MDB discussed and approved the correction in shelf life of above mentioned medical devices from 03 years to 05 years.

**Item No.XV. EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017**

M/s 3M Pakistan (Pvt) Ltd, Islamic Chamber of Commerce Building, St-2/A, Block-9, KDA Scheme-5, Clifton, Karachi has requested for approval from Medical Device Board for printing of local labeling information (establishment license detail, registration number and MRP) for their following registered medical devices for import. The printing /labeling of local labeling information will be done on shipper carton of individual unit: -

S.No	Reg.No.	Name of medical device(s)
1.	MDIR-0000946	3M TM Bair Hugger TM Model 675 Total Temperature Management System
2.	MDIR-0001080	3M TM Ioban TM 2 (Antimicrobial Incise Drape)
3.	MDIR-0001081	3M TM Steri-Drape TM Ioban TM 2 (Specialty Drapes with Ioban 2 Incise Film)
4.	MDIR-0001082	3M TM Bair Hugger TM Model 775 Total Temperature Management System
5.	MDIR-0001083	3M TM Tegaderm TM CHG (Chlorhexidine Gluconate I.V Securement Dressing)

**Decision:** The Board discussed the matter at length and allowed one time permission to label their products in the their licensed premises and asked the MDMC Division to come up with SOPs for dealing exemption of labeling or permission of labeling under the Rules.

**Item No.XVI. APPLICATION OF M/S DKT PAKISTAN (PVT) LTD, FOR THE REGISTRATION OF PRODUCT LEVOPLANT (LEVONORGESTREL SILASTIC IMPLANTS) 75 MG**

**Decision:** The MDB discussed and decided to reject the above mentioned application of M/s DKT Pakistan (Pvt) Ltd, R.J building, Plot # 37-C, Stadium Commercial Lane # 2 Phase -V, DHA, Karachi due to the reasons that the product is a Drug and does not fall under Medical Devices Rules, 2017.

**Item No.XVII. SUBMISSION OF FREE SALE CERTIFICATE OR CE MARKED DOCUMENTS BY IMPORTERS.**

**Case No.1**

The case of the M/s Fresenius Medical Care Pakistan (Pvt) Ltd, Lahore for the below medical device was considered by the MDB in its 13<sup>th</sup> meeting held 05-08-2019 and approved subject to inspection of manufacturer abroad: -

1.	M/s Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660  ELI-00315	<b>Legal manufacturer</b>  M/s. Fresenius Medical care (Jiangsu) Co.Ltd., Guli Industrial Park, Guli Zhen, Changshu City, Jiangsu Province, China, 215533  FSC China  Issued on June 22, 2017	<b>AV-Set-DT-E</b>  (Hemodialysis Bloodlines)  Class B  Shelf Life: 03 years  Rs.25,000/-	Bloodlines are intended for single use only for extracorporeal blood purification.	<b>Approved</b> subject to inspection by the panel of inspectors. The board also authorized secretary MDB to issue registration certificate in case of recommendation by panel of inspectors
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**Decision:** The Board approved the above medical device on the basis of CE marked documents.

### Case No.2.

The case of M/s United International, Karachi for the below mentioned product was considered in the 15<sup>th</sup> MDB meeting held on 30-12-2019 and approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017: -

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description	Remarks
	M/s United International,  GNB-F 18/A Ground Floor, F-Block, Mehar Sons Estate, Karachi.  (ELI-00061)	<b>Legal Manufacturer:</b>  Jiangsu Kangyou Medical Instrument Co., Ltd. Tangzhuang ,Yaotang Town 213223 Jiantan/ Jiangsu China.  Provided Export Only Certificate from China validity 08-01-2022	Jazz Sterile Hypodermic Needles  Sterile Hypodermic Needles  Class B  Shelf Life: 5 Years  Codes/Sizes:  31G, 30G, 29G, 28G, 27G, 26G, 25G, 24G,	It is used by medical institutions to give patients intra muscular injection and pharmaceutical solutions, used with syringes. In addition, it can be used	Approved subject to foreign inspection of manufacturer or provision of CE marked documents and provision of Embassy attested Free Sale Certificate, Stability Study protocol and data.

			23G, 22G, 21G, 20G, 19G, 18G, 16G, 15G.  Rs.25,000/-	in conjunction with other instruments that need to input the drug solution into the vein.	
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**Decision:** The Board approved the above medical device on the basis of CE marked documents.

### Case No.3.

The case of M/s. Mian Scientific Corporation (Pvt) Ltd, Faisalabad for the below mentioned product was considered in the 16<sup>th</sup> MDB meeting held on 03-02-2020 and approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017: -

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description	Remarks
1.	M/s. Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad  ELI: 00442	<b>Legal Manufacturer &amp; Manufacturing Site:</b> Guangzhou Improve Medical Instruments Co., Ltd. No 102, Kaiyuan Avenue, Science City, Guangzhou Economic & Technological Development District, Guangzhou, China.  FSC: China	<b>Imrosafe</b>  Blood Collection Set Class: B  Self-Life: 3 years  0.5×19, 0.5×20, 0.55×19, 0.55×20, 0.6×19, 0.6×20, 0.7×19, 0.7×20, 0.7×24,	Blood collection needle is used matching with Vacuum Blood Collection Tube for the purpose of venous blood collection.	Approved subject to in 16 <sup>th</sup> meeting for clarification of brand name since LOA mention Improve while documents show Improvacuter, CE marked documents or inspection of manufacturer abroad.  Firm has Changed

		Validity: 15.07.2020	0.7×25, 0.8×20, 0.8×24, 0.8×25, 0.8×28		the name. it is pertinent mentioned here that the device is not from the reference country.
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**Decision:** The Board approved the above medical device on the basis of CE marked documents with change of brand name i.e from Improvacuter to Imrosafe Blood Collection Set to

#### **Case No.4.**

The case of M/s. Pharma Supply Corporation, Karachi for the below mentioned product was considered in the 14<sup>th</sup> MDB meeting held on 11-10-2019 and approved subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description	Remarks
1.	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 Issuance20-09-2018)	Kinmed Disposable Syringe  Class B  Shelf Life: 5 Years  Sizes: 10ml, 20ml	Disposable Syringe	<b>Approved</b> subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data in 14 <sup>th</sup> meeting. The firm has submitted CE marked document.
2.	-do-	<b>Legal Manufacturer:</b> Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12 <sup>th</sup> Floor, No. 588 Yingkou Road, Shanghai, China.	Kinmed Infusion Set (with/ without needle) 100ml.  Class B  Shelf Life: 5 Years  Sizes:	Infusion Set	<b>Approved</b> subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data in



		(FSC Issuance20-09-2018)	100mL		14 <sup>th</sup> meeting. The firm has submitted CE marked document only for Infusion set whereas the firm has to apply separately for Infusion set with Burrete having valid CE marked document to be submitted.
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**Decision:** The Board approved the above medical devices on the basis of CE marked documents.

**Item No. XVIII. DRAFT FOR OUTSOURCING OF MANUFACTURE, ANALYSIS & RELATED ACTIVITIES FOR LOCAL PRODUCTION OF MEDICAL DEVICES IN ACCORDANCE WITH MEDICAL DEVICES RULES, 2017**

**Decision:** The Board in principle agreed to the Guidelines for outsourcing and recommended to present the same before Authority with slight amendments.

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

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s FM Health Care203, Al Rehman Centre Block 7/8 KCHS, Shaheed-e-	<b>Legal Manufacturer:</b> Duzey Medical Cih. San. Tic. Ltd. Sti. Icmeler Mah. Ozyaman Sok. No:	Duzey Mesh  Surgical Polypropylene Mesh  Class C	Surgical Polypropylene Mesh	<b>Approved.</b>

	Millat Road, Karachi.  (ELI-00082)	23/A Tuzla/ Istanbul Turkey  (FSC Turkey issue 27-05-2020)  FSC Spain issuance 22-05-2019	Shelf Life: 3 Years  Sizes & Codes as Per FSC		
2.	-do-	<b>Manufacturer:</b>  Duzezy Medical Cih. San. Tic. Ltd. Sti.  Icmeler Mah. Ozyaman Sok. No: 23/A Tuzla/ Istanbul Turkey  (FSC Turkey valid till 26-05-2023)  FSC Spain issued on 22-05-2019	Duzyey Neuro Surgical Sponge  Class D  Shelf Life: 3 Years  Sizes and Codes as Per FSC Spain dated 22-05-2019  Fee submitted: Rs. 50,000/-	Used for absorption of liquids from surgical operations including neurosurgical operations. Sterile, single- use	<b>Approved.</b>
3.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	<b>Legal Manufacturer:</b> M/s Abon Biopharm (Hangzhou) Co. Ltd. No.198 12th Street East, Hangzhou Economic &Technologies Development Area, Hangzhou, 310018, P.R. China. FSC China validity 07- 01-2023  FSC Germany Issuance Date (11-02-2020 valid for 1 year)	Influenza A&B Rapid Test Strip (Swab)  Class B  Shelf Life: 24 Months  Codes & Sizes as per FSC  IIN-501(20tests/ kit)	Influenza A&B Rapid Test	<b>Approved.</b>  The firm shall submit valid FSC of Germany before issuance of registration certificate.

4.	<p><b>M/S Tek Enterprises</b></p> <p>Office No.MZ-9 Al-Hafeez Heights, 65-D, Sir Syed Road, Gulberg III, Lahore, Pakistan.</p> <p>ELI-00189</p>	<p><b>Legal Manufacturer:</b> ASAHI INTECC CO.Ltd., 3-100 Akatsuki Cho Seto Shi Aichi-pre. Japan 4890071</p> <p>2. ASAH IIntecc (Thailand) co., Ltd 158/1 Moo 5 Bangkadi Industrial park, Tiwanon Road Tambol Bangkadi Amphur Muang Pathumthani Thailand.</p> <p>FSC: Thailand (validity 11-07-2020)</p> <p>FSC: Japan (25-07-2018 issuance)</p>	<p>SHEATHLESS EUCATH</p> <p>PTCA Guiding catheter</p> <p>Class: D</p> <p>Shelf Life: 3 years</p> <p>Codes: AS PER FSC</p>	<p>PTCA Guiding Catheter</p> <p>Invasive TRI (Radial)Approach</p>	<b>Approved.</b>
5.	<p>M/s Johnson &amp; Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)</p>	<p><b>Legal Manufacturer/ Manufacturing Site:</b></p> <p>M/s Johnson &amp; Johnson International, c/o European Logistics Centre, Leonardo Da Vincilaan 15, BE-1831 Diegem, Belgium</p> <p>(FSC Belgium Issuance 02-07-2019)</p>	<p>Ethicon Physiomesh™</p> <p>Class D</p> <p>Shelf life: 2 Years</p> <p>Sizes &amp; Codes as Per FSC</p> <p>OPHY1010, OPHY1215, OPHY1520, OPHY1525, OPHY2030, OPHY2536</p>	<p>Open may be used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.</p>	<b>Approved.</b>
6.	<p>M/s Popular International (Pvt) Ltd., House</p>	<p><b>Legal Manufacturer:</b> M/s Coviden LLC, 15 Hampshire Street</p>	<p>Steel™ Monofilament</p>	<p>Non-Absorbable Stainless-Steel Sutures are</p>	<b>Approved.</b>

	<p>No. 141, Justice Inamullah Road, Block 7 &amp; 8 KMCHS, Near Hill Park, Karachi (ELI-00091)</p>	<p>Mansfield, MA 02048, USA</p> <p><b>Manufacturing Site:</b></p> <p>(i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA</p> <p>(ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic</p> <p>(FSC USFDA Valid Till 26-11-2021)</p>	<p>Stainless Steel</p> <p>Class C</p> <p>Shelf Life: 5 Years</p> <p>8886222269 222269 8886240763 240763 8886252309S 252309s</p> <p>8886222289 222289 8886240873 240873 VW651M 8886222449 222449 8886240883 240883 W20G 8886222469 222469 8886241069 241069 W22G</p> <p>8886222489 222489 888624 1089 241089 W23G 8886222669 222669 8886241289 241289 W467G 8886222689 222689 8886241383 241383 W497G</p> <p>8886222889 222889 8886241489 241489 W618G 8886234553</p>	<p>indicated for use in abdominal wound closure, intestinal anastomosis, hernia repair and sternal closure.</p>	
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			240749 8886240409S 240409S  8886240753 240753 8886250063S 250063S		
7.	M/s Burraq Enterprise,  Kishwer House office No. 1/7B, 2nd floor Muhammad Ali Cooperative Housing Society Commercial area Karachi.  (ELI-00394)	<b>Legal Manufacturer:</b>  Jiangxi Hongda Medical Equipement Group Ltd. 39 South Shengli RD, Jiaxian County, 3317300 Nanchang, Jiaxian Province, P.R. China.  Certificate of exportability, China validity till 17-06-2019  (FSC Germany 29-05-2019)	Hemocare A.V Fistula Needle for single.  Class B  Shelf Life: 3 Years  <b>Sizes &amp; Codes as Per FSC</b> 1.4 (17G) 1.6(16G), 1.8(15G), 2.1(14G)	This product is used in blood vessel puncture of clinical hemodialysis. The hemodialysis patient fistula arteriovenous, establishing blood circulation passage insert one of the needles into the patient vein when puncture.	<b>Approved.</b>
8.	-do-	<b>Legal Manufacturer:</b>  SWS Hemodialysis Care Co., Ltd, No. 1, Ciji Road, Liangjinag New district, Chongqing 401123, China.  (FSC China validity 23-04-2020)  <b>FSC MHRA</b> issuance 22-02-2019	SES Hemocare Heamodialysis Machine  Class C  Shelf Life: 5 Years  <b>Sizes &amp; Codes as Per FSC</b> SWS-6000, SWS-6000A, SWS-6000B	The Hemodialysis machine is used with consumables, such as perfusion filter, dialyzer, blood tube and puncture needle cooperatively, and it can be used as dialysis, filtration and hemoperfusion for chronic and	<b>Approved.</b>

				acute kidney failure and multiple organ failure clinically. The hemodialysis machine is applied for acute chronic renal failure, multiple organs failure, toxicant and drug intoxication treatment in clinical practices.	
9.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Jiangxi Hongda Medical Equipment Group Ltd. 39 South Shengli RD, Jiaxian County, 3317300 Nanchang, Jiaxian Province, P.R. China.</p> <p>Certificate of exportability, China validity till 17-06-2019</p> <p>(FSC Germany 29-05-2019)</p>	<p>Hemocare</p> <p>Blood Tubing Set for Hemodialysis.</p> <p>Class B Shelf Life: 3 Years</p> <p>Sizes &amp; Codes as Per FSC</p> <p>Model: 20, 20-A, 20-B, 22, 22-A, 22-B, 30, 30-A, 30-B</p>	<p>Be use to Establish blood pathway blood tubing set line for single use, medical personal will connect patients vein and artery with blood pump, dialyzer and monitoring device manually establish and extracorporeal closed circuit. The blood pump will lead the blood to vitro continuously the blood gets into venous chamber through dialyzer. After venous chamber through dialyzer. After venous chamber the blood will flow through</p>	<b>Approved.</b>

				bubble detector and get back to the patient finally.	
10.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Jiangxi Hongda Medical Equipment Group Ltd. 39 South Shengli RD, Jiaxian County, 3317300 Nanchang, Jiaxian Province, P.R. China.</p> <p>Certificate of exportability, China validity till 17-06-2019 (FSC Germany 29-05-2019)</p>	<p>Hemocare Hemodialysis Unit extracorporeal tubing sets</p> <p>Class B</p> <p>Shelf Life: 03 Years</p> <p><b>Sizes &amp; Codes as Per FSC</b> 20, 20-A, 20-B, 22, 22-A, 22-B, 30, 30-A, 30-B</p>	<p>Be use to establish blood pathway blood tubing set line for single use, medical personal will connect patient vein and artery with blood pump, dialyzer and monitoring device manually establish an extracorporeal closed circuit. The blood pump will lead the blood to vitro continuously the blood gets into venous chamber through dialyzer. After venous chamber the blood will flow.</p>	<b>Approved.</b>
11.	<p>M/s Digital Imaging Systems</p> <p>121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore</p> <p>ELI-00094</p>	<p><b>Legal Manufacturer:</b></p> <p>Abbott Medical</p> <p>5050 Nathan Lane North Plymouth, MN 55442 USA</p> <p><b>Manufacturing Site:</b></p> <p>1. St. Jude Medical Costa Rica Ltda Edificio# 44, Calle 0, Ave. 2, Zona Franca Coyol, El Coyol, Alajuela, Costa Rica 1897-4050</p>	<p><b>Pressure Wire™ X Guidewire</b></p> <p>Codes: C12009 C12059 C12359</p> <p>Class: D</p> <p>Shelf Life: 2 years</p> <p>Fee submitted:</p>	<p>Indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. It can also measure</p>	<b>Approved.</b>



		2. Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol, Alajuela, Costa Rica 20102  FSC USFDA valid till 08-10-2021	Rs. 50,000/-	blood temperature. Sterile, single use	
12.	-do-	<b>Legal Manufacturer:</b> ABBOTT VASCULAR 3200 Lakeside Drive Santa Clara, CA 95054, USA  <b>Manufacturing Site:</b> ABBOTT VASCULAR 26531 YNEZ ROAD Temecula, CA USA 92591  FSC US FDA valid till 16-04-2021	<b>HI-TORQUE TurnTrac Guide Wire</b>  <b>Code:</b> 1020013 1020013J 1020014 1020014J 1020015 1020015J 1020016 1020016J Class-D  Shelf Life : 2 years  Fee submitted: Rs. 50,000/-	Steerable guide wire intended to facilitate the delivery of catheter-based interventional devices during the Percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) procedures Sterile, single-use	<b>Approved.</b>  Firm shall submit MRP, valid ISO 13485 and Full Quality Assurance Certificate before issuance of registration letter
13.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore  (ELI: 00150)	Legal Manufacturer Draeger Medical Systems Inc. 3135, Quarry Road, Telford PA USA 18969.  <b>Manufacturing site:</b>  Draeger Medical Systems Inc. 6 Tech Drive, Andover, MA USA 01810  FSC US FDA valid till	Infinity Delta XL monitor (Physiological Monitoring System)  Class C  Ref: MS18596  Shelf Life: N/A  Fee submitted: Rs. 50,000/-	Intended for multi-parameter monitoring of adult, pediatric and neonatal patients.	<b>Approved.</b>

		19-06-2021			
14.	-do-	<p>Legal Manufacturer Drager Medical System Inc. 3135, Quarry Road Telford PA USA 18969.</p> <p>Manufacturing site:  Drager Medical Systems Inc. 6 Tech Drive, Andover, MA USA 01810</p> <p>FSC US FDA valid till 19.06.2021</p>	<p>Infinity Acute Care System (IACS) Monitoring with C700 (Physiological Monitoring System)</p> <p>Class-C</p> <p>Ref: MS25520</p> <p>Shelf Life: N/A</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Intended for multi-parameter patient monitoring of adult, pediatric and neonatal patients.</p>	<b>Approved.</b>
15.	<p>M/s Verizon. 60- D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore.</p> <p>(ELI-00087)</p>	<p>Manufacturer: COOK, INC. 750 DANIELS WAY Bloomington, IN USA 47404</p> <p>FSC US FDA valid till September 17, 2020</p>	<p>Cantata Microcatheter</p> <p><b>Code:</b></p> <p>MCS-2.5-NT- 100-15-HP MCS-2.5-NT- 110-15-HP MCS-2.5-NT- 135-15-HP MCS-2.5-NT- 150-15-HP MCS-2.8-NT- 100-15-HP MCS-2.8-NT- 110-15-HP MCS-2.8-NT- 135-15-HP MCS-2.8-NT- 150-15-HP MCS-2.9-NT- 100-15-HP MCS-2.9-NT- 110-15-HP MCS-2.9-NT- 135-15-HP MCS-2.9-NT-</p>	<p>The Cantata Microcatheter is a shapeable-tip, Braided, kink restraint microcatheter with hydrophilic coating. Sterile, single use</p>	<b>Approved.</b>  The firm shall submit valid FSC at the time of issuance of registration letter

			150-15-HP Class D Shelf Life: 3 years Fee submitted: Rs. 50,000/-		
16.	-do-	<b>Manufacturer:</b> Wilson-Cook Medical Inc. 4900 Bethania Station Road Winston Salem, NC USA 27105  FSC US FDA valid till 19-06-2021	Balloon Replacement Tube (Gastrostomy Replacement Devices)  Codes: PEG-14-BRT-S, PEG-18-BRT-S PEG-24-BRT-S  Class C  Shelf Life: 2 years  Fee submitted: Rs. 50,000/-	Intended to be used as a replacement gastrostomy tube through an established gastrostomy tract. Sterile, single use	<b>Approved.</b>
17.	-do-	<b>Manufacturer:</b> Wilson-Cook Medical Inc. 4900 Bethania Station Road Winston Salem, NC USA 27105  FSC US FDA valid till 19-06-2021	Percutaneous Endoscopic Gastrostomy Set  <b>Code:</b> FLOW-20-PULL-I-S  FLOW-20-PUSH-I-S  PEG-24-PULL-I-S  PEG-24-PUSH-I-S  Class C	Intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition to patients requiring nutritional support. Sterile, single use	<b>Approved.</b>

			Shelf Life: 03 years Fee Submitted: Rs. 50,000/-		
18.	-do-	<b>Manufacturer:</b> Wilson-Cook Medical Inc. 4900 Bethania Station Road Winston Salem, NC USA 27105  FSC US FDA valid till 19-06-2021	Tri-Tome PC Triple Lumen Sphincterotome  Class C  <b>Code:</b> TRI-20, TRI-20M, TRI-25, TRI-25M, TRI-25M-SLT, TRI-30, TRI-30M  Shelf Life: 03 years  Fee submitted: Rs. 50,000/-	Used for cannulation of the ductal system and for sphincterotomy. Sterile, single use	<b>Approved.</b>
19.	-do-	<b>Manufacturer:</b> COOK, INC. 750 DANIELS WAY Bloomington, IN USA 47404 FSC US FDA valid till 09-07-2022	Torcon NB® Advantage Catheter Codes: Codes as per FSC No. 111873-7-2020 dated 10-07-2020  Class D Shelf Life: 03 years Fee submitted: Rs. 50,000/-	Intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures. Sterile, single-use	<b>Approved.</b>
20.	M/s. Cardiac Care, 848-C, Shadman-I Lahore. ELI-00070	<b>Manufacturer:</b> M/s Vygon GmbH & Co. KG  Prager Ring 100, D-52070 Aachen,	Lifecath-PICC PUR (Single lumen peripherally inserted central catheter)	Peripherally inserted central venous catheter for mid to long term IV therapy. Sterile, single use	<b>Approved.</b>

		Germany FSC Germany issued on 29.03.2019	Class: D Code: 1294.113 1294.114 1294.115 Shelf Life: 3 years Fee submitted: Rs. 50,000/-		
21.	-do-	Manufacturer: M/s KOO Medical Equipment Co. Ltd., 100 Zhongde Road, Xiaokunshan Town, songjiang, Shanghai 201614, P.R. China	Anesthesia Mask Class: B Code: KM-201, KM-202, KM-203, KM-204, KM-205, KM-206 Fee submitted: Rs. 25,000/- Codes as per FSC	Anesthesia Mask	<b>Deferred</b> for provision of FSC of any reference country or CE marked documents.
22.	M/s Muslim Trading Agencies, Ground Floor, 3 Syed Moj Darya Road, Lahore. (ELI-00359)	<b>Legal Manufacturer:</b> Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom  (FSC UK valid till 18-8-2021)	Randox Calibration Serum Class C 1. Calibration Serum Level 2 (CAL 2) Code: CAL2350 Shelf Life: 30 Months  2. Calibration Serum Level 3 (CAL 3) Code: CAL2351 Shelf Life: 30 Months	It is used as a calibrator in clinical chemistry assays. The Human Assayed Multi-sera is for control of accuracy	<b>Approved.</b> The firm shall submit valid Letter of Authorization before issuance of registration certificate.

			Fee submitted: Rs. 50,000/-		
23.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Radox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom</p> <p>(FSC UK valid till 18-8-2021)</p>	<p>Radox Haemoglobin A1c (HbA1c) (kit)</p> <p>Class B</p> <p>1. Haemoglobin A1c (HbA1c) Code: HA3830 Shelf Life: 24 Months</p> <p>2. Haemoglobin A1c (HbA1c) Code: HA8321 Shelf Life: 24 Months</p> <p>3. Haemoglobin A1c Control Set (HbA1c Control) Code: HA5072 Shelf Life: 12 Months</p> <p>4. Haemoglobin A1c Calibrator (HbA1c Cal) Code: HA3444 Shelf Life: 24 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	Intended for quantitative in vitro determination of Haemoglobin A1c concentration in whole blood.	<p><b>Approved.</b></p> <p>The firm shall submit valid Letter of Authorization before issuance of registration certificate.</p>
24.	-do-	<p><b>Legal Manufacturer:</b></p>	Radox Liquid	Intended for invitro	<p><b>Approved.</b></p>

		<p>Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom</p> <p>(FSC UK valid till 18-8-2021)</p>	<p>Cardiac Control Class C</p> <p>1. Liquid Cardiac Control Level 1 Code: CQ5051 Shelf Life: 24 Months</p> <p>2. Liquid Cardiac Control Level 2 Code: CQ5052 Shelf Life: 24 Months</p> <p>3. Liquid Cardiac Control Level 3 Code: CQ5053 Shelf Life: 24 Months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>diagnostic use, in the quality control of cardiac markers on clinical chemistry and immunoassay systems</p>	<p>The firm shall submit valid Letter of Authorization before issuance of registration certificate.</p> <p>Other types to be applied separately.</p>
25.	-do-	<p><b>Legal Manufacturer:</b></p> <p>Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom</p> <p>(FSC UK valid till 18-8-2021)</p>	<p>Randox CK-MB (kit)</p> <p>Class C</p> <p>1. CK-MB reagent Code: CK1296 Shelf Life: 36 Months</p> <p>2. CK-MB reagent Code: CK3813 Shelf Life: 36 Months</p> <p>3. Liquid CK-MB reagent</p>	<p>Intended for quantitative invitro determination of CK-MB in serum and plasma.</p>	<p><b>Approved.</b></p> <p>The firm shall submit valid Letter of Authorization before issuance of registration certificate.</p>

			<p>Code: CK4043 Shelf Life: 12 Months</p> <p>4. CK-MB control Code: CK1212 Shelf Life: 36 Months</p> <p>5. CK-MB calibrator (CK-MB CAL) Code: CK2393 Shelf Life: 48 Months</p> <p>Fee submitted: Rs. 50,000/-</p>		
26.	-do-	<p><b>Legal Manufacturer:</b> Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, Country Antrim, BT29 4QY, United Kingdom</p> <p>(FSC UK valid till 18-8-2021)</p>	<p>Randox CK-NAC (kit) Class C</p> <p>1. CK-NAC activated reagent Code: CK110 Shelf Life: 36 Months</p> <p>2. CK-NAC reagent Code: CK3878 Shelf Life: 12 Months</p> <p>3. CK-NAC activated reagent Code: CK8313 Shelf Life: 12 Months</p> <p>Fee submitted:</p>	Intended for quantitative invitro determination of creatinine kinase in serum and plasma.	<b>Approved.</b>  The firm shall submit valid Letter of Authorization before issuance of registration certificate.



			Rs. 50,000/-		
27.	M/s Meditec Instruments Co., Suit No. 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi  (ELI-00233)	<b>Manufacturer:</b> Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China  FSC China valid till 06-12-2020  FSC Belgium issued on 16-03-2020	Finecare™ β-hCG Rapid Quantitative Test (Kit)  Code: W225  Class: B  Shelf Life: 24 months  Fee submitted: Rs. 25,000/-	A fluorescence immunoassay used along with Finecare™ FIA system for quantitative determination of β-hCG in human blood, serum or plasma. This test is used as an aid to assist in the diagnosis of early detection of pregnancy	<b>Approved.</b>  The firm shall submit valid ISO 13485 and details of QC before issuance of registration certificate
28.	-do-	<b>Manufacturer:</b> Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China  FSC Belgium issued on 16-03-2020	Finecare™ Vitamin D Rapid Quantitative Test (Kit)  Code: W241  Class: B  Shelf Life: 24 months  Fee submitted: Rs. 25,000/-	A fluorescence immunoassay used along with Finecare™ FIA meter for quantitative determination of total 25(OH) D2/D3 level in human serum or plasma. Results assist in the assessment of vitamin D sufficiency	<b>Approved.</b>  The firm shall submit valid ISO 13485 and details of QC before issuance of registration certificate
29.	-do-	<b>Manufacturer:</b> Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China	Finecare™ D-Dimer Rapid Quantitative test (Kit)  Class: C  Code: W211	A fluorescence immunoassay used along with Finecare™ FIA system for quantitative determination of D-Dimer in	<b>Approved.</b>  The firm shall submit valid ISO 13485 and details of QC before issuance of registration

		FSC China valid till 06-12-2020  FSC Belgium issued on 16-03-2020	Shelf Life: 24 months  Fee submitted: Rs. 50,000/-	human whole blood and plasma. This test is used as an aid to assist in the diagnosis of thrombosis and thrombotic diseases	certificate
30.	-do-	Manufacturer:  Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China  FSC China valid till 06-12-2020  FSC Belgium issued on 16-03-2020	Finecare™ CTnl Rapid Quantitative Test (Kit)  Class: C Code: W203  Shelf Life: 24 months  Fee submitted: Rs. 50,000/-	A fluorescence immunoassay used along with Finecare™ FIA system for quantitative determination of cardiac troponin I (cTn I) in human whole blood. Serum, or plasma. This test is used as an aid to assist in the diagnosis of acute myocardial infarction	<b>Approved.</b>  The firm shall submit valid ISO 13485 and details of QC before issuance of registration certificate
31.	-do-	Manufacturer:  Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science city, Luogang District, 510663, Guangzhou, China  FSC China valid till 06-12-2020  FSC Belgium issued on 16-03-2020	Finecare™ HbA1c Rapid Quantitative Test (Kit)  Class: B Code: W207  Shelf Life: 24 months  Fee submitted: Rs. 50,000/-	A fluorescence immunoassay used along with Finecare™ FIA system for quantitative determination of Hemoglobin A1c in human blood. Used as an aid to monitor long-term glycemic status in patients with diabetes mellitus	<b>Approved.</b>  The firm shall submit valid ISO 13485 and details of QC before issuance of registration certificate

32.	-do-	<p>Manufacturer: M/s Medica Corp., 5 Oak Park Drive, Bedford, MA USA 01730.</p> <p>FSC US FDA valid till 02-07-2021</p>	<p>EasyRa Cholesterol Reagent Kit, CHOL</p> <p>Class B</p> <p>Code: 10204-4</p> <p>Shelf life: 27 months</p> <p>2. EasyRa HDL Cholesterol Reagent Kit, HDL</p> <p>Code: 10211-4 Shelf life: 24 months</p> <p>3. EasyRa LDL Cholesterol Reagent Kit, LDL</p> <p>Code: 10224-4 Shelf life: 24 months</p> <p>4. EasyRa Triglyceride Reagent Kit, TRIG</p> <p>Code: 10216-4 Shelf life: 15 months</p> <p>5. EasyRa HDL Cal Kit</p> <p>Code: 10653 Shelf life: 24 months</p> <p>EasyRa LDL Cal Kit</p> <p>Code: 10655</p>	<p>Intended for the quantitative measurement of cholesterol, high density lipoprotein cholesterol, low density lipoprotein cholesterol, triglycerides in human serum or plasma using MEDICA EasyRA Clinical Chemistry Analyzer</p>	<p><b>Approved.</b></p> <p>The firm shall submit valid ISO 13485 and details of QC before issuance of registration certificate</p>

			Shelf life: 48 months  Fee submitted: Rs. 25,000/-		
33.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)	<p>Manufacturer: Fisher &amp; Paykel Healthcare Limited., 15 Maurice Paykel Place, East Tamaki, Auckland, 2013, New Zealand</p> <p>FSC New Zealand issued on 5-3-2020</p> <p>Copy of Health Canada Medical Device License for the applied product is also provided</p>	<p>Fisher &amp; Paykel Healthcare Bi-level CPAP system hospital mask-Non-vented face mask</p> <p>Class B</p> <p>Shelf life: The manufacturer has written that they do not have lifetime expectancy test report for the applied product</p> <p>Codes: RT041L RT041M RT041S</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>Non-vented hospital full face mask is an oronasal patient interface for use as an accessory to therapy devices providing non-invasive bi-level or continuous positive airway pressure support therapy. Single use</p>	<p><b>Approved.</b></p> <p>Firm shall submit QC details before issuance of registration certificate.</p> <p>Firm shall apply separately for vented mask with anti-asphyxiation valve.</p>
34.	-do-	<p>Manufacturer: Fisher &amp; Paykel Healthcare Limited., 15 Maurice Paykel Place, East Tamaki, Auckland, 2013, New Zealand</p> <p>FSC New Zealand issued on 5-3-2020</p> <p>Copy of Health Canada Medical Device License for the applied product is also provided</p>	<p>Fisher &amp; Paykel Healthcare CPAP/BPAP Infant Nasal mask</p> <p>Class B</p> <p>Shelf life: The manufacturer has written that they do not have lifetime expectancy test report for the applied product</p> <p>Codes: BC800-10 BC801-10</p>	<p>Designed to deliver noninvasive positive pressure ventilation to a spontaneously breathing patient weighing up to 10kg in a hospital or clinical setting Single use</p>	<p><b>Approved.</b></p> <p>Firm shall submit QC details before issuance of registration certificate.</p>

			BC802-10 BC803-10  Fee submitted: Rs. 25,000/-		
35.	M/s Diag. M (Pvt) Limited. B-270, Sector 6-F EBM Causeway, Mehran Town, Korangi, Karachi. (ELI-00184)	<b>Manufacturer:</b> Biosystems, S.A., C/Costa Brava, N 30, 08030 Barcelona, Spain  (FSC Spain issued on 27-04-2018)	BioSystems Biochemistry Calibrator (Human)  Class B  Shelf Life: 24 months  Code: 18044  Fee submitted: Rs. 25,000/-	Lyophilized human serum containing component concentrations suitable for the quality control of the clinical laboratories.	<b>Approved.</b>
36.	-do-	<b>Manufacturer:</b> Biosystems, S.A., C/Costa Brava, N 30, 08030 Barcelona, Spain  (FSC Spain issued on 27-04-2018)	BioSystems Uric Acid (reagent)  Class B  Shelf Life: 36 months  Code: 12521, 11821, 11521, 11522, 11540, 21521, 23521  Fee submitted: Rs. 25,000/-	Reagents for the measurement of uric acid concentration in human serum, plasma or urine.	<b>Approved.</b>
37.	M/s. Cardiac Care, 848-C, Shadman-I Lahore. (ELI-00070)	<b>Manufacturer:</b> EUROSETS s.r.l STRADA STATALE 12, n. 143, 41036 MEDOLLA (MO) Italy  FSC Italy issued on 04.10.2019	Eurosets Cardio plegia CIRC. W/SPIRAL PK (Cardioplegia Custom Packs)  Code: EU81155  Class: B  Shelf Life: 3 years	Cardioplegia tubing set. Sterile, single- use	<b>Approved.</b>

			Fee submitted: Rs. 25,000/-		
38.	M/s Eastern Medical Care (Pvt) Ltd. 7A, Block N, Model Town Extension, Lahore (ELI-00130)	Manufacturer: ForaCare Suisse AG Neugasse 55, 9000 St. Gallen Switzerland  FSC Switzerland valid till 11-02-2022	FORA Diamond Blood Glucose Test Strip  Code: ACS044  Class C  Shelf Life: 21 months  Fee submitted: Rs. 25,000/-	Test Strip used together with FORA Diamond Blood Glucose monitoring system. Single use	<b>Approved.</b>
39.	-do-	Manufacturer: ForaCare Suisse AG Neugasse 55, 9000 St. Gallen Switzerland  FSC Switzerland valid till 11-02-2022	FORA Diamond GD50a (Blood Glucose Monitoring System)  Class C  Shelf Life: N/A  Fee submitted: Rs. 25,000/-	Blood Glucose Monitoring System	<b>Approved.</b>
40.	-do-	Manufacturer: ForaCare Suisse AG Neugasse 55, 9000 St. Gallen Switzerland  FSC Switzerland valid till 11-02-2022	FORA Tender Sterile lancet  Class B  Code: ACS024  Shelf Life: 5 years  Fee submitted: Rs. 25,000/-	Used together with a lancet device intended to penetrate the skin for obtaining micro blood samples. Sterile, single use	<b>Approved.</b>
41.	M/s. Progressive Corporation, 147-D Commercial Broadway, Phase 8, DHA, Lahore (ELI-00114)	<b>Manufacturer:</b> Farcomake for Advanced Medical Industry, New Borg Al- Arab Industrial	Farco Fistula Fistula Needle (with Fixed Wing) Code:	Intended for use as a vascular blood access device for blood purification in	<b>Approved.</b>

		City, Area 4, Block 2, Part 7, 16 Alexandria, Egypt.  FSC Egypt valid till 18-04-2023  FSC Germany issued on 20.3.2019	FSN1620 FSN1720 FSN1520  Class: B  Shelf Life: 5 years  Fee submitted: Rs. 25,000/-	hemodialysis. Sterile, single use	
42.	M/s Flowtronix Systems, Flat No. 02, 1 <sup>st</sup> Floor, Al-Ashraf, Range Road, Rawalpindi (ELI: 00217)	Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany  FSC Germany issued on 25.03.2020	Enitra 8 HFT-QP (Triple Chamber Pacemaker-MR Conditional) Code: 407141  Class: D  Shelf Life: 19 months  Fee submitted: Rs. 50,000/-	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), MR conditional, sterile, single-use	<b>Approved.</b>
43.	-do-	Manufacturer: Biotronik SE & Co.KG Woermannkehre 1, 12359 Berlin, Germany  FSC Germany issued on 25.03.2020	Enitra 6 DR (Dual Chamber Pacemaker-MR Conditional)  Code: 407153  Class: D  Shelf Life: 19 months  Fee submitted: Rs. 50,000/-	Implantable pacemaker, MR conditional, sterile, single-use	<b>Approved.</b>
44.	-do-	Manufacturer: Biotronik SE & Co.KG	Rivacor 3 VR-T (Single Chamber	Implantable pacemaker, MR	<b>Approved.</b>

		<p>Woermannkehre 1, 12359 Berlin, Germany</p> <p>FSC Germany issued on 25.03.2020</p>	<p>Implantable Cardioverter Defibrillator, MR Conditional)</p> <p>Code: 429574</p> <p>Class: D</p> <p>Shelf Life: 25 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>conditional, sterile, single- use</p>	
45.	-do-	<p><b>Legal Manufacturer:</b> MED Michigan Holdings LLC 2680 Walker Ave NW, Suite C, Walker, MI (49544), USA</p> <p>FSC USA Valid till 3<sup>RD</sup> March, 2021</p>	<p><b>Surge Cardiovascular Suction Safety Device</b></p> <p>Class B</p> <p>Shelf life 4 years</p> <p>Code: SSD-100AS</p>	<p>Helps prevent build-up of excess vacuum pressure or inadvertent flow when suctioning from the heart or the Surgical field.</p>	<b>Approved.</b>
46.	<p>Lab Link Enterprises, M- 203, Block 2, PECHS, Opposite Ghousiya Masjid, Karachi (ELI-00007)</p>	<p><b>Legal Manufacturer:</b> M/s Amsino International, Inc. 708 Corporate Center Drive, Pomona CA USA, 91768,</p> <p><b>Manufacturing site:</b> M/s Amsino Medical (Kunshan) Co. Ltd., 582 Shipu Lidu Road, Qiandeng Town Kunshan City, Jiangsu 215343, China</p> <p>FSC USFDA valid till 29-04-2020</p>	<p>Nipro Infusion Set</p> <p>Code: N-IS-009B-NIJ- ECEPK</p> <p>N-IS-009P-NIJ- ECEPK</p> <p>Class B</p> <p>Shelf life: 5 years</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>It is used to administer fluids from a container to a patient's vascular system. Sterile, single use</p>	<p><b>Approved.</b> Firm shall submit valid ISO13485, Full QA, FSC and LOA before issuance of registration letter.</p>
47.	<p>M/s Batla Impex, Sh. 40, Namco</p>	<p><b>Legal Manufacturer:</b></p>	<p>New Golden</p>	<p>It is a device specialized for</p>	<b>Approved.</b>



	Centre, Cambell Street, Karachi (ELI-00170)	M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China  FSC China issuance (03-09-2019) valid for 5 years  FSC MHRA issuance 27-09-2019	Scalp Vein Set Class-B Shelf life: 04 year Codes & Sizes as per FSC  17, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 27G, 28G, 29G, 30G	vein puncture for accessing a superficial vein for either intravenous injection.	
48.	-do-	<b>Legal Manufacturer:</b> M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China  FSC China issuance (03-09-2019) valid for 5 years  FSC MHRA issuance 27-09-2019	Foleys Catheter Class-B Shelf life” 5 years Codes & Sizes as per FSC  1 way, 2 way & 3 way Sizes: 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28	It is a flexible tube that a clinician passes through the urethra and into the bladder to drain urine.	<b>Approved.</b>
49.	-do-	<b>Legal Manufacturer:</b> M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China  FSC China issuance (03-09-2019) valid for 5 years	New Golden IV Cannula Class-B Shelf life: 04 years Codes & Sizes as per FSC  16G, 18G, 20G, 22G, 24G, 26G	A Cannula is a tube that can be inserted into the body, often for the delivery or removal of fluid or for the gathering of samples.	<b>Approved.</b>

		FSC MHRA issuance 27-09-2019			
50.	-do-	<p><b>Legal Manufacturer:</b></p> <p>M/s Zibo Eastmed Healthcare Products Co. Ltd., No.118, Huaguang Road, Zhangdian District Zibo 255000 Shandong, China</p> <p>FSC China issuance (03-09-2019) valid for 5 years</p> <p>FSC MHRA issuance 27-09-2019</p>	<p>New Golden Disposable Hypodermic Needle</p> <p>Class-B</p> <p>Shelf life: 04 years</p> <p>Codes &amp; Sizes as per FSC</p> <p>17, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 27G, 28G, 29G, 30G</p>	It is intended to inject below the surface of the skin	<b>Approved.</b>
51.	M /s Alliance Medical, 12-B, 1 <sup>st</sup> Floor, Agro Flats, Shadman, Lahore.  ELI-00147	<p><b>Legal Manufacturer:</b></p> <p>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</p> <p>Date of issue 2.08.2017</p> <p>FSC Netherland validity 06-12-2023</p>	<p>GENOSS DES Sirolimus Eluting Coronary Stent System.</p> <p>(Drug Eluting Coronary Artery Stent)</p> <p>Class: D</p> <p>Shelf life: 2 years</p> <p>Code:</p> <p>GDES-08-225, GDES-08-250, GDES-08-275, GDES-08-300, GDES-08-325, GDES-08-350, GDES-08-375, GDES-08-400,</p>	Drug Eluting Stent	<b>Approved.</b>

			<p>GDES-13-225,  GDES-13-250,  GDES-13-275,  GDES-13-300,  GDES-13-325,  GDES-13-350,  GDES-13-375,  GDES-13-400,  GDES-15-225,  GDES-15-250,  GDES-15-275,  GDES-15-300,  GDES-15-325,  GDES-15-350,  GDES-15-375,  GDES-15-400,  GDES-20-225,  GDES-20-250,  GDES-20-275,  GDES-18-300,  GDES-18-325,  GDES-18-350,  GDES-GDES-33-325, GDES-33-350, GDES-33-375, GDES-33-400, GDES-38-225, GDES-38-250, GDES-38-275, GDES-38-300, GDES-38-325, GDES-38-350, GDES-38-375, GDES-38-400.</p>		
52.	<p>M/S Maqsood Brothers   Office No. 503-B, 5th Floor, SAIMA TRADER TOWER, LI</p>	<p><b>Legal Manufacturer:</b>   XUYI CAREYOU MEDICAL PRODUCT CO., LTD   NO. 2 keyuan Third Road, Xuyi Industrial</p>	<p>LIFE CARE   NEBULIZER MASK   Class: B</p>	<p>Intended for connecting with active respiration equipment and introducing oxygen to human body</p>	<p><b>Approved.</b>   Firm shall submit attested copies of legal documents before issuance of registration certificate.</p>

	CHUNDRIGAR ROAD KARACHI  (ELI-00282)	Park, 211700, Jiangsu Province, CHINA.  FSC Spain 07-09-2020	Shelf life: 5 years  Codes and sizes as per FSC  Neonates, Child & Adult	and intended for rhinitis, pharyngitis, laryngitis, tracheitis, bronchitis and other respiratory diseases treated by inhalation.	
53.	-do-	<b>Legal Manufacturer:</b>  XUYI CAREYOU MEDICAL PRODUCT CO., LTD  NO. 2 keyuan Third Road, Xuyi Industrial Park, 211700, Jiangsu Province, CHINA.  FSC Spain 07-09-2020	LIFE CARE  OXYGEN MASK  Class: B  Shelf life: 5 years  Codes and sizes as per FSC  Neonates, Child & Adult	Intended for connecting with active respiration equipment and introducing oxygen to human body.	<b>Approved.</b>  Firm shall submit attested copies of legal documents before issuance of registration certificate.
54.	-do-	<b>Legal Manufacturer:</b>  XUYI CAREYOU MEDICAL PRODUCT CO., LTD  NO. 2 keyuan Third Road, Xuyi Industrial Park, 211700, Jiangsu Province, CHINA.  FSC Spain 07-09-2020	LIFE CARE  OXYGEN NASAL CANNULA  Class: B  Shelf life: 5 years  Codes and sizes as per FSC  Neonates, Pediatric, Child & Adult	Intended for connecting with active respiration equipment and introducing oxygen to human body.	<b>Approved.</b>  Firm shall submit attested copies of legal documents before issuance of registration certificate.
55.	M/s 4A International Plot 7, Street 11, Lawyers Society	<b>Legal manufacturer:</b> Detro Healthcare Kimya Sanayi A.S Ataturk mah. Adnan	<b>Detro Hemoplus</b> (Citric acid, Lactic acid, Malic acid)	Haemodialysis device cleaner.	<b>Approved.</b>

	Chaklala, Rawalpindi. (ELI-00099)	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	Class- B  Shelf Life: 3 years  Sizes: 5L, 20L		
56.	Ghazali Brothers, 1st Floor, Azzainab Court Campbell Street, Karachi (ELI-00240)	<b>Legal Manufacturer:</b> Ningbo Yingmed Medical Instruments Co., Ltd. Uingsheng Building No. 456 Tai'an Road, Southern Business Zone, 315199, Ningbo, China	YINGMED SAFETY SYRINGE (AUTODISABL E) STERILE  Class-B  Shelf life: 05 years  Codes and sizes as per FSC 2ml, 3ml, 5ml, 10ml, 20ml	Used in human body hypodermic injection and solution aspiration.	<b>Deferred</b> for provision of FSC of any reference country or CE marked documents.
57.	M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi (ELI-00029)	<b>Legal Manufacturer:</b> Nucletron B.V. Waardgeler 1 3905 TH veenendaal The Netherlands.  (FSC Netherlands Valid 26-05-2024)	Flexitron HDR System  Class C  Service life: 10 years  Sizes & Codes as Per FSC	Flexitron is intended to serve as an overview of the various components of Elekta brachytherapy solution, Flexitron after loading system.	<b>Approved.</b>
58.	M/s Mehran International, 498/C Feroz Shah Mehta Road Karachi ELI: 00351	<b>Legal Manufacturer:</b> M/Jiangxi Glance Medical Equipmetn Co., Ltd Jinxian Medical Device Industrial Area Nanchang City, Jiangxi Province P.R China	Endotracheal Tube Uncuffed  Class-B  Shelf life: 5 years  Codes & Sizes: As per FSC		<b>Approved</b> on the basis of CE marked documents.

		FSC: China Valid till: 2021.10.07			
59.	<b>-do-</b>	<b>Legal Manufacturer:</b> M/s Tianchang Ganor Medical Device Co., Ltd Shuangliu Village Datong Town Tianchangcity anhui Province, P.R China  FSC: China Valid till: 3.09.2022	Urine Drainage Bag  Class-A  Shelf life: 5 years  Sizes:  500ml, 1000ml, 1500ml, 2000ml		<b>Approved</b> on the basis of CE marked documents.
60.	<b>-do-</b>	<b>Legal Manufacturer:</b> Human Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China  FSC: China Valid till: 12.03.2022	M.I Sterile Hypodermic disposable syringes  Class-B  Shelf life: 5 years  Sizes:  20ml, 30ml, 50ml	M.I Sterile Hypodermic disposable syringes 20ml, 30ml, 50ml, 60ml	<b>Approved</b> on the basis of CE marked documents.
61.	<b>-do-</b>	<b>Legal Manufacturer:</b> Shandong Qinkai Medical Industry Co., Ltd  (The Southern Tip of Quancheng Road in Industrial Park, Chengwu, County, Heze City, Shandong Province P.R.China  FSC China validity 21- 10-2023	RELATION INFUSION SET  Class: B  Shelf life: 3 years  Codes & sizes as per FSC	Infusion set	<b>Approved</b> on the basis of CE marked documents.
62.	<b>-do-</b>	<b>Legal Manufacturer:</b> Shandong Yiguang Medical Instruments	M.I Infusion set	Infusion set	<b>Approved.</b>

		Co., Ltd Sanjiu Science-Technology Industrial park, Chiping county, Shandong Province, China.  FSC China validity 04- 03-2022  FSC Germany issuance 22-12-2020	Class-B  Shelf life: 5 years  Codes & sizes as per FSC		
63.	Ms.JK Traders Suite No. 13, 2 <sup>nd</sup> Floor Majeed Plaza Bank Road Saddar Rawalpindi.  ELI-00014	<b>Legal Manufacturer:</b> Xiamen New Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicing Biomedicine Building No.2026, West Wengjiao Road Haicang district, Xiamen, Fujian, China  FSC China  Date of issue 12 <sup>th</sup> July, 2019  FSC Spain Issuance: 11-07-2019	<b>NCMT</b> (Balloon Inflation Device)  Class B  Shelf life 3 years  Code: YB-B-20	Balloon Inflation Device	<b>Approved.</b>
64.	M/s.Neutro Health care. 22- M, Gulberg-III, Lahore. ELI-00191	<b>Legal Manufacturer:</b> M/s. BikarIlac San. ve Tic. Ltd. sti. GullubaglarMah. Ankara Cad. SirinSokak No: 14 Pendik / ISTANBUL / TURKEY.  FSC:18-09-2019 valid for 36 months	<b>Ankaferd Blood Stopper</b> (Wet Tampon gauze Pad)  Class-D  Shelf Life: 04 years	Ankaferd Blood Stopper Bleeding stopper pad is indicated in topically stopping bleedings that arise out of pathological damage to skin and mucosa.	<b>Deferred</b> for provision of FSC of any reference country or CE marked documents

			Codes/ models: As per FSC		
65.	M/s. Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad  ELI: 00442	<b>Legal Manufacturer</b>  Wuxi Bio Hermes and Bio-medical technology Co. Ltd, No 136 Mashan Meiliang Road Binhu wuxi Jiangsu 214092, China  <b>Manufacturing Sites:</b> 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  FSC: China Valid till 17.07.2021	Bio HermesGLYCOH EMOGLOBIN ANALYZER  Class: C  Service Life: 5 years  Model: A1C-M21	In vitro diagnostic test used for quantitative analysis of A1c Glycohemoglobin or A1c glycohemoglobin fraction in whole venous blood.	<b>Deferred</b> for provision of FSC of any reference country or CE marked documents.
66.	M/s Abdullah Traders, 3 Green Town, Ghous-ul-Azam Road, Multan  ELI-00444	Manufacturer: GeneAll Biotechnology Co. Ltd. GeneAll Bldg., 303-7, Dongnam-ro, Songpa-gu, Seoul, Korea. 05729  FSC Korea issued on 07-09-2020	Genti™ Viral DNA/RNA Extraction Kit  Class B  Codes: 902-096 902-048  Shelf Life: 12 months Fee submitted: Rs. 50,000/-	For the isolation of total RNA and DNA from cell-free fluid, cell culture medium, plasma, serum, swab, stool, tissues, body fluids, whole blood, urine and virus infected liquid	<b>Approved</b> subject to inspection of manufacturer abroad under rule 71 of MDR, 2017.



				samples.	
67.	-do-	<p>Manufacturer: GeneAll Biotechnology Co. Ltd. GeneAll Bldg., 303-7, Dongnam-ro, Songpa-gu, Seoul, Korea. 05729</p> <p>FSC Korea issued on 09-12-2020</p>	<p>Genti™ Advanced Viral DNA/RNA Extraction Kit</p> <p>Class B</p> <p>Codes: 902-096A 902-048A</p> <p>Shelf Life: 12 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>For the isolation of total RNA and DNA from cell-free fluid, cell culture medium, plasma, serum, swab, stool, tissues, body fluids, whole blood, urine and virus infected liquid samples.</p>	<p><b>Approved</b> subject to inspection of manufacturer abroad under rule 71 of MDR, 2017.</p>
68.	M/s Meher Traders, Office No. A-21- 22 First Floor Zeenat Medecine Market North Nappier Road, Karachi. (ELI-00128)	<p><b>Manufacturer:</b> Hunan Luzhou Huikang Development Co., Ltd Located at No. 122 Luzhou Road, Suining County 422600 Hunan China.</p> <p><b>FSC China validity</b> <b>13-11-2021</b></p>	<p>Wellmed IV Burette</p> <p>IV Burette</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Sizes &amp; Codes as per FSC</p>	<p>Sterile IV Burette for single use</p>	<p><b>Deferred</b> for provision of FSC of any reference country or CE marked documents.</p>

**Item No.XX. RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).**

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf	Brief Description	Decision

			<b>Life</b>		
1.	M/s Atco Pharma International (Pvt) Ltd., B-18 S.I.T.E. Karachi ELI- 00106	<b>Manufacturer</b> Alvimedica,Tibbi Urunler San Ve Dis. Tic. A.S. Istanbul Trakya, Serbest Bolgesi Ferhatpasa Mahallesi Ataturk Bulvari Manolya Sokak No. 7 34540 Catalca, Istanbul, Turkey  FSC Turkey valid till 4-3-2023 FSC France issued on 3-12-2020	ALVISION Interventional Cardiology Diagnostic Catheter  Class D  Shelf life: 03 Years  Codes & Sizes as per FSC France dated 3-12-2020  Fee submitted: Rs. 25,000/-	Intended for use in the delivery of radio-opaque media to selected sites in the coronary vascular system. Sterile, single-use	<b>Approved.</b>
2.	-do-	<b>Manufacturer</b> Alvimedica,Tibbi Urunler San Ve Dis. Tic. A.S. Istanbul Trakya, Serbest Bolgesi Ferhatpasa Mahallesi Ataturk Bulvari Manolya Sokak No. 7 34540 Catalca, Istanbul, Turkey  FSC Turkey valid till 4-3-2023 FSC France issued on 3-12-2020	INVADER CTO Balloon Dilatation Catheter  Class D  Shelf life: 03 Years  Codes & Sizes as per FSC France dated 3-12-2020  Fee submitted: Rs. 25,000/-	Intended to be used for dilating stenoses in the coronary artery or bypass graft so as to increase myocardial perfusion. Sterile, single use	<b>Approved.</b>
3.	-do-	<b>Manufacturer</b> Alvimedica,Tibbi Urunler San Ve Dis. Tic. A.S. Istanbul Trakya, Serbest Bolgesi Ferhatpasa Mahallesi Ataturk Bulvari Manolya Sokak No. 7	COMMANDER CoCr Bare Metal Stent  Class D  Shelf life: 03 Years	Bare Metal Stent for coronary use. Sterile, single use	<b>Approved.</b>

		34540 Catalca, Istanbul, Turkey  FSC Turkey valid till 4-3-2023 FSC France issued on 3-12-2020	Codes & Sizes as per FSC France dated 3- 12-2020  Fee submitted: Rs. 25,000/-		
4.	-do-	<b>Manufacturer</b> Alvimedica, Tibbi Urunler San Ve Dis. Tic. A.S. Istanbul Trakya, Serbest Bolgesi Ferhatpasa Mahallesi Ataturk Bulvari Manolya Sokak No. 7 34540 Catalca, Istanbul, Turkey  FSC Turkey valid till 4-3-2023 FSC France issued on 3-12-2020	INVADER PTCA Balloon Dilatation Catheter  Class D  Shelf life: 03 Years  Codes & Sizes as per FSC France dated 3- 12-2020  Fee submitted: Rs. 25,000/-	Intended to be used for dilating stenoses in the coronary artery or bypass graft so as to increase myocardial perfusion. Sterile, single use	<b>Approved.</b>

**Item No.XXI. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).**

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s. Total Technologies (Pvt) Ltd., 696, J-2, Johar Town, Lahore.  ELI-00129	<b>Legal Manufacturer:</b> M/s. Flow-Meter S.p.A., Via del Lino 6, 24040 Levate (BG) Italy.  FSC Italy Issued on 02.01.2019	<b>Flowmeter</b> (Safety Jar)  Easy Safe Easy Safe Plut  Class A  Shelf Life:	Safety Jar.	<b>Approved.</b>

2.	-do-	<p><b>Legal Manufacturer:</b> M/s. Flow-Meter S.p.A., Via del Lino 6, 24040 Levate (BG) Italy.</p> <p>FSC Italy Issued on 02.01.2019</p>	<p><b>Flowmeter</b> Mak Collection Containers</p> <p>Suction Jar Mak 1000 Complete Suction Jar Mak 2000 Complete Suction Jar Mak 4000 Complete Suction Jar Mak 2000 PSU Complete</p> <p>Class A Shelf Life: Not defined</p> <p>Codes: 000110000 000110120 000030050 000100000</p>	Mak Collection Containers	<b>Approved.</b>
3.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019)	<p><b>Legal Manufacturer:</b> M/s Abbott Molecular Inc., 1300 East Avenue Des Plaines Illinois, USA.</p> <p>FSC USFDA Valid Till (30-01-2021)</p>	<p>m2000rt Instrument</p> <p>Class A</p> <p>Shelf Life: N/A</p> <p>Rs. 5000</p> <p>Codes &amp; Sizes as per FSC 9K15-01</p>	The m2000rt system provides for real time measurement of the stages of the PCR. Real time 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.	<b>Approved.</b>  Firm shall submit valid FSC before issuance of registration certificate.
4.	Sultan Sons, 133 Kutchi Gali No.1, Marriott Road, Karachi (ELI-00051)	<p><b>Legal Manufacturer:</b> M/s Bever Medical Industry Co. Ltd., 470 Mu 4, Soi</p>	BMI Disposable Urinary Drainage Bag, Sterile	Disposable Urinary Drainage Bag, Sterile, for collection of	<b>Approved.</b>

		Cheun-Sin, Phaholyotin Road, Lamluka, Pathumthanee 12130, Thailand  FSC Thailand Valid Till (08-07-2021)	Class-A  Shelf life: 5 years  Codes & Sizes as per FSC  2000ml	urine from human body.	
5.	-do-	<b>Legal Manufacturer:</b> M/s Linyi 2H Healthcare Products Co., Ltd., No.37 Luoqi Road, Luo Zhuang District, Linyi Shandong Province, China  FSC China Valid Till (19-11-2019)	Classic Medical Underpad  Class-A  Shelf life: N/A  Codes & Sizes as per FSC M (60cmx60cm) L (60x90cm) XL (76x90cm)	To be placed on mattress, chair, absorbent side up, or can be used as extra protection from accidental diaper leakage.	<b>Approved.</b>
6.	M/s Curelink Pharmaceuticals, Office No. 06, 3 <sup>rd</sup> Floor, B.B. Shopping Mall, Opp. NED University Road, Block 1, Gulistan- e-Jauhar, Karachi (ELI-00151)	<b>Legal Manufacturer:</b> M/s Magister Hoeveler & Co GmbH CARLBERGERGA SSE /38/Top 3/1. OG 1230 Wein Austria. <b>Manufacturing facility:</b> M/s MAG. Hoeveler & Co. GmbH, Magister Hoeveler & Co GmbH Moosham 40, A-4943 Geinberg, Aurstria  FSC Austria Valid (15-05-2021)	Fittydent Denture Adhesive 40g, 20g, 15's  Class A Shelf Life: 48 Months  Sizes & Codes as per FSC F0120FPK, F0140FPK	Denture Adhesive/ Cement	<b>Approved.</b>  Apply separately for Adhesive cushions.
7.	-do-	<b>Legal Manufacturer:</b> M/s Magister Hoeveler & Co GmbH CARLBERGERGA	Fittydent Denture Cleansing Tablets 16's & 32's	Denture Cleansing Tablets	<b>Approved.</b>

		<p>SSE /38/Top 3/1. OG 1230 Wein Austria. <b>Manufacturing facility:</b> M/s MAG. Hoeveler &amp; Co. GmbH, Magister Hoeveler &amp; Co GmbH Moosham 40, A-4943 Geinberg, Aurstria</p> <p>FSC Austria Valid (15-05-2021)</p>	<p>Class A Shelf Life: 48 Months</p> <p>Sizes &amp; Codes as per FSC F0204FPK</p>		
8.	<p>M/s Aftab life care Impex, 1<sup>st</sup> floor Al Falah Chambers Tilak Road Hyderabad. (ELI-00357)</p>	<p><b>Legal Manufacturer:</b> PT. Sugih Instrumendo Abadi JL. Tembokan Rt. 001 Rw.001 Desa Cipeundeuy</p> <p>(FSC Indonesia validity 29-07-2021)</p>	<p>ABN™ PALM Aneroid Sphygmomanom eter System 3</p> <p>Sphygmomanom eter</p> <p>Class A Shelf Life: 10000 cycles Sizes &amp; Codes as per FSC AS-07M3</p>	<p>The device is intended to measure Human Blood Pressure both systolic and diastolic</p>	<b>Approved.</b>
9.	<p>M/s Rafi Sultan Enterprises Office No M-5, Mezzanine floor, Business Center, Plot No. 19-1A, PECHS Block 6, Main Shahrah-E- Faisal, Karachi. (ELI-00232)</p>	<p><b>Legal Manufacturer:</b> Feather Razor Co., Ltd., 3-70, Ohyodo- miami 3-Chome, Kita-ku, Osaka, Japan</p> <p><b>Manufacturing Site:</b> 6001-Matsumori, Mino City, Gifu 501- 3753, Japan</p> <p>(FSC Japan issue 06-</p>	<p>Feather Trimming Knife Handle Trimming Blades</p> <p>Class A</p> <p>Shelf Life: N/A</p> <p>Sizes &amp; Codes as per FSC: F-80 mini, F- 130P, F-260P, F- 80P, F-80HL</p>	<p>Intended for attaching a Feather Trimming blade for making pathologic specimen. They are safe and convenient in handling.</p>	<b>Approved.</b>

		06-2019)			
10.	-do-	<p><b>Legal Manufacturer:</b> Feather Razor Co., Ltd., 3-70, Ohyodo- miami 3-Chome, Kita-ku, Osaka, Japan</p> <p><b>Manufacturing Site:</b> 6001-Matsumori, Mino City, Gifu 501- 3753, Japan</p> <p>(FSC Japan issue 06- 06-2019)</p>	<p>Feather Trimming Blades</p> <p>Trimming blades</p> <p>Class A Shelf life: N/A</p> <p>Sizes &amp; Codes as per FSC No. 130, No. 260</p>	<p>Feather Trimming Blades</p> <p>Is intended for cutting and trimming blade of the pathologic tissue or organ. An ideal trimming Knife, with sharp Edges, for cutting tissues without causing deformation.</p>	<b>Approved.</b>
11.	-do-	<p><b>Legal Manufacturer:</b> Feather Razor Co., Ltd., 3-70, Ohyodo- miami 3-Chome, Kita-ku, Osaka, Japan</p> <p><b>Manufacturing Site:</b> 6001-Matsumori, Mino City, Gifu 501- 3753, Japan</p> <p>(FSC Japan issue 06- 06-2019)</p>	<p>Feather Microtome Blade Holder</p> <p>Feather Microtome Blade Holder</p> <p>Class A Shelf Life: N/A</p> <p>Sizes &amp; Codes as per FSC NO.130A, NO.130AE, NO.130C-A, NO.130C-AO, NO.130C-CR, NO.160, NO.160E, NO.130C, NO.240S, NO.240W, NO.240E</p>	<p>Intended for attaching a Feather Microtome Blade for making pathologic specimen.</p>	<b>Approved.</b>
12.	-do-	<p><b>Legal Manufacturer:</b> Feather Razor Co., Ltd., 3-70, Ohyodo- miami 3-Chome,</p>	<p>Feather Microtome Blade</p> <p>Microtome</p>	<p>Feather Microtome Blade is intended for sectioning</p>	<b>Approved.</b>

		<p>Kita-ku, Osaka, Japan</p> <p><b>Manufacturing Site:</b> 6001-Matsumori, Mino City, Gifu 501-3753, Japan</p> <p>(FSC Japan issue 06-06-2019)</p>	<p>Blades</p> <p>Class A</p> <p>Shelf Life: N/A</p> <p>Sizes &amp; Codes as per FSC: S35, S22, A22, C35, S35L, R35, S35LL, High Profile, A35, H35S, N35HR, SH35W</p>	<p>paraffin-embedded tissue or frozen tissue for making pathologic specimen.</p>	
13.	<p>Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi, 75300 Pakistan</p>	<p><b>Legal manufacturer:</b> Tan Sin Lian Industries Sdn Bhd No.1-12, Jalal Indah 2, Tamn Indah Jalan Haji Abdullah, 84000 Muar Johar Malaysia.</p> <p><b>FSC Malaysia issuance 02-12-2020</b></p>	<p>OPTISHIELD Examination Gloves (Powder free)</p> <p>Class-A</p> <p>Shelf life:</p> <p>Codes/ Sizes: X-small, Medium, Large, X-Large.</p>	<p>Examination gloves</p>	<p><b>Approved.</b></p>
14.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p>Manufacturer: M/s Alere Technologies GmbH Loebstedter Strasse 103-105 07749 Jena, Germany.</p> <p>FSC Germany issued on 22-06-2017</p>	<p>Pima™ Analyzer</p> <p>Code: 260300003</p> <p>Class A</p> <p>Lifetime: 5 years</p> <p>Fee submitted: Rs. 5,000/-</p>	<p>Portable bench-top fixed volume cytometer used for processing an analysis of a Pima CD4 test cartridge</p>	<p><b>Approved</b> as class A medical device</p> <p>Firm shall submit valid ISO13485 before issuance of registration certificate.</p>



15.	M/s Abdullah Traders, 3 Green Town, Ghous-ul-Azam Road, Multan  ELI-00444	Manufacturer: GeneAll Biotechnology Co. Ltd. GeneAll Bldg., 303-7, Dongnam-ro, Songpa-gu, Seoul, Korea. 05729  FSC Korea issued on 07-09-2020	Genti™ Advanced Automatic Extraction Equipment  Class A  Codes: GTI032A  Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for use in combination with series of Genti™ Advanced Extraction kits as an invitro diagnostic purpose to perform automated isolation of nucleic acid from samples	<b>Approved</b> Extraction Equipment. However, the firm shall apply separately for advance extraction kits
16.	M/s Biomadics, No.4, Ground Floor, Happy Heights, Modern Housing Society, Shaheed-e-Millat Road, Karachi (ELI-00432)	Manufacturer: M/s Biocytech Corporation SDN BHD No.820, Simpang Empat, Jalan Lahat Menglembu, Ipoh Perak, 31450 Malaysia  Manufacturing site: M/s Biocytech Corporation SDN BHD 7, Laluan Perusahaan Kledang 9 Chandan Raya Industrial Estate 31450 Ipoh, Perak, Malaysia  FSC Malaysia valid till 18-04-2021	PathTezt EasyVial (Preserve cell solution)  Class A  Shelf Life: 3 years  Code: EV-60010  Fee submitted: Rs.5,000/-	A liquid based cytology procedure for the liquid-based preparation Gyn and non-Gyn cytology specimens.	<b>Approved.</b>
17.	M/s Schazoo SPL Consumer Healthcare 71B/C2, Gulberg 3, Lahore  ELI: 00095	Legal Manufacturer:  M/s Suzhou Shengtain Biotechnology Co, Ltd F2, Unit 2, B3, No 58, Dongfu Road Suzhou Industrial	Sampling swab Kits  ( Viral Transport Medium (VTM)  Class-A	Viral Transport Medium (VTM)	<b>Approved</b>

		Park Suzhou, Jiangsu, 215000, China  FSC: China Valid till: 2023.03.23	Shelf Life:2Year  Codes & Sizes: As per FSC		
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**Item No.XXII. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).**

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi (ELI-00109)	<b>Legal Manufacturer and Manufacturing Site:</b> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France.  FSC France issued on 28-05-2020	VIDAS® SARS-COV-2 IgG (9COG)  Class C  Shelf life: 12 months  Code:423834  Fee submitted: Rs. 50,000/-	Automated qualitative assay for use on the VIDAS family of instruments for the detection of IgG specific for SARS-CoV-2 in human serum or plasma (lithium heparin) using the ELFA technique. Intended for use as an aid to determine if individuals may have been exposed and infected by this virus and if they have mounted a specific anti-SARS-CoV-2 IgG immune response The test provides preliminary test results. Negative result don't preclude SARS-CoV-2 infection and they	<b>Approved.</b>  Firm shall submit MRP and original Embassy attested FSC before issuance of registration letter

				cannot be used as the sole basis for treatment or other management decision.	
2.	-do-	<p><b>Legal Manufacturer and Manufacturing Site:</b> BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France.</p> <p>FSC France issued on 28-05-2020</p>	<p>VIDAS® SARS-COV-2 IgM (9COM)</p> <p>Class C</p> <p>Shelf life: 12 months</p> <p>Code:423833</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Automated qualitative assay for use on the VIDAS family of instruments for the detection of IgG specific for SARS-CoV-2 in human serum or plasma (lithium heparin) using the ELFA technique. Intended for use as an aid to determine if individuals may have been exposed and infected by this virus and if they have mounted a specific anti-SARS-CoV-2 IgG immune response. 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.</p>	<p><b>Approved.</b></p> <p>Firm shall submit MRP and original Embassy attested FSC before issuance of registration letter</p>
3.	-do-	<p>Legal Manufacturer: BioMerieux SA, 376 Chemin de l'Orme 69280</p>	<p><b>ARGENE® SARS- COV-2 RESPI R- GENE® Kit</b></p> <p>(Real Time</p>	<p>For qualitative detection and differentiation of SARS-CoV-2, Influenza A,</p>	<p><b>Approved.</b></p> <p>Firm shall submit MRP before issuance of</p>

		<p>Marcy, l'Etoile France.</p> <p>Manufacturing site:</p> <p>BioMerieux SA, 138 rue Louis Pasteur, Parc Technologique Delta Sud, 09340 Verniolle, France.</p> <p>FSC France issued on 15-12-2020</p>	<p>Detection Kit)</p> <p>Code: 423732</p> <p>Class: C</p> <p>Shelf Life: 12 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Influenza B, Respiratory Syncytial Virus (RSV) and human metapneumovirus using the real time PCR technology after extraction of the viral RNA in nasopharyngeal swabs</p>	<p>registration certificate.</p>
4.	<p>M/s Hooraa Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi</p> <p>(ELI-00037)</p>	<p><b>Legal Manufacturer:</b> M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA</p> <p><b>Manufacturing Site:</b> M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA</p> <p>FSC Ireland valid till 27-05-2025</p>	<p>ADVIA Centaur SARS-CoV-2 IgG (sCOVG) Kit</p> <p>Class C</p> <p>ADVIA Centaur SARS-CoV-2 IgG(sCOVG) Code: 11207376 (100 tests) Shelf life: 9 months</p> <p>ADVIA Centaur SARS-CoV-2 IgG (sCOVG) Code: 11207377 (500 tests) Shelf life: 9 months</p> <p>ADVIA Centaur SARS-CoV-2 IgG Quality Control (sCOVG QC) Code: 11207378</p>	<p>For invitro diagnostic use in the qualitative and quantitative detection of IgG antibodies, including neutralizing antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin) obtained by venipuncture or capillary puncture using the ADVIA Centaur XP, ADVIA Centaur XPT and ADVIA Centaur CP systems. Intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection as an aid in identifying patients with adaptive</p>	<p><b>Approved.</b></p>

			Fee submitted: Rs. 50,000/-	immune response to SARS-C-V-2 indicating recent or prior 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.	
5.	-do-	<p><b>Legal Manufacturer:</b> M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA</p> <p><b>Manufacturing Site:</b> M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA</p> <p>FSC Ireland valid till 27-05-2025</p>	<p>Atellica IM SARS-CoV-2 IgG (sCOVG) Kit</p> <p>Class C</p> <p>Atellica IM SARS-CoV-2 IgG (sCOVG) Code: 11207386 (100 tests) Shelf life: 9 months</p> <p>Atellica IM SARS-CoV-2 IgG (sCOVG) Code: 11207387 (500 tests) Shelf life 9 months</p> <p>Atellica IM SARS-CoV-2 IgG (sCOVG QC) Quality Control Code: 11207388</p>	For invitro diagnostic use in the qualitative and quantitative detection of IgG antibodies, including neutralizing antibodies to SARS-CoV-2 in human serum and plasma (lithium heparin) obtained by venipuncture or capillary puncture using the Atellica IM Analyzer Intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection as an aid in identifying patients with adaptive immune response to SARS-C-V-2 indicating recent or	<b>Approved.</b>

			Fee submitted: Rs. 50,000/-	prior 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.	
6.	-do-	<p><b>Legal Manufacturer:</b> M/s Siemens Healthcare Diagnostics Inc, 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, USA</p> <p><b>Manufacturing Site:</b> M/s Siemens Healthcare Diagnostics Inc, 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, USA</p> <p>FSC Ireland valid till 18-06-2025</p>	<p>Siemens Dimension® EXL™ SARS-CoV-2 Total Antibody Assay (CV2T) Kit</p> <p>Class C</p> <p>Siemens Dimension® EXL™ SARS-CoV-2 Total Antibody Assay (CV2T) Code: RF812/ 11417412 Shelf life: 12 months</p> <p>Siemens Dimension Vista/Dimension EXL SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL) Code: KC813/ 11417413 Shelf life: 12 months</p> <p>Siemens</p>	<p>For invitro diagnostic use in the qualitative detection of total antibodies, including IgM and IgM to SARS-CoV-2 virus in human serum and plasma (EDTA, lithium heparin) using the Dimension EXL integrated chemistry system with LOCI Module. Intended as an aid in diagnosis of patients with suspected SARS-CoV-2 infection and as an aid in identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection</p>	<p><b>Approved.</b></p> <p>Firm shall submit Embassy attested FSC of Ireland before issuance of registration certificate.</p>

			<p>Dimension Vista/Dimension EXL SARS-CoV-2 Total antibody Quality Control (COV2T/CV2T Pos/Neg) Code: KC815/11417415</p> <p>Fee submitted: Rs. 50,000/-</p>		
7.	<p>M/s Noor International, Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061)</p>	<p><b>Legal Manufacturer:</b> M/s QuantuMDx Group Ltd. Lugano Building 57 Melbourne Street, Newcastle upon Tyne, NE1 2JQ United Kingdom</p> <p>(FSC UK valid till 19-05-2025)</p>	<p>QuantuMDx SARS-CoV-2 RT-PCR Detection Assay (Kit)</p> <p>Class C</p> <p>Code: Q22003</p> <p>Shelf life: 12 months</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Real-time reverse transcription polymerase chain reaction (RT-PCR) detection assay is a qualitative RT-PCR assay for the detection of SARS-CoV-2 genomic RNA from upper respiratory specimens (e.g nasopharyngeal or oropharyngeal swabs, etc) collected from individuals who meet criteria for SARS-CoV-2 testing. Results are for presumptive detection and identification of SARS-CoV-2 targeted genomic RNA sequences. Negative result don't prelude SARS-CoV-2 infection and they cannot be used as</p>	<p><b>Approved.</b></p> <p>The Firm shall submit valid sole /exclusive Letter of Authorization before issuance of registration certificate.</p>

				the sole basis for treatment or other management decision.	
8.	M/s SY'AH Impex, 1-6/15 Sector 5 Korangi Industrial Area, Karachi. ELI-00440	Manufacturer: Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China.  FSC of China valid till 27 <sup>th</sup> June 2021	Shifa Nitrile Examination gloves (Powder free)  Sizes: S, M, L, XL  Class: A  Shelf life: 3 years  Fee submitted: Rs. 25,000/-	Disposable device made of synthetic material intended for medical purposes that are worn on the examiner's hand or finger(s) to prevent contamination of potentially infectious materials between patient and examiner. Non-sterile, single use	<b>Approved.</b> The firm shall submit Essential principles of safety and performance before issuance of registration certificate
9.	M/s Schazoo SPL Consumer Healthcare 71-B/C2, Gulberg-III, Lahore ELI-00095	Manufacturer: Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, China FSC Belgium issued on 02-02-2021	Wondfo 2019-nCoV Antigen Test Device (Lateral Flow Method)  Code: W196  Class C  Shelf Life: 1 year Fee submitted: Rs. 50,000/-	assay for rapid, qualitative detection of novel coronavirus antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimen. The test is to be used as an aid in the diagnosis of coronavirus infection disease which is caused by 2019-nCoV. The test provides preliminary test results. Negative results cannot exclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision Immunochromatogr	<b>Approved.</b> Firm shall submit original Embassy attested FSC, Notarized ISO13485 and Letter of Authorization before issuance of registration certificate.



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10.	-do-	<p>Manufacturer: Guangzhou Wondfo Biotech Co., Ltd. No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, China FSC Belgium issued on 02-02- 2021</p>	<p>Wondfo 2019- nCoV Real Time- RT PCR Assay kit</p> <p>Code: W275P002</p> <p>Class C</p> <p>Shelf Life: 1 year</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>Real-time reverse transcription PCR (RT-PCR) assay for rapid, qualitative detection of novel coronavirus nucleic acid in oropharyngeal swabs, nasopharyngeal swabs and sputum specimens. The test is to be used as an aid in the diagnosis of coronavirus infection disease which is caused by 2019-nCoV The test provides preliminary test results. Negative results cannot exclude 2019- nCoV infection and they cannot be used as the sole basis for treatment or other management decision</p>	<p><b>Approved.</b></p> <p>Firm shall submit original Embassy attested FSC, Notarized ISO13485 and Letter of Authorization before issuance of registration certificate.</p>
11.	M/S Meher Enterprises 1st Floor, Azzainab Court, Campell Street, Karachi (ELI_00241)	<p><b>Legal</b> <b>Manufacturer:</b> Changzhou Zongyou Medical Device Co., Ltd. Wugang Zhenglu Town, Changzhou, Jiangsu, 213115, China</p>	<p>Unicare Nebulizer Masks</p> <p>Class: B</p> <p>Shelf life: 5 years</p> <p>Codes and sizes as per FSC</p>	<p>Intended for connecting with active respiration equipment and introducing oxygen to human body and intended for rhinitis, pharyngitis, laryngitis, tracheitis, bronchitis and other respiratory diseases treated by inhalation.</p>	<p><b>Deferred</b> for provision of the following documents:</p> <ul style="list-style-type: none"> <li>• valid LOA, duly notarized.</li> <li>• original and valid FSC in the country of origin mentioning the subject device, duly attested by Embassy of</li> </ul>

					<p>Pakistan.</p> <ul style="list-style-type: none"> <li>• FSC of reference country as provided in rule 71 of MDR, 2017, duly attested.</li> <li>• valid ISO 13485, duly notarized.</li> <li>• labels with all applied sizes, approved in the country of origin.</li> <li>• complete description of the device.</li> <li>• Essential principle checklist of the subject device.</li> <li>• detailed manufacturing and QC processes.</li> <li>• the information on validation for medical devices with sterile or with measuring function.</li> <li>• stability studies of claimed shelf life. And MRP of the device.</li> </ul>
12.	-do-	<p><b>Legal Manufacturer:</b> Changzhou Zongyou Medical Device Co., Ltd.</p>	Unicare Disposable Non-Rebreathing Masks	A non-rebreather mask (NRB, non-rebreather, non-rebreather facemask, etc.) is a device used to assist	<p><b>Deferred</b> for provision of the following documents:-</p>

		Wugang Zhenglu Town, Changzhou, Jiangsu, 213115, China	Class: B Shelf life: 5 years  Codes and sizes as per FSC	in the delivery of oxygen therapy.	<ul style="list-style-type: none"> <li>• Valid LOA, duly notarized.</li> <li>• original and valid FSC in the country of origin mentioning the subject device, duly attested by Embassy of Pakistan.</li> <li>• FSC of reference country as provided in rule 71 of MDR, 2017, duly attested.</li> <li>• valid ISO 13485, duly notarized.</li> <li>• labels with all applied sizes, approved in the country of origin.</li> <li>• complete description of the device.</li> <li>• Essential principle checklist of the subject device.</li> <li>• detailed manufacturing and QC processes.</li> <li>• the information on validation for medical devices with sterile or with measuring</li> </ul>
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					function. <ul style="list-style-type: none"> <li>stability studies of claimed shelf life. And MRP of the device.</li> </ul>
13.	M/s Meher Traders, Office No. A 21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi.  (ELI-00128)	<b>Legal Manufacturer:</b> Ningbo Great Mountain Medical Instruments Co., Ltd. E-Building 1606 Room, 655 Xueshi Road, Yinzhou District Ningbo China. <b>Manufacturing sit:</b> No. 309 Xigu Road, Xingshan County, 315700 Ningbo City, Zhejiang Province.  FSC China issued by Chamber of Commerce for import and Export: Issuance: 19-08-2019  FSC Spain issuance: 02-03-2021	Wellmed Disposable Caps  Class A Shelf Life: 03 Years Reference: GM-202-005	Disposable Caps	<b>Approved.</b>
14.	-do-	<b>Legal Manufacturer:</b> Ningbo Great Mountain Medical Instruments Co., Ltd. E-Building 1606 Room, 655 Xueshi Road, Yinzhou	Wellmed Disposable Shoe Cover  Class A Shelf Life: 03 Years Rs. 5000/- Reference: GM-202-007	Disposable Shoe Cover	<b>Approved.</b>

		<p>District Ningbo China.</p> <p><b>Manufacturing sit:</b> No. 309 Xigu Road, Xingshan County, 315700 Ningbo City, Zhejiang Province.</p> <p>FSC China issued by Chamber of Commerce for import and Export: Issuance: 19-08- 2019</p> <p>FSC Spain issuance: 02-03- 2021</p>			
15.	-do-	<p><b>Legal Manufacturer:</b> Ningbo Great Mountain Medical Instruments Co., Ltd. E-Building 1606 Room, 655 Xueshi Road, Yinzhou District Ningbo China.</p> <p><b>Manufacturing sit:</b> No. 309 Xigu Road, Xingshan County, 315700 Ningbo City, Zhejiang Province.</p> <p>FSC China issued by Chamber of Commerce for import and Export:</p>	Wellmed Disposable Face Mask Class A Shelf Life: 03 Years Reference: GM-202-001	Disposable Face Mask	<b>Approved.</b>

		Issuance: 19-08-2019  FSC Spain issuance: 02-03-2021			
16.	The Healers 206/2, Satellite Town D Block Rawalpindi (ELI-00535)	<b>Legal</b> <b>Manufacturer:</b> Qingdao Future Medical Technology Co., Ltd Room 401 Building F, No. 169 Zhuzhou Rd, Laoshan District, 266000, Qingdao City, PEOPLES REUBLIC OF CHINA.  FSC China validity 18-02-2022	YIRDOC Portable Mesh Nebulizer  Class- B  Service Life: 3 years  Models: NEB-016, NEB- 001, NEB-002	Device is used to provide aerosolized medication primarily to patients with respiratory disorders.	<b>Approved</b> on the basis of CE mark documents.
17.	Health Care Supplies B1 - Islamic Plaza, Block 13 B University Road, Gulshan-e- Iqbal Karachi ELI-00595	<b>Legal</b> <b>Manufacturer:</b> Xiantao Rhycon Non-Woven Product Coorporation, China.  FSC China validity17-05-2022	Rhycon Medical Face Mask  Class-A  Shelf life: 3 years  Codes and sizes as per FSC 17.5 x 9.5cm	Face mask	<b>Deferred</b> for provision of following documents: <ul style="list-style-type: none"><li>• FSC of reference country as provided in rule 71 of MDR, 2017, duly attested or CE marked document (FQA certificate) issued by Notified body, duly notarized.</li><li>• MRP of the device.</li><li>• Essential</li></ul>

					<p>principle checklist.</p> <ul style="list-style-type: none"> <li>description of the device and details of manufacturing and QC processes.</li> </ul>
18.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	<p><b>Legal Manufacturer:</b> KNGMED Medikal Ltd STI 29 Ekim Mah. 10007 Sk. No:26/B Ulukent/Menemen/Izmir/Turkey.</p> <p>FSC Turkey issuance 29-07-2020 valid for 36 months</p>	<p>KNGMED Full Face Masks Class B</p> <p>Shelf life: 5years</p> <p>Codes and sizes as per FSC</p>	Full face masks	<p><b>Deferred</b> for provision of following documents:</p> <ul style="list-style-type: none"> <li>Provide differential fee of Rs. 25,000/-.</li> <li>Provide FSC of reference country as per Rule 71 of MDR, 2017, duly attested.</li> <li>Provide MRP of the device.</li> <li>Provide details of manufacturing and QC processes.</li> </ul> <p>Provide labels off all applied codes, approved in the country of origin.</p>
19.	-do-	<p><b>Legal Manufacturer:</b> KNGMED Medikal Ltd STI 29 Ekim Mah. 10007 Sk. No:26/B Ulukent/Menemen/Izmir/Turkey.</p> <p>FSC Turkey</p>	<p>KNGMED Anesthesia Face Masks Reusable Silicon mask</p> <p>Class B</p> <p>Shelf life: 5 years</p>	Anesthesia mask	<p><b>Deferred</b> for provision of following documents:</p> <ul style="list-style-type: none"> <li>Provide differential fee of Rs. 25,000/-.</li> <li>Provide FSC of reference</li> </ul>

		issuance 29-07-2020 valid for 36 months	Codes and sizes as per FSC		country as per Rule 71 of MDR, 2017, duly attested. <ul style="list-style-type: none"> <li>• Provide MRP of the device.</li> <li>• Provide details of manufacturing and QC processes.</li> </ul> Provide labels off all applied codes, approved in the country of origin.
20.	<p>M/s Hashir Surgical Services</p> <p>Office No. 16, Street 1, F-2, Phase 6, Hayatabad, Peshawar</p> <p>Office No. 05, 2nd Floor, Syed's Tower, University Road, Peshawar</p> <p>House No. 2, Street No, 1, Gulshan Colony, GT, Road, Peshawar</p> <p>ELI: 00075</p>	<p><b>Legal Manufacturer:</b> M/s Shanghai Dassheng Health Products Manufacturing Co., Ltd, No. 228 Shihui Road, Songjina, Shanghai, P.R. China.</p> <p><b>FSC China validity 22-04-2021</b></p>	<p>DASHENG (N95 Surgical Mask)</p> <p>Class-A</p> <p>Shelf life: 3 years</p> <p>Codes/ models: DTC 3M-1 N96, DTC3W N95 DTC3X N95, DTC 3M-F N95 DTC 3 B N95, DTC3M-F N95</p>	<p>The N95 Surgical Masks are intended for Single Use by operating room personnel and other healthcare workers to protect both the patients and healthcare workers from transfers of microorganism, blood and body fluids, virus, pathogens, bacteria and airborne particulate materials.</p>	<p><b>Deferred</b> for provision of following documents:</p> <ul style="list-style-type: none"> <li>• Provide original and notarized sole agency agreement.</li> <li>• Provide original FSC in the country of origin, duly attested.</li> <li>• Provide FSC of reference country as per Rule 71 of MDR, 2017, duly attested.</li> <li>• Provide notarized ISO 13485.</li> <li>• Provide valid FQA/CE certificate, duly notarized.</li> <li>• Provide MRP of</li> </ul>



					<p>the device.</p> <ul style="list-style-type: none"> <li>• Provide details of manufacturing and QC processed.</li> <li>• Provide labels of all applied codes and clarify the difference between all applied models.</li> </ul>
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**Item No.XXIII. 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 Meher Traders, Office No. A 21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi.  (ELI-00128)	<b>Manufacturer:</b>  Hunan Luzhou Huikang Development Co., Ltd. Xiangshang Industrial Park, Guanxia County, Suining, 422601, Hunan Province, China.  FSC China valid till 13-10-2021	Wellmed Auto-disable syringe  Class B  Shelf Life: 5 Years  Sizes: 1ml, 3ml, 5ml, 10ml, 20ml  Fee submitted: Rs. 25,000/-	Sterile, single use auto disable syringe	<b>Approved</b> on the basis of CE marking documents subject to provision of stability studies
2.	Zenith International, Room No.104, Tahir Plaza, A/20, Block 7 & 8 KCHSU, Karachi	<b>Legal Manufacturer:</b> Jiangyin Jinfeng Medical Equipment Co., Ltd No. 74 Zhoujia Village, Jinfeng Village, Xuxiake	PERFECT MED A.D Syringe  Class B  Shelf life: 5 years	Disposable Auto Disable Syringe, Sterile with needle	<b>Approved.</b>

	(ELI-00090)	Town, Jiangyin, China.  FSC China validity  FSC UK MHRA issuance	Codes and Sizes as per FSC Sizes: 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml		
3.	M/s Hashir Surgical Services, Office No 15 , Street 1m F-2, Phase 6, Hayatabad, Peshawar  • Office No, 05, 2nd Floor, Syed 's Tower, University Road, Peshawar •House No. 2 Street No. 1m Gulshan Colony, GT Road, Peshawar ELI: 00075	<b>Legal Manufacturer</b> M/s Fenglin Medical Appliances Co., Ltd., Fulin Road, Fuzhou City, Jiangxi Province, China  FSC China Valid Till (20-01-2022)	Bio Soft Auto Lock Safety Syringe (Sterile Safety Auto Disable Syringe with Needle)  1ml, 2ml, 3ml, 5ml, 10ml, 20ml  Class B Shelf Life: 05 Years	It is used on intravenous Injection	<b>Approved</b> on the basis of CE mark documents.
4.	-do-	<b>Legal Manufacturer</b> M/s Fenglin Medical Appliances Co., Ltd., Fulin Road, Fuzhou City, Jiangxi Province, China  FSC China Valid Till (20-01-2022)	Bio Soft Retract- Lock Safety Syringe (Sterile Safety Auto Disable Syringe with Needle)  1ml, 2ml, 3ml, 5ml, 10ml, 20ml Codes & Sizes: As per FSC Class B Shelf Life: 05 Years	It is used on intravenous Injection	<b>Approved</b> on the basis of CE mark documents.

**Item No.XXIV. DEFERRED/APPROVED SUBJECT TO 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	Decision
1.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030)	Legal Manufacturer: Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerzeland  Manufacturing site: Kimball Electronics Poland Sp. z.o.o. ul. Poznanska 1C, 62-080 TarnowoPodgorne Poland (FSC Switzerland valid till 14.06.2022)	Diastix Reagent Strip (Urine Test Strip) Class B Shelf Life: 42 Months Fee submitted: Rs. 25,000/-	Intended for self-testing by persons with diabetes and by healthcare professionals to monitor the level of glucose in urine.	<b>Approved.</b>
2.	M/s JK Traders Suite No. 13, 2 <sup>nd</sup> Floor, Majeed Plaza, Bank Road Saddar Rawalpindi.	<b>Manufacturer:</b> Xiamen New Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicang	NCMT <b>INTRODUCER SHEATH SETS</b>  <b>DQ-A-5F</b> <b>DQ-A-6F</b> <b>DQ-A-7F</b>	INTRODUCER SHEATH SETS	<b>Approved.</b>

	ELI-00014	<p>Biomedicine Building No.2026, West Wengjiao Road Haicang disctrict, Xiamen, Fujian, China</p> <p>Certificate of Export: China validity: 04-12-2019</p> <p>FSC China validity: 02-06-2021</p> <p>FSC Spain Issuance: 11-07-2019</p>	<p>Class B</p> <p>Shelf life 3 years</p>		
3.	-do-	<p><b><u>Legal</u></b> <b><u>Manufacturer:</u></b> Xiamen New Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicang Biomedicine Building No.2026, West Wengjiao Road Haicang disctrict, Xiamen, Fujian, China</p> <p>Certificate of Export: China</p>	<p>NCMT <b>Guide Wires</b>  <b>DS-B-035</b>  <b>Class B</b></p> <p>Shelf life 3 years</p>	<p>This product is mainly used for ureteral calculi, kidney stones and other surgical operation, used in conjunction with pigtail catheter, providing the catheter lumen support and guidance.</p>	<b>Approved.</b>

		<p>validity: 25-01-2020</p> <p>FSC China validity: 02-06-2021</p> <p>FSC Spain Issuance: 11-07-2019</p>			
4.	<p>M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi (ELI-00051)</p>	<p><b>Legal Manufacturer:</b> Hospital &amp; Homecare Medical Device Co., Ltd. China. No.188 east Jingwu Rd, West side, Ye ya Science and technology Park, Jiangsu, China.</p> <p>(FSC Valid 18- 04-2021)</p> <p>FSC Germany issuance 21-10- 2019</p>	<p>CLASSIC Disposable Umbilical Cord Clamp, Sterile Class A Shelf Life :05 years</p>	<p>Disposable Umbilical Cord Clamp, Sterile</p>	<p><b>Approved</b> as class B medical devices subject to submission of differential fee of Rs.20,000/-</p>
5.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)</p>	<p><b>Manufacturer:</b> M/s Alere Technologies GmbH Loebstedter Strasse 103-105 07749 Jena, Germany.</p> <p>FSC Germany issued on 25-01- 2019</p>	<p>m-Pima Analyzer  Code: 27030R001  Class A  Lifetime: 4 years 3 months</p>	<p>Portable automated multi-assay bench-top instrument for processing and analysis of m- pima test cartridges</p>	<p>Below</p>

Decision: <b>The MDB discussed and approved the correction of manufacturer name from M/s Abbott Laboratories 100 Abbott Park Road, Abbott Park, IL 60064, USA to M/s Alere Technologies GmbH Loebstedter Strasse 103-105 07749 Jena, Germany and approved the product as class A medical device</b>					
6.	M/s Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi, ELI-00109	<p>Manufacturer: Manufacturing site: Sacace Biotechnologies srl. via Scalabrini, 44 - 22100 Como, Italy.</p> <p>FSC Italy issued on 25-05-2018</p>	<p>SaCycler-96 Real time PCR System Code: SC-96I</p> <p>Class: A</p> <p>Shelf life: N/A</p> <p>Fee submitted: Rs. 5,000/-</p>	Instrument intended for carrying out quantitative and qualitative studies of DNA. It uses the method of polymerase chain reaction (PCR) with reagents based on fluorescence effect.	<b>Approved.</b>
7.	M/s Flowtronix Systems, Flat No. 02, 1 <sup>st</sup> Floor, Al-Ashraf Plaza, Range Road, Rawalpindi. (ELI-00217)	<p><b>Manufacturer:</b></p> <p>Nipro Medical Ltda, Avenida Nipro, 451, Regiao Norte CEP, Sorocaba Sau Paulo, 18087-127, Brazil.</p> <p>FSC Brazil issued on 25-1-2018</p> <p>FSC Australia issued on 31-01-2019</p>	<p><b>Nipro Brizio-BRZ+12345A</b> (Brizio membrane oxygenator and venous reservoir with integrated cardiotomy filter nipro coated preconnected with manifold with recirculation line with vacuum line sealed, Adult)</p> <p>Class B</p> <p>Shelf Life: 3 years</p> <p>Fee submitted: Rs.</p>	For exchanging gas and for adjusting temperature of blood (heat exchanging) through extracorporeal circulation and reservoir is used for reserving drained and sucked blood and also for removing air or bubbles in it during open-heart surgery under direct vision. Sterile,	<b>Approved.</b>

			25,000/-	single use.	
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**Item No.XXV. REGISTRATION 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 Injection Systems (Pvt) Ltd., Plot No. 271, Main Road, Industrial Estate Gadoon Amazai (ELM-Not Issued)	Biosafe Auto Disable Syringes 2ml, 2.5ml, 3ml, 5ml with needle  Class B  Shelf Life: 05 Years	Auto Disable Syringes	<b>Approved.</b>  Stability Studies Required
2.	M/s Al Badar Manufacturing (Pvt) Ltd., Plot No. 193/3, Road No.7, Industrial Estate, Gadoon Amazai, District Swabi (ELM-0029)	Zindagi Auto Disable Syringe 2ml, 2.5ml, 3ml, 5ml  Class B  Shelf Life: 05 Years	Auto Disable Syringe	<b>Approved.</b>  Stability Studies Required

**Item No.XXVI. RENEWAL OF REGISTRATION 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 Silver Surgical Complex (Pvt) Ltd., C-40/41, Scheme 33, SITE,, Super Highway, Industrial Area, Karachi (ELM-007)	Silver IV Cannula/Catheter with wings injection port cap  Class B  Shelf Life: 02 Years	IV Cannula/Catheter	<b>Approved.</b>

		Pervious Reg No. 067476 16G, 18G, 20G, 22G, 24G		
2.	M/s Silver Surgical Complex (Pvt) Ltd., C-40/41, Scheme 33, SITE,, Super Highway, Industrial Area, Karachi (ELM-007)	Green + IV Cannula Moveable wings with or without heparin lock.  Class B Shelf Life: 02 Years Pervious Reg No. 067474 16G, 18G, 20G, 22G, 24G	IV Cannula	<b>Approved.</b>
3.	M/s Silver Surgical Complex (Pvt) Ltd., C-40/41, Scheme 33, SITE,, Super Highway, Industrial Area, Karachi (ELM-007)	Green (Straight Type pen shape) IV Cannula/ Catheter.  Class B Shelf Life: 02 Years Pervious Reg No. 067475 16G, 18G, 20G, 22G, 24G	IV Cannula	<b>Approved.</b>